



## MEDICARE DRUG PRICE NEGOTIATION PROGRAM

### 1 Drug selection

HHS Secretary selects from a list of drugs with the highest total expenditures in Part B and Part D programs that are single-source drugs outside their initial exclusivity periods.

Small molecule: At least 7 years since approval with no generic competition

Large molecule: At least 11 years with no biosimilar competition

Product exemption is based on reference for another drug with the inclusion of a “bona fide marketing” of generic – “robust and meaningful competition”

Authorized generics are not exempt from selection

### 2 Manufacturer agreement

HHS Secretary and manufacturer enter agreement that governs negotiations, manufacturer reporting, and related compliance.

This remains in effect until a drug is no longer subject to the negotiation program.

### 3 Negotiation process

HHS Secretary and manufacturer engage in negotiations from March 1 through November 1 of selected drug publication date.

### 4 Negotiated prices take effect

Negotiated price takes effect 2 years after the negotiation period.

Exclusions include:

Certain orphan drugs, low spend drugs, plasma-derived products, small biotech drugs.

Example	Date for first indication	Earliest possible selection date	Earliest possible price cap	Data used to calculate spend for drug ranking
Small Molecule	FDA approval: Feb. 2, 2024 to Feb. 2, 2025	Feb. 1, 2032	Jan. 1, 2034	Nov. 1, 2030 to Oct. 31, 2031
Large Molecule	BLA license: Feb. 2, 2024 to Feb. 2, 2025	Feb. 1, 2036	Jan. 1, 2038	Nov. 1, 2034 to Oct. 31, 2035

## MFP CEILING SET BY CMS

The price offered by CMS in the negotiation may not be above a ceiling or (for small biotech drugs) below a floor.

**Part B Drugs:** Non-Federal Average Manufacturer Price (Non-FAMP) for 2021, first full year of marketing or prior to selection

**Part D Drugs:** Weighted amounts for prior year

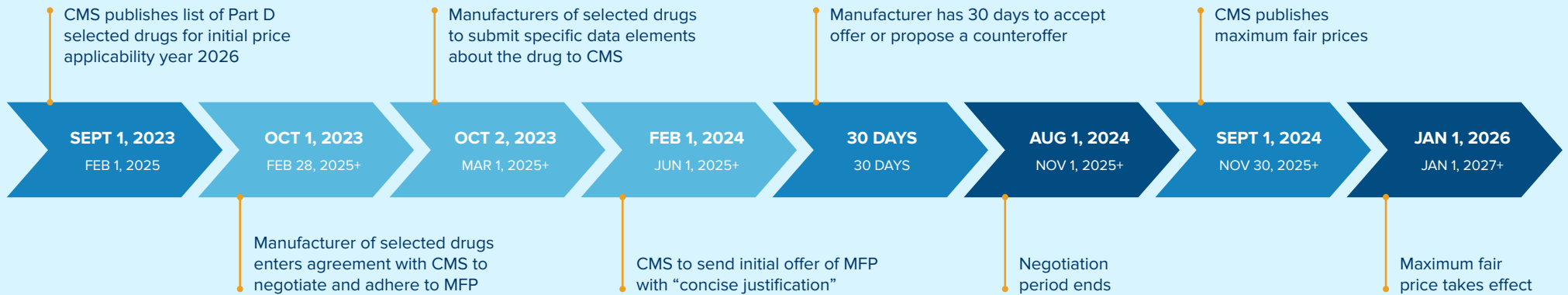
**75% Cap** | Short Monopoly Drug | Approved for < 12 years

**65% Cap** | Extended Monopoly Drug | Approved 12-16 years, excluding vaccines

**40% Cap** | Long Monopoly Drug | Approved > 16 years, excluding vaccines

**66% Floor** | Small biotech drugs | Only in 2029-2030

## MEDICARE DRUG PRICE NEGOTIATIONS TIMELINE



## INFLATION REBATE POLICY

### PART D inflation rebates

#### Price changes based on Average Manufacturer Price (AMP)

Units used for calculation are those dispensed in Part D, excluding those with a 340B discount.

#### Starting point for measuring drug price increases effective in 2022

Rebate payments required to begin 2023 (modified date expected to be Dec. 2025)

#### Rebate calculation:

Annual AMP calculation starts October each year.

Rebate Per Unit (RPU) at unit dose is annual AMP for the period, minus the base benchmark period AMP, plus the inflation adjustment

### PART B inflation rebates

#### Price changes based on Average Sale Price (ASP)

Units used for calculation are those paid for under Part B, excluding those with a 340B discount.

#### Starting point for rebate provisions effective in 2023 (modified date expected to be Dec. 2025)

**Rebate calculation:** ASP + 6%  
Biosimilars are ASP + 8% of reference biologic

Benchmark ASP is 3rd full quarter after market entry

CPI-U baseline is 1st month of 1st full quarter after market entry

Penalty based on current quarter ASP calculation compared to baseline plus inflation

## PENALTIES



Failure to comply with the agreement to negotiate  
**\$1 million per day of violation**



Submission of false information  
**\$100 million for each item**



Charging more than the MFP  
**10 times the amount of the overcharge**



Excise tax with potential of  
**millions per day**

## BIOSIMILAR DELAY PROVISION

- Biosimilar manufacturer can submit a request to delay the drug's inclusion in price negotiations
- Includes drugs that would be extended-monopoly drugs only
- Manufacturer must show a "high likelihood" that the biosimilar will be licensed and marketed within 2 years
- Provide "clear and convincing evidence" based on details of patent environment and operational readiness