

Drug Negotiation Timeline Released

New Dates & Guidance Process Means Industry Input

Today, the U.S. Department of Health and Human Services (HHS) announced key dates for the first year of the Medicare Drug Price Negotiation Program under the Inflation Reduction Act. Specified dates are in line with statutory deadlines set out in the legislative text, but some new ones are added. CMS remains open to feedback on data collection and negotiation process. The memo highlights agency plans to continue to engage with manufacturers, insurers, and the general public [here](#).

- **By September 1, 2023, CMS will publish the first 10 Medicare Part D drugs selected.** This is not a new date, as it was specified in the law. Recall that ten Part D drugs are eligible for negotiations in 2026 based on Medicare spend.
- **The first round of drugs to be negotiated appear to be somewhat straightforward...its 2027+ that gets trickier.** Based on 2020 data, top drugs we could see on the negotiation list include Eliquis, Xarelto, Januvia, Imbruvica, Enbrel, Jardiance, Ibrance, Levemir, Symbicort, Xtandi, Victoza, Myrbetriq.
- **Key dates outlined include the deadline for manufacturers of selected drugs to submit data elements and CMS initial offer date.** See 2023-2024 schedule for the program below.
 - **Spring 2023:** Initial guidance for 2026 published.
 - **May 31, 2023:** Ending of the time period for total expenditure calculation used in determining negotiation-eligible drugs for initial price applicability year 2026
 - **Summer 2023:**
 - Revised guidance for Medicare Drug Price Negotiation Program initial price applicability year 2026 published
 - Deadline for request by a manufacturer of a biosimilar biological product for a delay in the selection of the reference biological product for negotiation due to high likelihood of biosimilar market entry
 - Deadline for submission to qualify for small biotech exception for initial price applicability year 2026
 - **September 1, 2023:** CMS publishes list of 10 Part D selected drugs for initial price applicability year 2026
 - **October 1, 2023:** Deadline for manufacturers of selected drugs to sign an agreement with the Secretary to conduct negotiations
 - **October 2, 2023:** Deadline for manufacturers of selected drugs to submit data elements
 - **February 1, 2024:** CMS sends initial offers of a maximum fair price with a justification to manufacturers, negotiation period begins
 - **March 2, 2024:** Manufacturer has 30 days from when it receives the offer to propose a counteroffer, if desired
 - **August 1, 2024:** Negotiation period ends
 - **September 1, 2024:** CMS publishes maximum fair prices
- **While the legislative text requires implementation through program guidance, CMS intends to release draft guidance and voluntarily solicit comments on certain topics (2026).** CMS will not accept feedback on topics that go beyond 2026 (e.g. renegotiations). Topics open to public feedback include
 - Terms and conditions contained in the manufacturer agreement, including the manufacturer's and Secretary's responsibilities.

- Approach for considering (1) the manufacturer-reported data elements and (2) evidence about alternative treatments
 - Process for the offer and counteroffer exchange between the Secretary and manufacturers
 - Content of an explanation for the maximum fair price
 - Method for applying the maximum fair price across different dosage forms and strengths of a selected drug
 - Dispute resolution process for specific issues that are not exempt from administrative and judicial review under section 1198.
 - Processes for compliance monitoring and imposition of civil monetary penalties for violations.
- **CMS is in over it's head: This is a complex law and few internally fully understand the economics of biopharma R&D, pricing and federal programs.** It also likely reflects concerns around equity and impact on drug development. We note that health equity has been a major theme for the Biden-Harris administration and CMS is likely looking for feedback on downstream effects for patients, insurers, and providers. CMS is also opening the door for manufacturers to engage with the administration in the start of a year that is expected to bring blockbuster innovations to patients including Leqembi (BIB).
 - **For early 2023, data collection is on the agenda re small biotech exemption & negotiation data elements.** CMS will propose and publish three new information collection requests (ICRs) related to negotiations in next few months, which will all be subject to a 60-day comment period. ICRs will cover the (1) small biotech exception, (2) negotiation data elements, and (3) negotiation offer and counteroffer exchange.
 - **NEXT UP: We do not believe that CMS wants to provide deep discounts on drug, ultimately being the agency to blame for killing biopharma innovation, with economy & job ripple effects.** With increased transparency and opportunities for public feedback, negotiations may not be as onerous to drug development as once expected. CMS plans to engage interested parties through national stakeholder calls, quarterly strategic meetings, and monthly technical calls. We wait to see the details of draft guidance for 2026 implementation in Spring 2023.