

The Future of the Medicare Drug Price Negotiation Program

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The Centers for Medicare and Medicaid Services (CMS) and pharmaceutical drug manufacturers are gearing up for the second round of negotiations as part of the Medicare Drug Price Negotiation Program (the Negotiation Program), but the Trump administration and a Republican majority in Congress leaves the future of the Negotiation Program uncertain. As outlined in the Q2 2024 edition of our [Mintz IRA Update](#), the second round of negotiations will take place throughout 2025, and the resulting maximum fair prices (MFPs) for the next 15 drugs are slated to become effective on January 1, 2027. In this article, we explore the recent changes made by CMS to the Negotiation Program following the first round of negotiations; manufacturers' reactions to the MFP explanations provided by CMS and the drugs targeted for the second round of negotiations; and the implications of the Trump administration for the future of the Negotiation Program.

Drug Manufacturers React to MFP Explanations and Drugs Targeted for Second Round of Negotiations

On December 20, 2024, months ahead of its March 1, 2025, deadline, CMS released redacted details about how it determined new prices for the 10 drugs it selected in the first round of negotiations. Each MFP explanation contained details that were unique to the specific drug in question, and consistently considered factors focused on R&D costs, relevant patents, net prices, wholesale acquisition costs, and unit volume changes over time. Despite hundreds of pages of information provided by CMS, many industry watchers and manufacturers were disappointed to find that the explanations lacked a systematic and quantitative approach to how CMS arrived at its negotiated prices. Such information, the foregoing parties argue, would have allowed the industry to forecast how selected drugs would be priced in future rounds of negotiation. However, even without such forecasting information, several drug manufacturers have expressed that they are not concerned by the second round of negotiations.

On January 17, 2025, CMS announced the set of 15 drugs for the second round of negotiations under the Negotiation Program — 15 days ahead of its February 1 deadline — and as expected, the popular diabetes drug, Ozempic, and the Huntington's disease medication, Austedo, are among the drugs selected. According to statements made by the CEO at [Teva](#) and a top executive at [Novo Nordisk](#), both manufacturers had considered the possibility that their popular drugs, Austedo and Ozempic, respectively, would be selected for negotiation and began adjusting their growth strategies in advance. Similarly, leaders at AstraZeneca and Pfizer told attendees during the 2025 JP Morgan Healthcare Conference that although their companies would face pressure and be impacted by the Negotiation Program, both manufacturers still predict a strong performance in the coming year.

The full list of the 15 selected drugs is below. Manufacturers with a selected drug will have until February 28, 2025, to decide if they will participate in the second round of negotiations.

Drugs Selected for Medicare Price Negotiation in 2025

Manufacturer	Brand Name	Generic
Novo Nordisk A/S	Ozempic, Rybelsus, & Wegovy	Semaglutide
GlaxoSmithKline	Trelegy Ellipta	N/A
Astellas Pharma Inc.	Xtandi	Enzalutamide
Bristol Myers Squibb	Pomalyst	Pomalidomide
Pfizer Inc.	Ibrance	Palbociclib
Boehringer Ingelheim	Ofev	Nintedanib
AbbVie Inc.	Linzess	Linacotide
AstraZeneca	Calquence	Acalabrutinib
Teva Pharmaceuticals	Austedo; Austedo XR	Deutetrabenazine
GlaxoSmithKline	Breo Ellipta	Fluticasone furoate/vilanterol
Boehringer Ingelheim	Tradjenta	Linagliptin
Salix Pharmaceuticals	Xifaxan	Rifaximin
AbbVie Inc.	Vraylar	Cariprazine
Merck and Co., Inc.	Janumet; Janumet XR	Sitagliptin/metformin
Amgen Inc.	Otezla	Apremilast

Implications of a Trump Administration

The future of the Negotiation Program under this Trump administration remains uncertain. In his prior term as president, President Trump took a hard stance against pharmaceutical prices in the US, and during his re-election campaign, President Trump reiterated that he is committed to lowering the price of drugs for Americans. However, immediately following his inauguration, President Trump revoked a Biden-era executive order aimed at lowering the costs of expensive medications and helping state Medicaid agencies pay for expensive treatments by setting up negotiations between CMS and manufacturers. This revocation may signal that President Trump's priorities have shifted and that he may be less focused on addressing drug costs during his second term.

Many of Trump's advisers appear divided on how and to what extent to regulate the pharmaceutical industry. The future of the Negotiation Program is further muddled by recent statements made by several high-ranking Republicans, such as US Senate Finance Committee Chairman Mike Crapo, who, in September of last year, stated he plans to repeal and replace the Negotiation Program during his tenure as chairman. Nonetheless, the Trump administration has yet to divulge details of its plans for the future of the Negotiation Program — but as we discuss in this issue's [litigation update](#), there are a number of paths forward available to the administration.

Final Guidance for Second Round Negotiation Cycle

Barring any changes made under the Trump administration, the second round of negotiations will take place throughout 2025, and CMS will be required to publish the new negotiated MFPs by the end of November 2025. The new MFPs will then go into effect in 2027.

The second round of negotiations will largely follow the same process as the first round of negotiations; however, drug manufacturers will now have more time and opportunities to submit counteroffers and to engage with CMS directly. CMS's **final guidance** for price applicability year 2027 outlines the new requirements and parameters for the Negotiation Program, including, but not limited to:

- **Patient Roundtables and Town Hall:** Up to 15 patient-focused roundtables and one clinically oriented town hall meeting will be held to collect input from patients, patient advocacy organizations, caregivers, and others on the selected drugs for consideration.
- **Negotiation Meetings:** The first optional negotiation meeting between CMS and participating drug companies will be held after the initial offer is announced and before the deadline for the company to submit a counteroffer. If CMS rejects a drug company's counteroffer, CMS will offer the drug company up to two additional negotiation meetings.
- **Data Exchange Parameters:** New guidelines have been established for data sharing between dispensing entities, participating drug companies, and CMS via the Medicare Transaction Facilitator (MTF) Data Module to facilitate access to MFPs of selected drugs.
- **Payment Facilitation:** A voluntary payment facilitation functionality through the MTF Payment Module (MTF PM) has been established to support access to the MFP by passing payment from the drug companies to the dispensing entity.
- **Reporting Requirements:** Drug companies must follow new guidelines and parameters for payments passed to dispensing entities outside of the MTF PM.

Authors



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