

CMS Revises Guidance for Medicare Drug Price Negotiation Program

The Centers for Medicare and Medicaid Services (CMS) released [revised guidance](#) on using its authority with pharmaceutical manufacturers in the Medicare Drug Negotiation Program. For the first time, Medicare can directly negotiate the prices of covered prescription drugs (Part B or Part D) due to President Joe Biden's Inflation Reduction Act.

“Negotiating with manufacturers on drug prices will improve access to lifesaving drugs for millions of people with Medicare while driving market competition and scientific innovation.”

- CMS Administrator Chiquita Brooks-LaSure

The CMS states that the following updates in the revised guidance are intended to improve transparency and the negotiation process:

- **Clarifications on how the CMS will identify selected drugs** (e.g., the CMS will only consider active designations and approvals when evaluating an orphan drug exclusion)
- **Revisions of and clarifications on the process for participating drug companies** (e.g., the CMS will release information about the

negotiation when the maximum fair price explanation is published, and drug companies may publicly discuss the negotiation at their discretion)

- **Additional opportunities for drug companies and the public to engage with the CMS during the negotiation process** (e.g., patient-focused listening sessions)

The CMS issued the initial guidance in March 2023 and sought public comment on program key elements. The agency received over 7,500 comments from consumer and patient groups, drug companies, pharmacies and individuals.

What's Next?

According to the release, the CMS will hold listening sessions this fall on the drugs for patients, caregivers and patient advocacy organizations to share input on the selected drugs. By Sept. 1, 2023, the CMS will announce the first 10 drugs covered under Part D selected for initial price applicability year 2026. The maximum fair prices negotiated for these drugs will be published by Sept. 1, 2024, and prices will be in effect on Jan. 1, 2026.

Looking ahead, the CMS will select up to 15 more negotiated drugs for 2027, up to 15 more drugs for 2028 and up to 20 more drugs for each year after that.

Employers should continue monitoring for program updates. Contact us for more information.