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Advocacy Resource: Ensuring the Medicare Drug Negotiation Program Prioritizes Families and Consumers

For the first time, there is now a federal law that helps make prescription drugs more affordable—but advocates have much work to do to make sure the promises of this law are realized. The Inflation Reduction Act of 2022 (IRA) gave Medicare the authority to negotiate prices for a select group of high-cost drugs in Medicare Part D (and later Part B). To ensure this law truly results in lower drug prices for people who rely on Medicare, it is critical for health advocates to weigh in as the Centers for Medicare & Medicaid Services (CMS) implements price negotiations through the regulatory and sub-regulatory processes. The drug industry and its army of lobbyists has publicly indicated that they will use any opportunity they can to weaken the law.[1] It is up to advocates to stop them, and this guide explains what and when advocates need to focus on to make sure prescription drug prices actually come down.

Key Areas for Ongoing Advocacy

Health advocates should engage CMS to ensure that the law lowers drug costs for the millions of families and people who need Medicare. CMS will need to make several key regulatory decisions when implementing the drug price negotiation provisions of the IRA. These key decisions include:

1. Whether CMS continues to give consumer and patient advocates an opportunity to review and comment on negotiation policy decisions;
2. The process CMS uses to calculate a maximum fair price for the group of drugs whose high prices it chooses to negotiate;
3. How CMS ensures that information from drug manufacturers is accurate and complete;
4. The amount of detail and the manner in which CMS publicizes the methodology and other negotiation policy decisions;
5. How CMS uses the renegotiation process when negotiated drugs change in ways that warrant an updated maximum fair price.

The Inflation Reduction Act's Drug Pricing Provisions

The IRA is the largest piece of federal health care legislation passed since the Affordable Care Act, and it contains a number of important provisions designed to lower prescription drug prices for people who rely on Medicare for their health care needs.

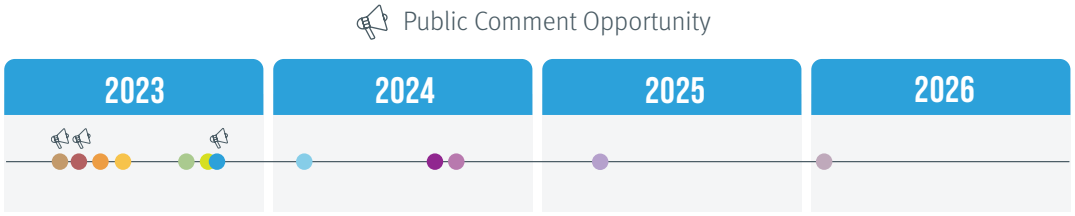
- First, the Inflation Reduction Act gives Medicare the ability to negotiate prices for a select group of drugs whose negotiated prices would take effect in Medicare starting in 2026.
- Second, it protects Medicare beneficiaries from excessive drug price increases by capping Medicare drug price increases at the rate of general inflation starting in 2023.
- Third, the law makes Medicare drug coverage more generous. It does so by capping monthly out-of-pocket costs for insulin at $35 starting in 2023. It also caps total out-of-pocket costs for prescription drugs at $2,000 by 2025. And in 2024, the law removes cost-sharing during the "catastrophic phase" of Part D drug coverage, which is reached after a Medicare beneficiary spends a certain amount of money on prescription drugs during the year.
- Fourth, the IRA expands eligibility for "full benefit" Part D low-income subsidies (LIS) to Medicare beneficiaries with incomes up to 150 percent of the federal poverty level starting in 2024. These subsidies fully cover Part D premiums and deductibles and reduce copays. Previously, full LIS benefits were available only to beneficiaries with incomes up to 135 percent of poverty.
- Fifth, the IRA makes all vaccines available at no cost to Medicare beneficiaries starting in 2023.

For a deeper dive into the Inflation Reduction Act's Medicare Drug Price Negotiation Provisions see Appendix 1 on page 11.

Initial Timeline of Medicare Drug Price Negotiations

Applicable to Drugs Whose Negotiated Prices Will Be Available Beginning in 2026

The timeline for implementing the Inflation Reduction Act's drug negotiation provisions starts in early 2023, as required by the legislation and scheduled by CMS. Advocates need to be aware of every critical deadline to prepare to engage with CMS privately and publicly to ensure that people who rely on Medicare are prioritized at every step of the way.



- **March 15, 2023***: CMS published initial draft guidance outlining how it will implement the Medicare drug negotiation program for negotiated drugs whose lower prices will be available beginning in 2026.[Δ] CMS has indicated that the public will have opportunities to comment on this draft guidance by April 14, 2023.
- **Spring 2023***: CMS will release two "data collection processes," inviting the public to comment on what data and information should be collected by the Federal government for negotiating the maximum fair prices, including data that is submitted for the offer and counteroffer process.
- **May 31, 2023**: CMS can begin using expenditure data from June 1, 2022 – May 31, 2023 to determine which 10 drugs are eligible for negotiation (that is, Part D drugs with highest total expenditures) for 2026.
- **Summer 2023***: CMS will revise its draft guidance on how it will implement the Medicare drug negotiation program for negotiated drugs whose lower prices will be available beginning in 2026 based on public feedback received in spring 2023.
- **September 1, 2023**: CMS is required to publicize the first 10 drugs it selects for negotiation.
- **October 1, 2023**: Beginning of the negotiation period.
- **October 2, 2023**: Deadline for drug manufacturers to submit information to CMS to inform its calculation of an initial price offer. Note: The public will also have an opportunity to provide information that may inform an initial price offer.* More information on which data may be requested by CMS will be published in summer 2023.
- **February 1, 2024**: CMS provides drug manufacturers with initial price offers. If a manufacturer elects to submit a counteroffer, it must do so within 30 days of receiving the initial offer from CMS.
- **August 1, 2024**: End of the negotiation period for the first 10 selected drugs.
- **September 1, 2024**: CMS will make public the final negotiated maximum fair prices.
- **March 1, 2025**: CMS will make public its explanation for how it arrived at the negotiated maximum fair prices.
- **January 1, 2026**: The negotiated prices for each of the 10 selected Medicare Part D drugs go into effect.

*These dates are based on CMS' January 2023 letter to interested parties and CMS' March 2023 fact sheet on implementation of the Medicare drug negotiation program.

[Δ] This draft guidance will lay out how CMS will implement key elements of the IRA's drug negotiation provisions, such as how the agency will calculate a maximum fair price offer using the factors listed in the IRA, the process by which it will provide a price offer to manufacturers and receive any counteroffers, and the process for monitoring compliance and imposing any penalties for violations.

5 Key Areas for Advocacy: What to Watch For

CMS will need to make several key regulatory decisions when implementing the drug price negotiation provisions of the IRA. Advocates should be aware of these decisions and be prepared to comment on each one.

KEY DECISION 1

Whether CMS continues to give consumer and patient advocates an opportunity to review and comment on negotiation policy decisions

KEY DECISION 2

The process CMS uses to calculate a maximum fair price for the group of drugs whose high prices it chooses to negotiate

KEY DECISION 3:

How CMS ensures that information from drug manufacturers is accurate and complete

KEY DECISION 4

The amount of detail and the manner in which CMS publicizes the methodology and other negotiation policy decisions

KEY DECISION 5

How CMS uses the renegotiation process when negotiated drugs change in ways that warrant an updated maximum fair price

KEY DECISION 1

Whether CMS continues to give consumer and patient advocates an opportunity to review and comment on negotiation policy decisions

Under the Administrative Procedures Act, CMS is required to provide an opportunity for public comment on any proposed rules or regulations as they relate to any new or existing law. However, in the case of the Inflation Reduction Act's drug price negotiation provisions, the IRA requires CMS to implement many of the law's drug negotiation provisions through sub-regulatory "program instruction or other forms of program guidance" for the parts of the process that lead to maximum fair prices that take effect beginning in 2026, 2027, and 2028.

Fortunately, CMS has recently indicated that it will give the public opportunities to provide feedback on a broad range of issues regarding the implementation of the Medicare negotiation program. Advocates should ensure that CMS follows through on its stated commitment to providing sufficient opportunities for the public to provide input to inform these negotiation policy decisions.

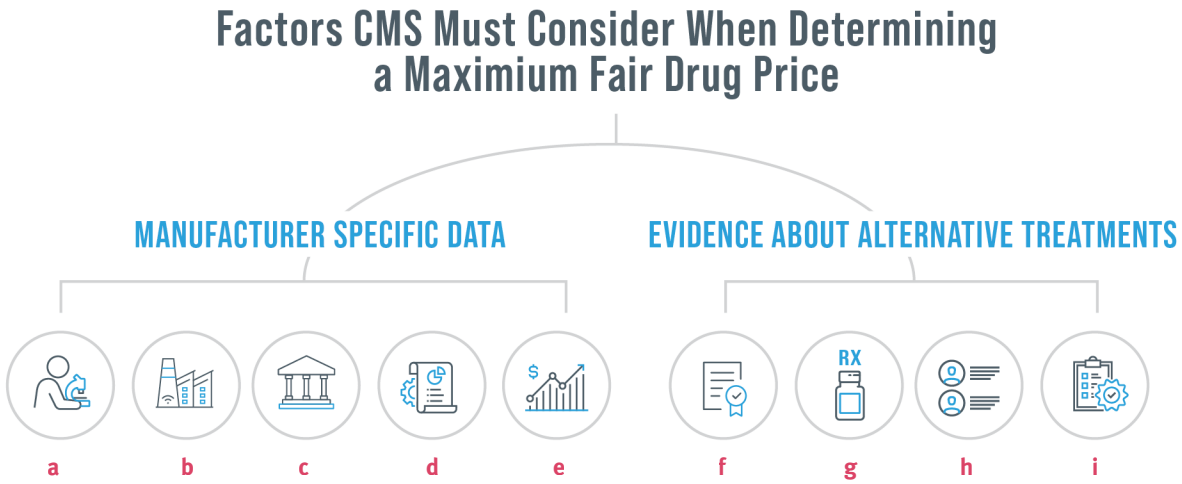
KEY DECISION 2

The process CMS uses to calculate a maximum fair price for the group of drugs whose high prices it chooses to negotiate

The Inflation Reduction Act requires CMS to develop and apply a consistent methodology and process for negotiating with drug manufacturers to arrive at a maximum fair price. It clearly states that CMS must develop a negotiation process that "aims to achieve the lowest maximum fair price for each selected drug." Advocates must hold CMS accountable for meeting that requirement and make sure that the process CMS develops provides a truly low and fair price.

A vital step in the negotiation process is how CMS arrives at the initial and final price that it offers to drug manufacturers. The law lists nine factors that CMS is required to "consider" when calculating an initial and final maximum fair price offer. However, there is no direction for how CMS should prioritize, weight, or define these factors when arriving at a pricing decision. This is an important opportunity for advocates to provide guidance and technical assistance to CMS privately and publicly to ensure that the process CMS develops prioritizes the needs and interests of older adults, people with disabilities, and families across the country.

The Inflation Reduction Act identified the following factors that CMS is required to consider (in no particular order) when calculating a maximum fair price offer for a given drug:



Manufacturer-Specific Data

a. Research and development (R&D) costs and the extent to which those costs have been recouped.

b. Current unit cost of production and distribution.

c. Prior federal financial support for therapeutic discovery and development.

d. Data on pending or approved patent applications, exclusivities recognized by the FDA, and applications and approvals by the FDA.

e. Market data and revenue and sales volume information for the United States.

Evidence About Alternative Treatments

f. Extent to which the drug is a therapeutic advance relative to other existing drugs and treatments available (and their associated costs).

g. Prescribing information on the drug per the FDA approval documentation (for example, which condition(s) the drug is approved to treat).

h. Comparative effectiveness research on the drug and other existing drugs and treatments available, with consideration of how specific populations are impacted (for example, individuals with disabilities).

i. Extent to which this drug addresses unmet medical needs that currently available therapies do not adequately address.

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HOW FAMILIES USA IS THINKING ABOUT THIS ISSUE

CMS should develop a methodology that determines a maximum fair price based primarily on the therapeutic value of the drug using a cost-effectiveness approach.

To determine the cost effectiveness of each selected drug, we suggest CMS first assess the clinical effectiveness using measures that examine the impact a drug has on longevity, day-to-day function, and quality of life. Then, it should calculate and consider additional measures of clinical effectiveness using alternative health outcomes, including condition-specific health outcomes or other desirable outcomes (for example, reductions in heart attacks or lower hospital readmission rates). Importantly, the Inflation Reduction Act specifically bars the use of so-called quality-adjusted life years in measuring cost effectiveness. CMS should conduct these cost-effectiveness analyses in a way that is consistent with this law and more broadly with a commitment to the equal value of all people regardless of their age, disability status, or whether they are terminally ill.

CMS should then establish cost-effectiveness targets or thresholds, in consultation with the HHS Office of the Assistant Secretary for Planning and Evaluation, that will serve as a foundational maximum fair price range for how it arrives at a maximum fair price. CMS should also consider relevant contextual and non-clinical factors to help guide where in the price range they choose. For instance, CMS should consider the extent to which the selected drug is relatively more or less clinically effective then any therapeutic alternatives currently available and the prices of those therapeutic alternatives to inform where within the price range it selects.

Lastly, to ensure that patients and other stakeholders have sufficient input into the process of calculating a fair price and any determinations of clinical effectiveness, CMS should convene a consumer or patient advocate advisory panel or panels to seek input from patients and patient advocacy groups that are not funded by the pharmaceutical industry or associated industries. These panels could be established on either a drug-by-drug basis or for classes of drugs and the types of conditions that the drug is indicated to treat. This will ensure CMS is prioritizing measuring the benefits (and harms) associated with the selected drugs that are most relevant and meaningful to patients.

Given that price calculation is such a critical step in the drug negotiation process, advocates should consider how each factor should be defined, used, and weighted when calculating a maximum fair price and be prepared to communicate their recommendations to CMS through direct and indirect advocacy.

Further, advocates should urge CMS not to take any shortcuts when calculating maximum fair prices. Some experts have suggested that CMS could simply use the "ceiling for maximum fair price" calculation included in the Inflation Reduction Act as the sole method for arriving at a fair price.

For context, the IRA sets this fair price ceiling for Part D drugs as the lower of two prices: a percentage (depending on how long the drug has been on the market) of the "Average Manufacturer Price"; or the net price that was already negotiated by Medicare Part D plan sponsors after rebates and other discounts. However, Congress did not intend this ceiling to be a substitute for price negotiation—Congress clearly directed CMS to achieve the truly lowest fair price. If CMS were to use the "ceiling" alone, it would almost certainly not achieve the maximum potential savings. And using the ceiling would eliminate the opportunity to collect, synthesize, and publicize more nuanced information about each selected drug, as CMS must do when explaining how it arrives at maximum fair prices. CMS should treat the price ceiling as an outer bound that is largely not relevant to the fair price calculation.

KEY DECISION 3

How CMS ensures that information from drug manufacturers is accurate and complete

As CMS begins the drug negotiation process, it will request proprietary information from drug manufactures to inform its calculation of maximum fair prices and as part of the subsequent negotiation process. This will likely include information about the drug manufacturer's research and development costs; current costs of production; market data; sales information; and any internal research, including safety and effectiveness studies that have been conducted. It is essential that this information is accurate and complete to ensure that CMS has the information it needs to calculate truly fair prices.

Drug manufacturers have often shown that they can and will game such reporting systems to their benefit. For example, it was found that many manufacturers have misclassified their drugs as generics, thus paying significantly less in rebates under the Medicaid Drug Rebate Program.[2]

Advocates should closely scrutinize any data that is reported by drug manufacturers associated with the drug negotiation process (to the extent it is made publicly available) and ensure that CMS

is verifying the accuracy of this information. For instance, advocates can help ensure that CMS compares the information it receives from drug manufacturers with independent data sources. Advocates may also push CMS to consider conducting third-party verification, such as contracting with an auditing firm or firms.

KEY DECISION 4

The amount of detail and the manner in which CMS publicizes the methodology and other negotiation policy decisions

Once CMS has negotiated maximum fair prices for its selected drugs, it is required to publish the final maximum fair prices and an explanation for how it arrived at each maximum fair price, including which factors it used. This reporting requirement is important because it provides the public and other payers of prescription drugs with access to information on the value of select high-priced prescription drugs and what a fair price may be. It is possible that private payers will use the published information from these Medicare negotiations as a reference point when conducting their own negotiations with drug manufacturers, which would help drive down drug prices in the private insurance market.

CMS is given wide discretion when deciding which information that is used to determine a fair market price is made public or not. Advocates should take every opportunity to push CMS to implement the IRA's reporting requirement in a way that publicizes as much information as possible. This includes which factors and value frameworks were used to come to their decision regarding a maximum fair price, as well as any information received from drug manufacturers. Further, once the information is made public, advocates should help circulate it as widely as possible to help maximize its potential impact on drug prices across the private market.

KEY DECISION 5

How CMS uses the renegotiation process when negotiated drugs change in ways that warrant an updated maximum fair price

Starting in 2028, the Inflation Reduction Act gives CMS the opportunity to renegotiate previously negotiated drug prices if any of the factors that informed the original maximum fair price have changed. As outlined in the law, CMS can initiate this renegotiation process if a selected drug has a new disease indication, changes to an extended-monopoly (i.e., 12 years or longer on the

It is important that advocates focus on how the Inflation Reduction Act is implemented, helping ensure that CMS puts strong regulations and guidance documents into place that will prioritize the needs of Medicare beneficiaries.

market post FDA approval) or long-monopoly drug (i.e., 16 years or longer on the market post FDA approval), or if any of the other factors used to calculate a fair price changed.

Advocates should hold CMS accountable to using this renegotiation authority, carefully tracking CMS' selected or negotiated drugs and any changes that may inform an updated maximum fair price. This will help ensure that CMS is using the renegotiation process aggressively so Medicare patients pay the lowest prices possible over time. Given the likelihood that at least one of the factors will change each year for most of its negotiated drugs, we expect that CMS should use this renegotiation process every year for at least a portion of their previously negotiated drugs.

Conclusion

The Medicare drug provisions in the Inflation Reduction Act are a significant victory for older adults, people with disabilities, and families across the country. However, critical decisions must still be made when CMS implements the law through regulatory and sub-regulatory processes. These decisions will determine whether negotiations with drug manufacturers produce truly fair prices, which will have significant impacts on the health and well-being of everyone who relies on Medicare. It is important that advocates focus on how the Inflation Reduction Act is implemented, helping ensure that CMS puts strong regulations and guidance documents into place that will prioritize the needs of Medicare beneficiaries for many years to come. Health advocates continued participation will play a critical role in making the Inflation Reduction Act truly a win for families across the country.

Appendix 1

Deep Dive: The Inflation Reduction Act's Medicare Drug Price Negotiation Provisions*

The Inflation Reduction Act's statutory language contains several important components regarding the drug price negotiation process. Advocates should familiarize themselves with these components to help inform and guide their work as CMS implements this historic law. Below, we list the components that Families USA believes are the most important for advocates to understand and act on. This list also provides context for the "Key Decisions" section of this guide starting on page 4.

- **Eligible Drugs:** Drugs and biological products are eligible for negotiation if they are:
  1. Single-source, brand-name drugs that were approved by the FDA at least seven years ago, or
  2. Biologics that were approved at least 11 years ago.

  Additionally, eligible drugs and biologics cannot have generic or biosimilar competition. (42 USC §1320f-1(e))†

- **Selecting Eligible Drugs for Negotiation:** To choose which drugs are subject to negotiation, CMS is required to rank eligible drugs by their total expenditures (gross covered prescription drug costs) under Parts B and D during a recent 12-month period and choose those drugs with the highest total costs. (42 USC §1320f-1(d))
  - CMS can negotiate prices for a certain number of drugs each year, with negotiated prices going into effect starting in 2026.
    - In 2026, CMS can implement negotiated prices for 10 Medicare Part D drugs.
    - In 2027, CMS can implement negotiated prices for 15 additional Medicare Part D drugs.
    - In 2028, CMS can implement negotiated prices for another 15 Medicare Part B and D drugs
    - In 2029 and each subsequent year, CMS can implement negotiated prices for 20 additional Medicare Part B and D drugs. (42 USC §1320f-1(a))

- **Negotiation Process:** CMS is required to develop and use a consistent process for negotiations that "aims to achieve the lowest maximum fair price for each selected drug." (42 USC §1320f-3(b)(1))
  - Once a drug is selected for negotiation, its manufacturer is required to enter into an agreement with CMS. As part of this agreement, CMS and the manufacturer will enter into a

* For a copy of the complete public law text related to the Inflation Reduction Act's Medicare Drug Negotiation, refer to 42 USC Chapter 7, Subchapter XI, Part E: Price Negotiation Program To Lower Prices for Certain High-Priced Single Source Drugs.

† There are a number of additional exceptions as to which drugs and biologics are eligible for negotiation. For instance, certain orphan drugs that treat only one rare disease cannot be subject to negotiation.

negotiation process where CMS will calculate and provide an initial fair price offer and give the manufacturer an opportunity to review and respond with a counteroffer.

- Once a fair price is agreed upon, the manufacturer is required to make the selected drug available and accessible at that price to Medicare beneficiaries and their health care providers.* (42 USC §1320f-2) (42 USC §1320f-3)
- To inform these negotiations, manufacturers are required to provide any information requested by CMS. (42 USC §1320f-2(4))

Maximum Fair Price Calculation

- CMS is given wide discretion to develop its own methodology for calculating the maximum fair price offer and counteroffers for the negotiation process. However, the IRA lists nine factors that CMS is required to "consider" when calculating that maximum fair price offer. These factors can be categorized into two main groups: ***manufacturer-specific data***, such as the drug's unit cost and research and development costs, and ***evidence about alternative treatments***, such as information on the comparative effectiveness of the drug and alternative drugs.† (42 USC §1320f-3(e))
- Importantly, CMS is restricted from offering a maximum fair price that is higher than the statutorily defined "Ceiling for Maximum Fair Price." This ceiling is calculated differently for Part D and B drugs, but it roughly equates to the lesser of: 1) the average sales price of the selected drug, or 2) a percentage‡ of the average non-federal manufacturer price for 2021 accounting for inflation. (42 USC §1320f-3(c))

Renegotiation Process: Starting in 2028, CMS has the option to renegotiate previously negotiated drug prices in the event that any of the factors that informed the original maximum fair price have changed. CMS can initiate this process if a selected drug has a new disease indication or stays on the market without generic or biosimilar competition for a certain period of time, or if any of the other factors used to calculate a fair price have changed. (42 USC §1320f-3(f))

Publication of Final Negotiated Fair Prices: CMS is required to make public the final maximum fair prices along with an explanation for how it arrived at each maximum fair price, including which factors it used. (42 USC §1320f-4)

* Drug manufacturers that do not comply with the requirements of the negotiation process with CMS, such as not agreeing to enter negotiation or to a maximum fair price, will be subject to an excise tax of up to 95 percent of their U.S. sales associated with the drug selected for negotiation (26 USC §5000D). CMS can also impose civil monetary penalties if manufacturers do not offer the maximum fair price that is agreed upon or knowingly provide false information to CMS during the negotiations (42 USC §1320f-6).

† A complete list of these factors can be found under Key Decision 2 on page 6.

‡ Note: this percentage varies based on the length of time a drug has been on the market since FDA approval. For instance, the fair price ceiling for drugs that have been on the market for less than 12 years is 75 percent of the Average Manufacturer Price, whereas for drugs that have been on the market for 16 years or more that price ceiling is 40 percent of the Average Manufacturer Price.

Endnotes

[1] Pharmaceutical Research and Manufacturers of America. (2022, August 16). *PhRMA Statement on the Inflation Reduction Act Becoming Law* [Press release]. https://phrma.org/resource-center/Topics/Access-to-Medicines/PhRMA-Statement-on-the-Inflation-Reduction-Act-Becoming-Law.

[2] Department of Health and Human Services, Office of Inspector General, *Potential Misclassifications Reported by Drug Manufacturers May Have Led to $1 Billion in Lost Medicaid Rebates* (OEI-03-17-00100) (HHS OIG, December 2017), https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf.

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RX2022-162