

How to Submit the 2023 Public Submission Form for Reporting Evidence about Selected Drugs and Their Therapeutic Alternatives

What Information is Requested

For the first time, the Inflation Reduction Act of 2022 (P.L. 117-169) allows Medicare, through CMS, to directly negotiate the prices of certain high expenditure, single source prescription drugs that have no generic or biosimilar competition with the drug's manufacturer. CMS is asking the public to provide information about these drugs, including personal experience taking these drugs and their therapeutic alternatives.

- **All questions, instructions and definitions are available in the [Information Collection Request Form for the Negotiation Data Elements](#).** You only need to look at Sections I and J, Questions 26 through 32 starting on page 36. *Certain manufacturers may answer more questions found in Sections A–H.*
- **Helpful Definitions:**
 - **Selected drugs:** drugs selected by CMS for potential negotiation; CMS selected 10 drugs for the first year of price negotiation with any negotiated prices effective starting in 2026.
 - **Therapeutic alternatives:** drugs that are clinically comparable to other drugs; the comparison drug for these therapeutic alternatives is the drug selected for negotiation.

Who May Respond

Anyone may respond, including individuals and organizations.

When Are Responses Due

Information may be shared with CMS between September 1, 2023 and October 2, 2023.

- **Information about other opportunities to share information with CMS at patient-focused public listening sessions is available [here](#).**

How Will CMS Use This Information

CMS may use this information in negotiating with the manufacturers of selected drugs regarding pricing.

- **While CMS asks that you do not include personally identifiable information (PII) or protected health information (PHI), CMS will protect PII and PHI from public disclosure. CMS will redact such information to protect individuals in any disclosures from this Information Collection Request made to outside entities.**

How to Provide This Information To CMS

Follow the steps below.

- 1) Access the Public Submission Form through either of these pathways:**
 - Click directly on the [submission platform](#).
 - Locate the Medicare Drug Price Negotiation [website](#) and click on "Public Submission Form for Reporting Evidence about Selected Drugs and Their Therapeutic Alternatives".
- 2) Follow the instructions to enter your email address.**
 - You will receive a registration email.
 - Follow the steps to confirm your email address. *You must provide a valid email address to access the questions.*
- 3) Follow the instructions to choose the drug for which you wish to share information.**
- 4) Answer the questions.**
 - *All questions are optional.*
 - Questions may have specific instructions about how long your answer may be and what information you should include.
 - **Important Information:** Once you begin your submission, you will not be able to save your responses and will have to complete your submission. Please be prepared to provide all information you would like to share on a selected drug at one time.
- 5) Submit your responses as instructed.**
- 6) Follow steps 3 through 5 again if you wish to provide information about an additional selected drug.**
 - *You may use the same link provided to submit answers to the same questions for each selected drug. You do not need to provide information for every drug.*

Please contact us at IRAREbateandNegotiation@cms.hhs.gov with any questions.