



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

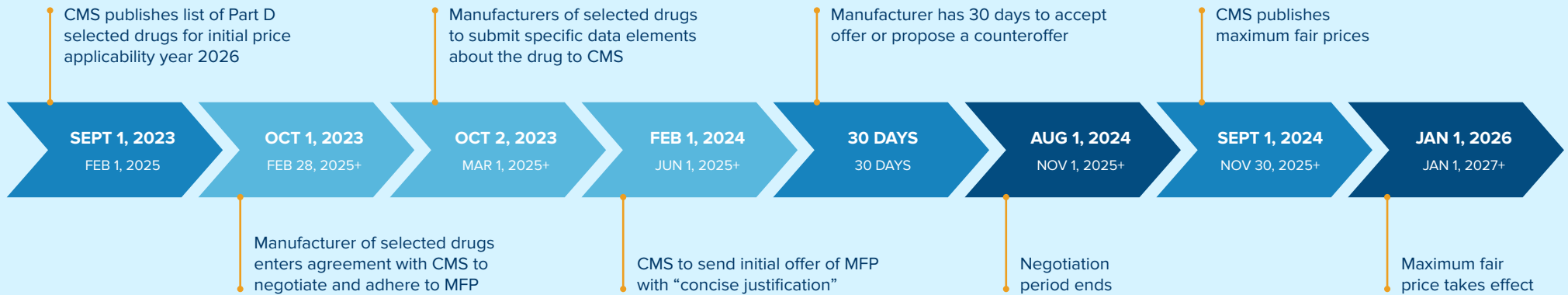
75% Cap | Short Monopoly Drug | Approved for < 12 years

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

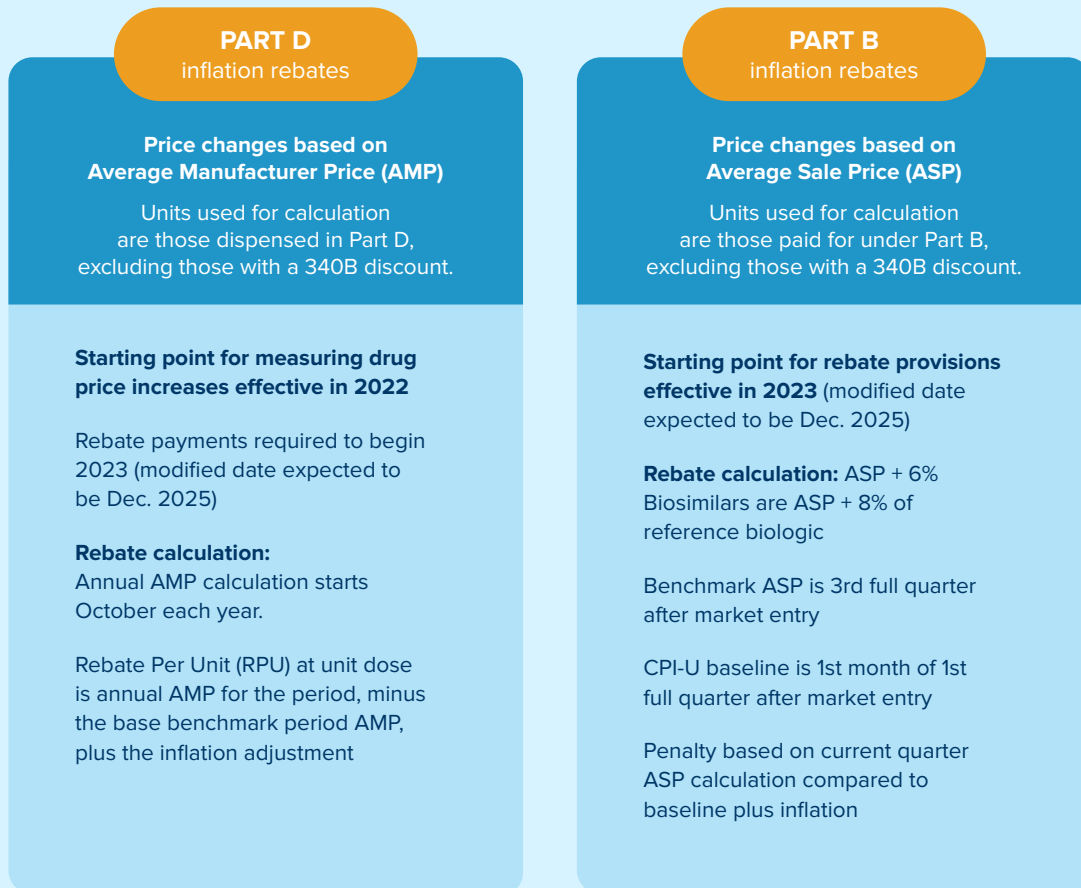
40% Cap | Long Monopoly Drug | Approved > 16 years, excluding vaccines

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

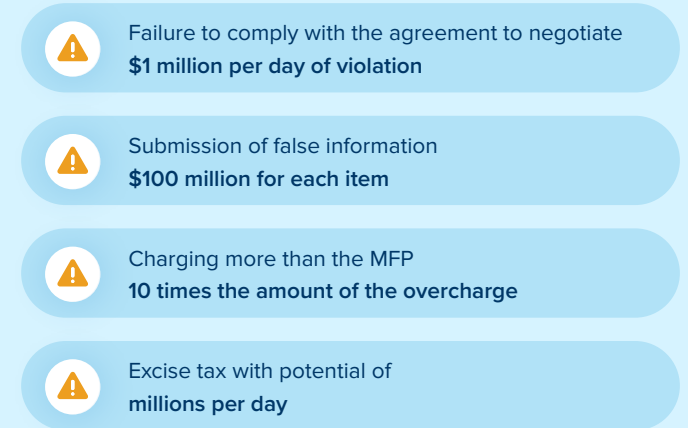
MEDICARE DRUG PRICE NEGOTIATIONS TIMELINE



INFLATION REBATE POLICY



PENALTIES



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