

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

## What Information is Requested

The Inflation Reduction Act (IRA) of 2022 (P.L. 117-169) instructs Medicare, through the Centers for Medicare & Medicaid Services (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. CMS will be seeking additional public input about implementation of the Medicare Drug Price Negotiation Program separately.

- **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 28 through 62 starting on page 43. *Certain manufacturers may answer the questions found in Sections A–H.*
- Section I questions are grouped into sections by examples of individuals and organizations that may choose to address a category of questions based on personal and/or professional insight and expertise (for example, patients and caregivers or clinicians). However, **ANY AND ALL INTERESTED PARTIES may respond to ANY AND ALL QUESTIONS.**
- For the “Patient or Caregiver-Focused Input” portion of Section I (Questions 36 through 42, starting on page 53), CMS is requesting information from patients and other individuals close to the patient experience, such as caregivers and patient organizations, on patients’ lived experiences with the selected drug, the condition(s) treated by the selected drug, and other medications that may be used to treat those condition(s).
- **Helpful Definitions:**
  - **Selected drugs:** drugs selected by CMS for potential negotiation; the IRA requires CMS to select up to 15 drugs covered under Part D for the second cycle of negotiations with any negotiated prices effective starting in 2027.
  - **Therapeutic alternatives:** drugs that are used to treat the same condition or disease state as the selected drug; the IRA directs CMS to consider how the selected drug compares to therapeutic alternatives when negotiating.
  - **Unmet medical need:** when no other treatment options exist for the relevant disease or condition or existing treatments do not adequately address the disease or condition.
  - **Indication:** the condition or disease state that the selected drug treats; may include FDA-approved indications and certain off-label uses.
  - **Off-label Use:** a use of a selected drug or therapeutic alternative that is not approved by the FDA but is included in nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia.

## Who May Respond

Anyone may respond, including individuals and organizations.

## When Are Responses Due

For initial price applicability year 2027, information may be shared with CMS by March 1, 2025.

- **Information about other opportunities to share information with CMS at patient- and clinical-focused public input sessions is forthcoming and will be available [here](#).**

## How Will CMS Use This Information

CMS may use this information in negotiating with the manufacturers of selected drugs regarding Medicare 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](#); or
  - 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.
  - Once you begin your submission, you **may** save your responses and complete your submission at a different time.
- 5) Submit your responses as instructed.** *If your responses are saved but not submitted to CMS, CMS will not be able to review the information.*
- 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](mailto:IRAREbateandNegotiation@cms.hhs.gov) with any questions.**