

IRA DRUG NEGOTIATION: AT A GLANCE

Maximum Fair Price: A manufacturer of a drug selected for negotiation will be required to offer a “maximum fair price” for the selected drug with respect to Medicare beneficiaries.

Timeline: The first set of drugs will be selected for negotiation in September 2023, with the negotiation process starting a month later. The first set of negotiated prices taking effect in “initial price applicability year” 2026.

Which drugs are subject to negotiation?

Qualifying Single Source Drugs

- **Certain drugs/biologics approved/licensed by FDA:**
 - **Drugs at least 7 years post-approval** by the selection date
 - **Biologics at least 11 years post-licensure** by the selection date
- With **no generic/biosimilar on the market** (an “authorized generic drug” does not count)

Negotiation-Eligible Drugs

- The **50 qualifying single source drugs with highest total expenditures under Part D** and the **50 qualifying single source drugs with highest total expenditures under Part B** during a specified 12-month lookback period.

Selected Drugs

- A specified number of the **highest ranked negotiation-eligible drugs**, published by February 1 of the selection year, which is two years before the initial price applicability year:
- The selection of drugs for negotiation is **cumulative**: The Secretary must select **10 drugs for 2026**, another **15 for 2027**, another **15 for 2028**, and another **20 for 2029 and each year thereafter**
- **Only Part D drugs may be selected for 2026 and 2027**

Drugs subject to negotiation

Which drugs are exempt from negotiation?

Small biotech drugs (2026, 2027, and 2028 only)

A drug that represents <1% of total Part B or D expenditures and is equal to at least 80% of the total expenditures for all covered Part B or D drugs for that company.

Low-spend drugs

Any drug that accounts for <\$200M in Medicare expenditures in the initial year, then in subsequent years based on data for the 12-month period prior to selected drug publication date.

Orphan drugs

A drug that is designated for only one rare disease or condition under section 526 of the Federal Food, Drug, and Cosmetic Act and for which the only approved indication (or indications) is for such disease or condition.

Any plasma derived product

*HHS may also delay selection of a biologic for negotiation if a biosimilar launch is likely.

Negotiation Timelines – Initial Negotiation Year*

2023	2024	2025	2026
September 1: Publication of 10 selected drugs (Part D only)* October 1: Negotiation period begins	August 1: Negotiation period ends October 1: Maximum fair price published	March 1: Considerations and explanation of maximum fair price published	January 1: Negotiated prices in effect

*For initial negotiation year, HHS will look at data for the 12-month period 6/1/2022 – 5/31/2023

Negotiation Process and Maximum Fair Price

- HHS is required to use a consistent methodology and process aimed at achieving the lowest Maximum Fair Price (MFP).
- The IRA outlines a ceiling for the MFP, which is lower for drugs that have been on the market for 16+ years
- HHS is also required to consider the following factors in calculating the MFP:

Manufacturer-specific data

- R&D costs and the extent to which the manufacturer has recouped such costs
- Current unit costs of production and distribution
- Prior federal financial support for discovery and development
- Data on pending and approved patents and exclusivity
- Market data and revenue and sales volume data

Evidence about alternative treatments

- The extent to which the drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such alternatives
- FDA-approved prescribing information for the drug and alternatives
- Comparative effectiveness of the drug and alternatives, including effects on specific patient populations
- The extent to which the drug and alternatives address unmet medical needs

How is compliance with the program enforced?

Excise Tax

A noncompliant manufacturer is subject to an excise tax on each sale of the drug during the period of noncompliance, with the amount of the tax escalating over time. For a drug that is in the 270th+ day of noncompliance, the excise would be 1,900% or 19x the price of the drug. The tax would apply to all sales of the drug – not just Medicare sales.*

Civil Monetary Penalties (CMPs)

Manufacturers are subject to CMP if they fail to offer the maximum fair price, violate terms of the negotiation agreement, or knowingly provide false information.

Preclusions of Administrative and Judicial Review

Negotiation program is largely precluded from any administrative or judicial review, including selection of drugs for negotiation and determination of MFP.

Broader Implications

Best price: The maximum fair price is included in best price

AMP: The maximum fair price is excluded from AMP

ASP: The maximum fair price is included in ASP

340B Program: The manufacturer must offer covered entities the lower of the 340B price or the maximum fair price (but not both)

Part D Manufacturer Discount Program:* A drug is not subject to the Part D Manufacturer Discount Program while it is subject to the maximum fair price

Commercial market: The negotiation program does not directly affect the price for commercial patients, however there is the potential for commercial customers to seek a price approximating the maximum fair price