



NewsBREAK | June 30

CMS Issues Revised IRA Negotiation Guidance

- On June 30, 2023, the Centers for Medicare and Medicaid Services (CMS) issued final guidance on the Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program for the initial price applicability year 2026 (Revised Guidance).
- This guidance revises CMS' March 15th guidance (Initial Guidance) and incorporates clarifications and changes in response to comments received in response to that initial guidance.
- The Revised Guidance includes numerous changes from the Initial Guidance, such as clarification on:
 - how CMS will identify selected drugs (for example, CMS will only consider active designations and approvals when evaluating a drug for the orphan drug exclusion);
 - how CMS will review and consider certain cost-effectiveness measures for the first round of negotiation;
 - how CMS intends to engage a Medicare Transaction Facilitator to facilitate the exchange of data between supply chain entities to verify eligibility of maximum fair price-eligible individuals;
 - Part D formulary inclusion for selected drugs (CMS will expect Medicare prescription drug plans to provide a reasonable justification to support the submitted plan design for non-preferred tier placement of a selected drug with a maximum fair price and will use its existing formulary review process to assess any instances where Part D plans place selected drugs on non-preferred tiers or apply utilization management); and
- Topics that are not relevant to the Negotiation Program for 2026, such as renegotiation, are not addressed in the Revised Guidance. CMS will provide additional information in the future related to program guidance for 2027 and 2028.

See the [Revised Guidance](#) for additional details.

More on This Topic

- [Revised Guidance](#)
- [Fact Sheet](#)
- [CMS Medicare Drug Price Negotiation resource page](#)

For questions, please reach out to [Tyler Thorne](#).

