Brief, High-Level, Summary of Medicare Negotiation Legislation as of 11/3/2021 House language[1]

Negotiation-Eligible Drug: Combined list of 50 highest spend Part D drugs, 50 highest spend Part B drugs, and insulins, based on prior year Medicare data.

Selected Drug: The list of that the Secretary has decided should be subject to negotiation as published each February beginning in 2023. For the first two years of implementation, selected drugs can only include Part D drugs and insulins.

Selected drugs must be sole source (except for insulins). Thus, a selected drug cannot be the reference drug from which biosimilars have been produced and licensed. A selected drug cannot be a drug with generic versions on the market. (Authorized generics are not considered generics for purposes of this program). Insulins are treated differently for a variety of historical regulatory and market reasons.

There are a variety of drug types that are prohibited as selected drugs (orphan drugs for example).[2]

Limit on selected drugs: 10 in 2025, 15 in 2026 and 2027, 20 in 2028 and thereafter.

Negotiations on Selected Drugs: Negotiations occur between the February publication of selected drugs and November 1st each year.

Maximum Fair Price (MFP): Negotiations would try to reduce the cost of the drug below the maximum fair price. The failure of negotiations means the maximum price/statutory ceiling price for a selected drug is no greater than:[3]

- 75% of average manufacturer price (AMP)[4] for drugs whose statutory market protection expired and was licensed at least 9 years prior to the year it was selected by the Secretary ('short monopoly' drugs).
- 65% of AMP for a biologic whose statutory market protection expired and was licensed at least 12 years prior to the year it became a selected drug ('post-exclusivity drug').
- 40% of AMP for a drug that was licensed at least 16 years before it became a selected drug.

MFP (or lower price as a result of a negotiation with a manufacturer) for a drug is published in November of the same year as it became a selected drug.

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[1] Implementation dates for biologics (part B drugs) changed/were delayed between 11/3 language and the vote on 11/4.

[2] Other exclusions include drugs that contribute very little to Medicare spending, drugs for which the Medicare revenue constitutes the predominate source of total company revenue (small biotech exemption). There are other exclusions.

[3] There are different calculations of AMP depending on the year, the type of drug and whether it is a B or D drug.

[4] The law specifies "non-federal" AMP which is sales to wholesalers, net of wholesale level discounts and price concessions. This means that the non-federal AMP is lower than the Medicaid AMP which does not net out price concessions for prompt payment etc. The issue of 'charge backs' should be reviewed -- where wholesalers get reimbursed for discounts they provide to purchasers to fulfill a manufacturer's price agreement with a large purchaser, such as a hospital system or group purchasing organization.

MFP (or negotiated price) applies to a drug two years after the year it became a selected drug, and the MFP is indexed to CPI U during this period and each year thereafter.

MFP can be renegotiated in later years when the drug is licensed for a new indication, and/or when a drug is on the market long enough to move from one category to the next category (post exclusivity to long term monopoly drug for example).

MFP is available to all Medicare B and D enrollees at the point of service which means to MFP is available to all providers who treat Medicare B and D enrollees. The Secretary is charged with sorting how to accomplish this.

MFP (or negotiated price) is included in a manufacturer's Medicaid best price calculations.

Inflation Rebates for All Medicare-Covered Drugs[5] (essentially all US prescription drugs)

The rebate calculation varies slightly depending on whether the drug is a Part D or Part B drug

A rebate is due if the price of the drug increased faster than inflation (the CPI-U) in a calendar quarter.

The rebate amount is the difference between the price indexed to CPI and the price as increased by the manufacturer.

The total rebate due to the federal government is the rebate amount multiplied by total US sales of the drug –not just sales to Medicare enrollees or drugs administered to Medicare enrollees.[6]

The unit rebate amount is not included in a manufacturer's calculation of Medicaid AMP or Medicaid best price.

Penalties

There are a variety of penalties for manufacturer failure to comply with different aspects of the program.

Upside of the legislation:

The program design would get a lower price through the supply chain to the Medicare enrollee at point of service

The price increase penalty is quite substantial and is intended to lead to a diminution of the frequency and size of price increases.).

It appears the price of small molecule drugs with 'evergreen' patents can be addressed while under patent.

Medicare can pursue price negotiations on all insulins.

[5] Medicare covered drugs are almost all US prescription drugs.

[6] This is different than the Medicaid inflation rebate total penalty is calculated -- based on sales to Medicaid enrollees. For Part B, the total rebate amount is based on the Medicare Average Sales Price formula (all US sales), and for Part D, the total amount due is based on the Medicaid Average Manufacturer Price formula (all US sales to wholesalers).

If Medicare can get a biologic negotiated price into market before the approval of a biosimilar, that negotiated price should have a sentinel effect on the price of the biosimilar product.

Downside of the legislation:

The substantial price increase penalty could lead to higher launch prices, which the legislation does not address.

Biologic products will be difficult to address because Medicare may not start negotiating until the data exclusivity period has ended (12 years). (Data exclusivity can run longer than a patent would normally run.) Then there is a two-year delay in getting the negotiated price into the marketplace once it is negotiated in year 12. It is possible that by year 14, there will be an approved biosimilar, at which point, it seems Medicare would not be able to implement the price on the original product, because it is no longer a sole source drug.

Biologic drugs like Humira – where the patent has been 'evergreened' or extended for at least a decade past normal patent life – could escape Medicare negotiation altogether. There are several Humira biosimilars approved by the FDA which cannot come to market until Humira patents have expired. So, the moment the negotiated price could be implemented, Humira may no longer be a sole source drug. Only sole source drugs can be part of the Medicare negotiation program.

The framework that would prohibit making a biologic a selected drug until after exclusivity expired and then waiting another two years before the negotiated price gets into the market could mean that the negotiated price cannot be implemented if a biosimilar is approved in the interim.

Upside/Downside of the legislation:

It is not possible to know how the legislation will affect the pharma industry going forward. It could be that a biologic manufacturer would want to share its data at a certain point before 12 years are up to encourage the development of a biosimilar before the negotiated price goes into effect on the original product. The biosimilar company would have incentives to get to market before the negotiated price of the original product was implemented as well since it will shadow price the original product. The good news is that we could have more biosimilars on the market sooner than they come to market today. The bad news is that it will be difficult to constrain costs/launch prices if drugs are not sole source.