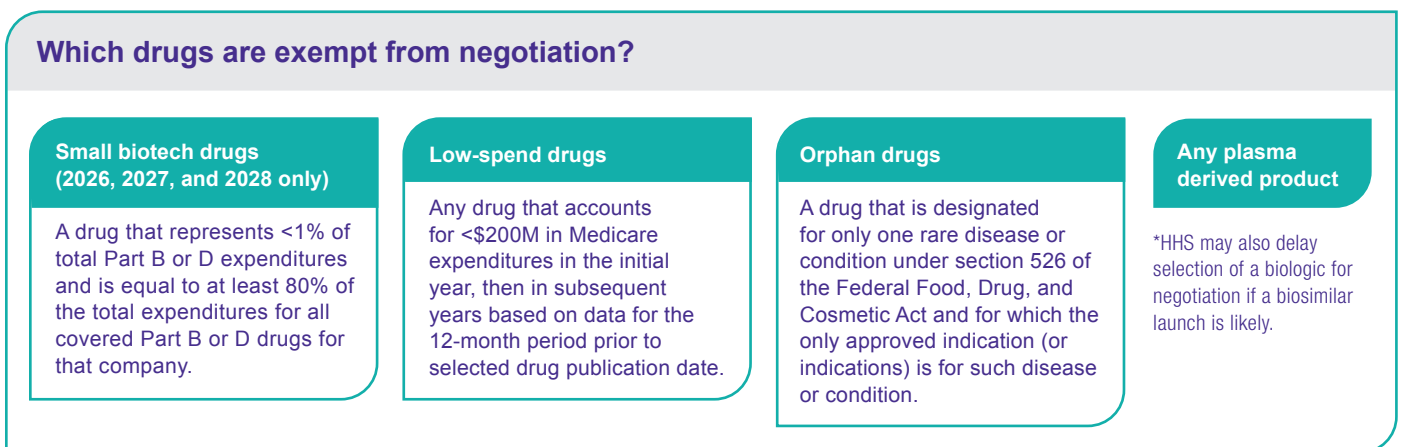


IRA DRUG NEGOTIATION: AT A GLANCE

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.



Negotiation Timelines – Initial Negotiation Year*

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

*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