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FAQs about the Inflation Reduction Act's Medicare Drug Price Negotiation Program

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Published: Aug 20, 2024

This brief was updated in August 2024 to reflect actions that have occurred in the Drug Price Negotiation Program since the August 2023 version, including the announcement of negotiated prices for the first round of selected drugs.

The Inflation Reduction Act of 2022 (https://www.congress.gov/bill/117th-congress/house-bill/5376) (the Act), signed into law by President Biden in August 2022, includes several provisions (https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/) to lower prescription drug costs for people with Medicare and reduce drug spending by the federal government. One of the Act's key drug-related policies is a requirement for the Secretary of Health and Human Services (HHS) to negotiate prices with drug companies for certain drugs covered under Medicare Part D (starting in 2026) and Part B (starting in 2028). This new requirement is the culmination of years of debate (https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/) among lawmakers over whether to grant the federal government the authority to negotiate drug prices in Medicare, and is being implemented at the same time that several lawsuits have been filed (https://www.nytimes.com/2023/07/23/us/politics/medicare-drug-price-negotiations-lawsuits.html) seeking to thwart this effort. CMS announced negotiated prices (https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf) for the list of 10 Part D drugs (https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf) selected for negotiation on August 15, 2024.

Drawing on CMS's guidance (https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf) for the first year of the new Medicare drug price negotiation program and the Act's statutory language, these FAQs address the following

questions related to the new negotiation program and CMS's plans for implementation, with a focus on the details that apply for 2026:

Which drugs were selected for price negotiation for 2026?

For 2026, CMS selected 10 Part D drugs for price negotiation with drug manufacturers. The list of 10 Part D selected drugs was published in August 2023 (https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf). The 10 drugs selected for the first round of negotiations include treatments for several medical

conditions, including diabetes (Farxiga, Fiasp/NovoLog, Januvia, Jardiance), blood clots (Eliquis, Xarelto), heart failure (Entresto, Farxiga), psoriasis (Stelara, Enbrel), rheumatoid arthritis (Enbrel), Crohn's disease (Stelara), and blood cancers (Imbruvica) (Table 1).

The number of drugs subject to price negotiation will increase in future years: 15 Medicare Part D drugs for 2027, another 15 drugs covered under Medicare Part D or Part B for 2028, and another 20 drugs covered under Part D or Part B drugs for 2029 and later years. The number of drugs with negotiated prices available will accumulate over time.
(Back to top)

What was the outcome of the first round of price negotiation for 2026?

On August 15, 2024, CMS announced negotiated prices (https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026) for the first 10 drugs that were selected for negotiation. These prices will take effect for Medicare beneficiaries on January 1, 2026. According to CMS, Medicare would have saved $6 billion if the prices that CMS negotiated for these 10 drugs had been in effect in 2023, amounting to net savings of 22% on these medications. CMS has also estimated that Medicare beneficiaries will save $1.5 billion when these negotiated prices take effect in 2026.

CMS will publish an explanation of the negotiated prices for the first 10 selected drugs by March 1, 2025, based on the factors that were considered in the negotiation process, including manufacturer-specific financial data about the selected drugs and evidence about the clinical benefits of selected drugs compared to alternative treatments.
(Back to top)

Which types of drugs qualified for price negotiation for 2026?

Drugs qualified for price negotiation for 2026 if they are covered under Medicare Part D, Medicare's outpatient prescription drug benefit program, and are single source brand-name drugs or biological products (https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers) without therapeutically-equivalent generic or biosimilar alternatives that are approved or licensed and marketed on a "bona fide" basis (see below). In addition, a drug product must be at least 7 years (for small-molecule drugs) or 11 years (for biologics) past its FDA approval or licensure date, as of the date that the list of drugs selected for negotiation is published. This means that for a single source drug to be eligible for negotiation for 2026, a drug product must have been approved on or before September 1, 2016, and a biological product must have been licensed on or before September 1, 2012. For drugs with multiple FDA approvals, CMS will use the earliest approval date to determine the number of years that have elapsed.

The definition of 'qualifying single source drug' excludes certain types of drugs: (1) drugs that are designated for only one rare disease or condition and approved for an indication (or indications) only for that disease or condition (known as the orphan drug exclusion); (2)

drugs with total spending under Part D and Part B combined of less than $200 million (based on data from June 1, 2022 to May 31, 2023 for the 2026 determination); and (3) plasma-derived products. For 2026 to 2028, the Act also makes an exception for so-called "small biotech" drugs (explained in more detail below).

According to CMS, a drug that is designated for more than one rare disease or condition will not qualify for the orphan drug exclusion, even if it is not approved for any indications for those additional diseases or conditions. CMS will only consider *active* designations and approvals when making determinations about whether a drug qualifies for the orphan drug exclusion.
(Back to top)

How did CMS identify the 10 drugs selected for price negotiation for 2026?

The 10 Part D drugs selected for price negotiation for 2026 were chosen from the top 50 negotiation-eligible Part D drugs with the highest total Medicare Part D expenditures. For this purpose, total expenditures are defined as total gross covered prescription drug costs (https://www.ssa.gov/OP_Home/ssact/title18/1860D-15.htm#:~:text=(3)-,Gross%20covered%20prescription%20drug%20costs,-.%E2%80%94For%20purposes). To determine this ranking, CMS first identified the qualifying single source drugs among all covered Part D drugs, applying the relevant statutory exclusions (as described above). CMS then calculated total expenditures for each qualifying drug, based on spending data for the 12-month period from June 1, 2022 to May 31, 2023. The top 50 drugs with the highest total expenditures for this 12-month period were the negotiation-eligible drugs for 2026.

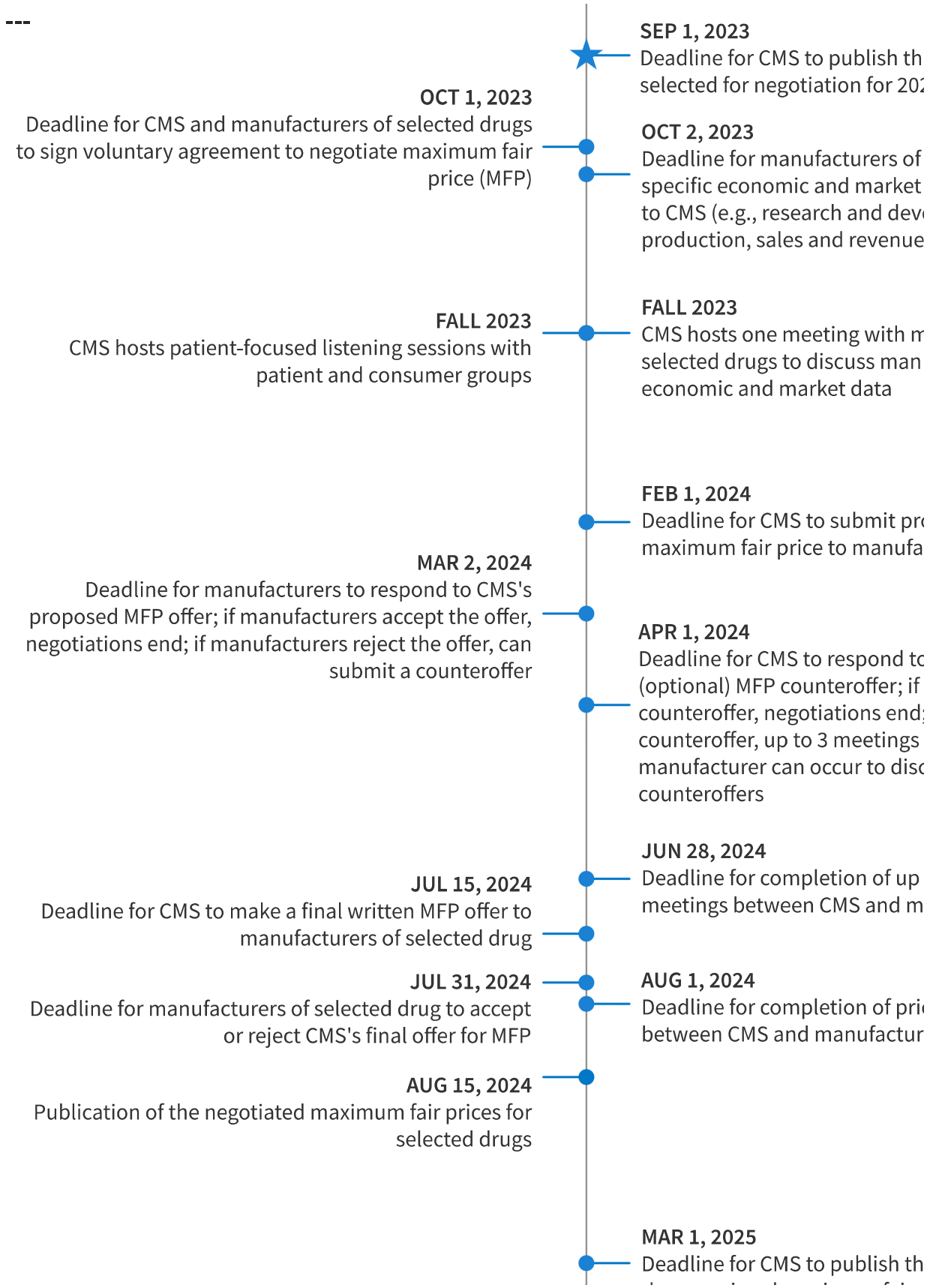
The Inflation Reduction Act provides for a delay in selecting drugs for negotiation if they are biological products where there is a "high likelihood" of biosimilar market entry within two years of the publication date of the selected drug list (see details below). Therefore, before selecting the 10 highest-ranked Part D drugs from this top 50 list, CMS first removed any biological products that might have qualified for delayed selection based on a high likelihood of biosimilar market entry before September 1, 2025. However, CMS did not identify any biological drugs that qualified for delayed selection based on the biosimilar delay provision.
(Back to top)

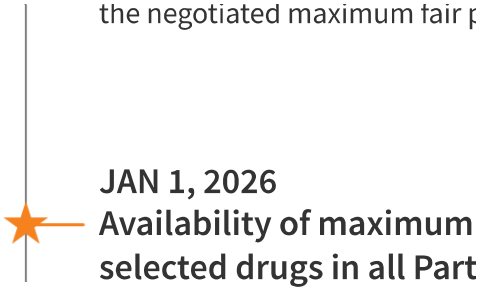
What is the timeline for key activities under the Medicare drug price negotiation program for 2026?

For the 10 Part D selected drugs with negotiated prices taking effect in 2026, Figure 1 provides a timeline of key dates and activities in the negotiation timeline.

Figure 1

Timeline of Key Activities Under the Medicare Drug Price Negotiation Program For Initial Price Applicability Year 2026





Note: CMS is Centers for Medicare & Medicaid Services. MFP is maximum fair price.
Source: KFF analysis of dates in Centers for Medicare & Medicaid Services, Medicare Drug Price Negotiation: Revised Guidance, June 30, 2023. • Download PNG • Download PDF

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(Back to top)

What is the timeline for key activities under the Medicare drug price negotiation program for 2027?

CMS will announce the next set of 15 Part D drugs selected for negotiation by February 1, 2025. The negotiation process for these 15 drugs will begin on February 28 and end on November 1. CMS will announce maximum fair prices for these drugs by November 30, 2025, with negotiated prices available on January 1, 2027.
(Back to top)

How will CMS determine if a generic or biosimilar is available and being marketed?

The availability and "bona fide" marketing of a generic or biosimilar for any strength or dosage form of a drug product will eliminate that drug from consideration as a qualifying single source drug. In determining whether a potential qualifying single source drug may be disqualified based on the availability and bona fide marketing of a generic or biosimilar, CMS intends to draw on information from multiple sources.

CMS will use FDA reference sources to determine whether a generic or biosimilar has been approved. In determining whether generic or biosimilar equivalents were available and marketed on a bona fide basis for the potential qualifying single source drugs for 2026, CMS reviewed Part D claims data from the period of August 16, 2022 to August 15, 2023, and Average Manufacturer Price (AMP) data for August 1, 2022 to July 31, 2023 to assess utilization and sales of generics or biosimilars.

According to CMS guidance, the determination of marketing on a bona fide basis will not be based on a strict quantitative definition but on the "totality of circumstances," which, in addition to utilization and sales data, could also include factors such as whether the generic or biosimilar is readily available for purchase and whether any agreements exist between

manufacturers of the brand and generic drug that might limit availability of the drug. CMS will conduct ongoing assessments to determine whether "meaningful" competition exists and ensure marketing on a bona fide basis.
(Back to top)

What is the Small Biotech Exception?

For 2026 through 2028, the Inflation Reduction Act specifies that so-called "small biotech" drugs will not be eligible for negotiation. To qualify under this "Small Biotech Exception" for 2026, total expenditures under Part D on the drug in 2021 must be both 1% or less of total Part D expenditures for all covered Part D drugs, and 80% or more of total expenditures under Part D for all of the manufacturer's drugs where a Coverage Gap Discount Program agreement (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/CGDPMfr-Agrmt-052018.pdf) was in effect in 2021. These calculations are made by CMS.

A manufacturer that seeks to have a drug considered for the Small Biotech Exception is required to submit information (https://www.cms.gov/files/zip/cms-10844.zip) about the company and its products to CMS. For 2026, exception requests were due on July 3, 2023 (https://www.cms.gov/files/document/small-biotech-exception-guidance-6223.pdf), allowing time for CMS to determine which drugs might qualify for the Small Biotech Exception prior to the September 1, 2023 selected drug publication date for 2026. For 2026, CMS determined that four drugs qualified for the Small Biotech exception, based on requests and information submitted by their manufacturers.

Manufacturers who want to have a drug considered for this exception for 2027 and 2028 will have to resubmit their request in the future, since CMS's determinations about the Small Biotech Exception for 2026 will not carry over to future years.
(Back to top)

What is the Biosimilar Delay?

The Inflation Reduction Act provides for a delay in selecting drugs for negotiation if they are biological products where there is a "high likelihood" of biosimilar market entry within two years of the publication date of the selected drug list. For 2026, this means that licensure and marketing of a biosimilar must be highly likely to occur before September 1, 2025. The rationale for this delay is to not create financial incentives that could deter biosimilars from entering the market if, for example, a reference product (https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf) (the original biological product approved by FDA against which a proposed biosimilar product is compared) is selected for negotiation and ultimately priced lower than potential competitor biosimilar products.

For CMS to consider whether to grant such a delay, the manufacturer of the biosimilar biological product for a given negotiation-eligible reference product will need to submit a delay request to CMS prior to the selected drug publication date. The biosimilar manufacturer must not be the same as the manufacturer of the reference product, and there must be no agreements between the two manufacturers that restricts the availability of the biosimilar in the U.S. A biosimilar manufacturer will not know if the reference product will be selected for negotiation when they submit this request, but CMS will disregard the request if the reference product does not end up being selected for negotiation. For 2026, the deadline for biosimilar manufacturers to submit a delay request to CMS, including the documentation required to support CMS's consideration of the request, was May 22, 2023.

CMS will make a determination of whether there is a high likelihood of biosimilar market entry based on two factors: (1) whether an application for licensure of the biosimilar product has been accepted for review or already approved by the FDA (no later than August 15, 2023 for the 2026 negotiation year), and (2) "clear and convincing" evidence that the biosimilar product will be marketed within two years of the selected drug publication date, including demonstrating that there are no patent barriers to entry and operational readiness to bring the biosimilar product to market. CMS will not grant a request to delay selection of a reference product for negotiation if more than one year has passed between licensure of the biosimilar and its marketing.

For 2026, CMS determined that there were no biological products that would otherwise have been selected for negotiation but for successful Initial Delay Requests.
(Back to top)

What factors does CMS use in negotiating the maximum fair price for a given selected drug?

The Inflation Reduction Act requires CMS to consider certain manufacturer-specific factors and information about therapeutic alternatives to selected drugs in negotiating the so-called "maximum fair price" for selected drugs, although the Act does not specify how CMS should weigh these different elements in the process of developing its offer for the maximum fair price.

The manufacturer-specific factors related to selected drugs include:

- The manufacturer's research and development costs and the extent to which the manufacturer has recouped these costs.
- The current unit costs of production and distribution.
- Federal financial support for novel therapeutic discovery and development related to the drug.
- Data on pending and approved patent applications, exclusivities, and certain other applications and approvals.

- Market data and revenue and sales volume data in the US.

For the manufacturers of the 10 Part D selected drugs for 2026, these data elements were required to be reported to CMS by October 2, 2023.

Information about therapeutic alternatives includes:

- The extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives and the costs of these alternatives.
- Prescribing information for the selected drug and its therapeutic alternatives, which may include generics or biosimilars.
- Comparative effectiveness of the selected drug and its therapeutic alternatives, taking into account their effects on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations.
- The extent to which the selected drug and its therapeutic alternatives address unmet needs for a condition that is not adequately addressed by available therapy.

According to CMS guidance, information on these factors may be submitted by several entities, including the manufacturer of the selected drug, other drug manufacturers, people with Medicare, academic experts, clinicians, and others. Submissions were due by October 2, 2023 for the selected drugs for 2026. In addition to evaluating the information in these submissions, CMS will review the literature and real-world evidence, conduct internal analysis, and consult with experts regarding evidence of the clinical benefits of the selected drugs and their therapeutic alternatives.

The Act explicitly directs (https://www.congress.gov/bill/117th-congress/house-bill/5376/text#:~:text=C)%2C%20the%20Secretary-,shall%20not%20use,-evidence%20from%20comparative) that the HHS Secretary "shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill." In other words, the use of health outcomes evidence based on quality-adjusted life years (https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.00343) (QALYs) in the process of negotiating a maximum fair price is not permitted.
(Back to top)

Who is eligible to receive the maximum fair price?

For selected drugs covered under Part D that are dispensed directly to individuals by a retail or mail order pharmacy, Medicare beneficiaries who are enrolled in Part D stand-alone drug prescription plans or Medicare Advantage plans offering drug coverage are eligible to receive the maximum fair price. For selected drugs covered under Part B that are administered to individuals in provider settings, Medicare beneficiaries enrolled in Part B, including those in both traditional Medicare and Medicare Advantage plans, are eligible to receive the maximum fair price. (Part B drugs will not be selected for negotiation until 2028.)

According to CMS guidance, the maximum fair price for a Part D selected drug must be provided to an enrollee when they use their Part D coverage to obtain that drug, but not when other coverage or payment arrangements are used, including plans that receive the Retiree Drug Subsidy, discount cards, or cash purchases.

While the Inflation Reduction Act requires manufacturers of selected drugs to ensure access to the maximum fair price to all eligible individuals and providers, CMS plans to contract with a so-called "Medicare Transaction Facilitator" to help with the exchange of information between different entities in the prescription drug supply chain to enable manufacturers to pass through the maximum fair price to dispensers of selected drugs for eligible individuals.

The Act establishes that manufacturers that do not ensure access to the maximum fair price for selected drugs to eligible individuals and dispensers may be subject to civil monetary penalties.
(Back to top)

Is there a ceiling on the maximum fair price? Does it vary depending on the type of drug?

The Inflation Reduction Act establishes an upper limit for the maximum fair price for a given drug. The upper limit is the lower of the drug's enrollment-weighted negotiated price (net of all price concessions, including rebates) for a Part D drug, the average sales price for a Part B drug (which is the average price to all non-federal purchasers in the U.S, inclusive of rebates, other than rebates paid under the Medicaid program), or a percentage of a drug's average non-federal average manufacturer price (non-FAMP) (which is the average price wholesalers pay manufacturers for drugs distributed to non-federal purchasers). This percentage of non-FAMP varies depending on the number of years that have elapsed since FDA approval or licensure: 75% for small-molecule drugs and vaccines more than 9 years but less than 12 years beyond approval; 65% for drugs between 12 and 16 years beyond approval or licensure; and 40% for drugs more than 16 years beyond approval or licensure. This approach means that the longer a drug has been on the market, the lower the ceiling on the maximum fair price.
(Back to top)

How will CMS determine its initial offer for the maximum fair price for a selected drug?

To determine its initial offer for a maximum fair price for a selected drug, CMS will: (1) identify therapeutic alternative(s) for the selected drug; (2) determine pricing information about the therapeutic alternatives to determine the starting point for the initial offer; (3) adjust the initial offer based on information about clinical benefit of the selected drug compared to its therapeutic alternatives; and (4) make further adjustments to the offer price as needed based on manufacturer-specific data to determine the initial offer price.

According to the guidance, CMS will use the price of therapeutic alternative(s) as the starting point for determining the initial offer for the maximum fair price for a given selected drug. Specifically, CMS will use the price net of all price concessions (including rebates) for Part D drugs and/or the Average Sales Price (ASP) of Part B drugs that are therapeutic alternatives to the selected drug, including generics and biosimilars (unless these prices are above the statutory ceiling for the maximum fair price). If there is more than one therapeutic alternative for a selected drug, CMS will determine the starting point within the range of prices for those products.

For selected drugs with no therapeutic alternative or where the price of the alternative(s) is above the ceiling price, CMS will use the Federal Supply Schedule (FSS) (https://www.gsa.gov/buy-through-us/purchasing-programs/gsa-multiple-award-schedule/about-gsa-schedule) or "Big Four Agency (https://www.cbo.gov/publication/57007)" price as the starting point. (Drug prices listed on the FSS, which establishes prices available to all direct federal purchasers, are determined through both statutory rules and negotiation. A statutory cap on drug prices for the Big Four agencies—the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard—means the prices they pay are generally lower than prices paid by other direct federal purchasers.) If the FSS or Big Four prices are above the statutory ceiling, CMS will use the statutory ceiling as the starting point for its initial offer.

CMS will adjust the starting point for the initial offer based on the "totality" of evidence about the clinical benefit the selected drug provides relative to its therapeutic alternatives, including information about potential safety concerns and side effects, whether the selected drug represents a therapeutic advance as measured by improvements in clinical outcomes, and information about the effects of the selected drug and its therapeutic alternatives on specific populations, including people with disabilities and older adults. CMS will also consider comparative effectiveness data on patient-centered outcomes and patient experiences.

If a selected drug has no therapeutic alternatives, CMS will evaluate evidence about the drug's clinical benefit and also will consider the extent to which the selected drug fills an unmet medical need, meaning the drug treats a disease or condition where there are very limited or no other treatment options or the existing treatments do not adequately address the disease or condition.

After considering information about clinical benefit, CMS will adjust its starting point for the initial offer price to arrive at a "preliminary price." After determining the preliminary price, CMS will take into account manufacturer-specific data elements. These data, and their illustrative effect on the preliminary price as described in the revised guidance, are:

- Research and development (R&D) costs: if a manufacturer has recouped its R&D costs, CMS could adjust the preliminary price downward, or upward if such costs have not been recouped.

- Current unit costs of production and distribution: if lower than the preliminary price, CMS could adjust the price downward, or upward if such costs are higher than the preliminary price.
- Prior federal financial support: if discovery and development of the selected drug was supported by federal funding, CMS could adjust the preliminary price downward.
- Patent information: this data will support CMS's evaluation of whether a selected drug represents a therapeutic advance or meets an unmet medical need.
- Market data and revenue and sales volume data for the drug in the U.S.: depending on how CMS's preliminary price compares to other market pricing data for the selected drug, CMS could, for example, revise downward the preliminary price if the average commercial net price is lower, or upward if the average commercial net price is higher.

After making any necessary adjustments to the preliminary price based on a review of manufacturer-specific data, CMS will arrive at its initial offer for the maximum fair price. (Back to top)

What are the steps in the negotiation process between CMS and manufacturers of selected drugs?

CMS's guidance outlines several steps in the negotiation process (Figure 1). These steps, and the relevant dates for selected drugs for 2026, are:

- CMS and manufacturers of selected drugs entered into a written agreement (https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf) to negotiate to determine the maximum fair price for selected drugs by October 1, 2023.
- Submission of economic and market data from manufacturers of selected drugs to CMS and information about therapeutic alternatives was due on October 2, 2023.
- CMS hosted one meeting with manufacturers of selected drugs in Fall 2023 after the submission of manufacturer-specific data elements so that manufacturers can provide context for their data submission.
- CMS hosted listening sessions (https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation-program-patient-focused-listening-sessions) in Fall 2023 with consumer and patient organizations to solicit patient-focused information on therapeutic alternatives and other information for CMS to consider in developing its initial offer for selected drugs.
- CMS made a written offer to the manufacturer of a selected drug with its initial offer of the maximum fair price by February 1, 2024. This written offer included a justification for CMS's initial offer based on the methodology used, including how CMS evaluated various data submitted by manufacturers and evidence about alternative therapies.
- Manufacturers respond to CMS's initial offer in writing either accepting the offer or making a counteroffer (https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849) within 30 days of receiving the initial offer (e.g., March 2, 2024, for initial offers made by CMS on February 1, 2024).

The written counteroffer should include the manufacturer's proposed maximum fair price, along with a justification for that amount and a response to CMS's justification for its initial offer. If the manufacturer does not accept CMS's initial offer, a written counteroffer must be submitted, If the manufacturer accepts CMS's initial offer, the negotiation process ends.

- CMS provides a written response to the manufacturer in response to an optional written counteroffer, either accepting or rejecting the counteroffer, within 30 days (e.g., April 1, 2024, if the manufacturer's counteroffer is made on March 2, 2024). If CMS accepts the manufacturer's counteroffer, the negotiation process ends.
- If CMS rejects the manufacturer's counteroffer, up to 3 in-person or virtual meetings could occur between CMS and the manufacturer to discuss offers and counteroffers. The meetings would focus on manufacturer-submitted data and information about therapeutic alternatives, and how that information should factor into the maximum fair price. The timeframe for negotiation meetings would end no later than June 28, 2024.
- After any negotiation meetings between CMS and the manufacturer, CMS makes a final written offer for the maximum fair price (no later than July 15, 2024 for the 2026 negotiation cycle).
- Manufacturers consider CMS's final offer and either accept or reject the offer in writing (by July 31, 2024 for the 2026 negotiation cycle).
- The negotiation process ends when CMS and manufacturers of selected drugs reach agreement on the maximum fair price, but no later than the statutorily defined deadline for the negotiation process (which was August 1, 2024 for the 2026 negotiation cycle).

If an agreement on the maximum fair price is not reached by the deadline for the negotiation process, manufacturers may be subject to an excise tax, which will be administered by the IRS (https://www.federalregister.gov/documents/2023/10/02/2023-21586/excise-tax-on-designated-drugs-procedural-requirements), as specified in the Inflation Reduction Act. CMS has outlined an expedited process manufacturers can follow if they choose to not participate in the negotiation program, which would enable them to withdraw their drugs from coverage under Medicare and Medicaid to avoid paying the excise tax.

According to CMS, manufacturers may disclose information related to the negotiation process with CMS if they choose to do so. CMS will not publicly discuss the specifics of the negotiation process related to any manufacturer but reserves the right to do so if manufacturers themselves choose to disclose this information.
(Back to top)

What happens if a generic or biosimilar drug becomes available after a drug has been selected for negotiation?

Drugs are not eligible to be selected for negotiation if there is a generic or biosimilar using that drug as the reference product approved or licensed by the FDA and being marketed. (Authorized generics (https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-

authorized-generic-drugs) do not count for this purpose, since they are not technically generic drugs as that term is commonly used, but rather the same drug product as the brand-name drug with a different label.) If a drug has already been selected for negotiation and CMS determines that a generic or biosimilar drug has been approved or licensed and is being "bona fide" marketed (as described above) – either before or during the negotiation process – the negotiation process will not start or will be suspended. The drug will continue to be a selected drug (not replaced by another drug), but no maximum fair price will be negotiated. To be removed from the list of selected drugs for 2026, CMS needed to make this determination between September 1, 2023 and August 1, 2024 (between the selected drug publication date and the end of the negotiation process.)

If CMS determines that a generic or biosimilar drug has been approved and marketed after a drug has been selected for negotiation and after a maximum fair price has been established, the maximum fair price will take effect, but depending on when the determination is made, that drug will no longer be a selected drug and the maximum fair price will not apply in subsequent years. For selected drugs for 2026, if the determination of generic drug availability is made between August 2, 2024 and March 31, 2026, the maximum fair price will only apply in 2026 and the drug will no longer be a selected drug for 2027; if the determination is made between April 1, 2026 and March 31, 2027, the maximum fair price will apply in 2026 and 2027 and the drug will no longer be a selected drug for 2028.
(Back to top)

Are there limitations on administrative or judicial review of various features of the drug price negotiation program?

The Act specifies several features of the drug price negotiation program that are not subject to administrative and judicial review, including:

- The determination of whether a drug is a qualifying single source drug
- The determination of whether a drug is a negotiation-eligible drug
- The selection of drugs for negotiation
- The determination of the maximum fair price for a selected drug
- The determination of whether a drug is subject to renegotiation
- The determination of units of a drug or biological product for the purposes (where unit is defined as the lowest amount of the product that is dispensed)
- The determination of whether a drug qualifies for the biosimilar delay

(Back to top)

How will people with Medicare benefit from the drug price negotiation program?

There is uncertainty about how many Medicare beneficiaries will see lower out-of-pocket drug costs in any given year under the drug price negotiation program and the magnitude of potential savings, since both will depend on which drugs are subject to the negotiation process and the price reductions achieved through the negotiation process relative to what prices would otherwise be. In addition, whether Part D enrollees pay lower out-of-pocket costs for a given Part D selected drug will depend in part on whether they pay flat copayment amounts or a coinsurance rate for the drug in their chosen Part D plan. If they pay coinsurance, they could see savings, assuming the negotiated maximum fair price is lower than their plan's negotiated price.

Aside from the potential for out-of-pocket cost savings, the drug price negotiation program could improve Medicare Part D enrollees' access (https://www.kff.org/medicare/issue-brief/how-medicares-new-drug-price-negotiation-program-could-expand-access-to-selected-drugs/) to Part D drugs that are selected for negotiation, since Part D plans are required to cover all selected drugs with negotiated maximum fair prices, including all dosage forms and strengths. In the absence of this coverage requirement, it is possible that not all selected drugs, or all forms of the drugs, would be covered on all Part D plan formularies. Under current law, Part D plans generally can choose which drugs to cover and not cover on their formularies, subject to CMS's formulary guidelines (https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/rxcontracting_formularyguidance) and requirements (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf), except for drugs in the six so-called "protected classes," where all or substantially all drugs must be covered. In the revised guidance, CMS stated that it intends to use the annual formulary review process to ensure that all Part D plans cover all dosages and formulations of selected drugs. CMS also expects plans to provide a justification if selected drugs are placed on non-preferred formulary tiers or on higher tiers than non-selected drugs in the same class, if more restrictive utilization management is applied to selected drugs relative to non-selected drugs in the same class, or if utilization management restrictions that are not based on medical appropriateness are applied to selected drugs. (Back to top)

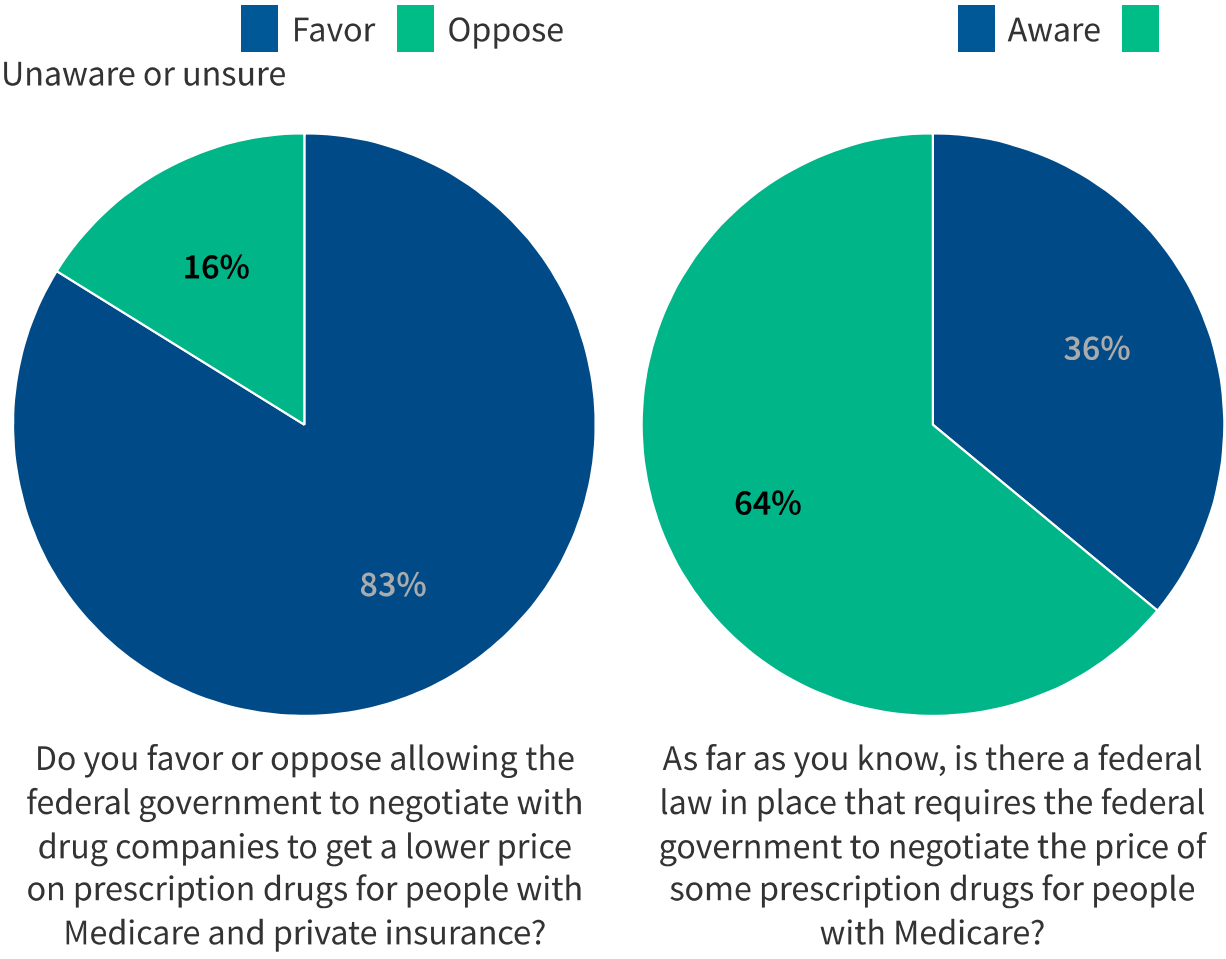
What is public opinion related to the drug price negotiation program?

According to a KFF Health Tracking poll, most adults favor (https://www.kff.org/health-costs/poll-finding/public-weighs-in-on-medicare-drug-negotiations/) allowing the federal government to negotiate drug prices with manufacturers to get a lower price on prescription drugs. More than 8 in 10 adults (83%) favor allowing the government to negotiate lower prices with drug companies that would apply to both Medicare and private insurance (Figure 2). Even after hearing arguments for and against drug price negotiation by the federal government, a majority of adults continue to favor (https://www.kff.org/health-costs/poll-finding/public-weighs-in-on-

medicare-drug-negotiations/) this approach. At the same time, KFF polling also shows (https://www.kff.org/medicare/poll-finding/kff-health-tracking-poll-may-2024-voters-views-of-health-policy-issues-in-context-of-presidential-campaigns/) that most adults are unaware that the law now requires the federal government to negotiate the price of some prescription drugs for people with Medicare. Just over one-third of adults overall (36%), and close to half (48%) of adults ages 65 and older, say they are aware of this provision of the Inflation Reduction Act.

Figure 2

People Overwhelmingly Support Medicare Drug Price Negotiations, but Most Don't Realize It's Happening



Source: KFF Health Tracking Poll (favorability: Sept. 23-Oct. 4, 2021; awareness: Apr. 23-May 1,

(Back to top)

What is the status of lawsuits challenging the drug price negotiation program?

Since June 2023, several lawsuits (https://litigationtracker.law.georgetown.edu/issues/inflation-reduction-act/) have been filed challenging the drug price negotiation program (https://www.healthaffairs.org/content/forefront/current-and-future-legal-attacks-against-medicare-drug-price-negotiation-program) by manufacturers of selected drugs and entities representing the pharmaceutical industry. These lawsuits – nine of which remain, as of August 2024 – have raised similar constitutional and statutory challenges against the program. Among the constitutional challenges raised are the following:

- Drug manufacturers will be forced to give selected drugs to the government without fair compensation, in violation of the Fifth Amendment.
- Drug manufactures are compelled to call this program a "negotiation" and say that final prices are "fair," in violation of the corporations' freedom of speech.
- The penalties levied on drug manufactures for not complying with the program and negotiation terms are so high they constitute "excessive fines," which are banned by the Eight Amendment.

Other constitutional challenges include that the program violates the separation of powers clause and the due process clause. In addition, plaintiffs are challenging the program on statutory grounds, such as the Administrative Procedures Act.

To date, none of these lawsuits have been decided in favor of industry plaintiffs, but a handful of cases are awaiting decisions at the district court level while several other cases have appeals pending before various U.S. appellate courts. In the event of conflicting rulings, an eventual hearing of one or more of these cases by the U.S. Supreme Court would be the likely outcome, but the timeframe for that is uncertain.
(Back to top)

This work was supported in part by Arnold Ventures. KFF maintains full editorial control over all of its policy analysis, polling, and journalism activities.

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