

# Frequently Asked Questions: Public Engagement Events for Initial Price Applicability Year 2027 of the Medicare Drug Price Negotiation Program



CENTERS FOR MEDICARE & MEDICAID SERVICES

CMS is hosting a series of public engagement events this spring as part of the [Medicare Drug Price Negotiation Program](#). The virtual public engagement events will provide an opportunity for patients, beneficiaries, caregivers, consumer and patient organizations, and other interested parties, such as clinicians and researchers, to share information relevant to the drugs selected for the second cycle of negotiations. CMS will be seeking additional public input about implementation of the Medicare Drug Price Negotiation Program separately.

Specifically, CMS is hosting 15 patient-focused roundtable events, which are open to patients, patient advocacy organizations, and caregivers, and will allow for discussion among speakers. CMS is also hosting one town hall meeting for all selected drugs, focused on the clinical considerations related to the selected drugs.

The public engagement events will be held at the following days and times.

## Roundtable Events

- **Austedo; Austedo XR:** Wednesday, April 16, 2025 at 10:00 – 11:30 AM ET
- **Breo Ellipta:** Wednesday, April 16, 2025 at 2:00 – 3:30 PM ET
- **Calquence:** Thursday, April 17, 2025 at 10:00 – 11:30 AM ET
- **Ibrance:** Thursday, April 17, 2025 at 2:00 – 3:30 PM ET
- **Janumet; Janumet XR:** Friday, April 18, 2025 at 11:00 AM – 12:30 PM ET
- **Linzess:** Monday, April 21, 2025 at 3:00 – 4:30 PM ET
- **Ofev:** Tuesday, April 22, 2025 at 10:00 – 11:30 AM ET
- **Otezla:** Wednesday, April 23, 2025 at 11:00 AM – 12:30 PM ET
- **Ozempic; Rybelsus; Wegovy:** Wednesday, April 23, 2025 at 3:00 – 4:30 PM ET
- **Pomalyst:** Thursday, April 24, 2025 at 10:00 – 11:30 AM ET
- **Tradjenta:** Thursday, April 24, 2025 at 2:00 – 3:30 PM ET
- **Trelegy Ellipta:** Friday, April 25, 2025 at 11:00 AM – 12:30 PM ET
- **Vraylar:** Monday, April 28, 2025 at 11:00 AM – 12:30 PM ET
- **Xifaxan:** Monday, April 28, 2025 at 3:00 – 4:30 PM ET
- **Xtandi:** Tuesday, April 29, 2025 at 11:00 AM – 12:30 PM ET

## Town Hall Meeting

- Wednesday, April 30, 2025
  - Session 1 at 10:00 AM – 12:15 PM ET
  - Session 2 at 1:00 PM – 3:00 PM ET

Questions regarding this document may be directed to [IRRebateandNegotiation@cms.hhs.gov](mailto:IRRebateandNegotiation@cms.hhs.gov) using the subject line “Public Engagement Events.”

## General Information

**Question:** What is CMS planning for public engagement events for drugs selected for negotiation for initial price applicability year 2027?

**Response:** For public engagement events for initial price applicability year 2027, CMS is hosting 15 patient-focused roundtable events, one for each selected drug, which are open to patients, patient advocacy organizations, and caregivers, and will allow for discussion among speakers. CMS is hosting one town hall meeting for all selected drugs, focused on the clinical considerations related to the selected drugs. CMS encourages practicing clinicians and researchers, as well as other interested parties, to register to participate in this town hall meeting. CMS may ask follow-up questions of participants during the roundtable events and town hall meeting. CMS will engage a moderator to facilitate discussions for both the patient-focused roundtables and the town hall meeting.

**Question:** Why is the patient voice important to CMS in drug price negotiations?

**Response:** Public engagement events allow CMS to hear from patients and other stakeholders close to the patient experience—directly and in their own words—about patients’ personal experiences and perspectives on their condition(s) and about the drug(s) used to treat those conditions. This type of information helps inform CMS’ understanding of what matters to patients.

**Question:** What type of information may CMS obtain from the roundtable events?

**Response:** CMS expects to obtain a range of information from the roundtable events. For example, participants in the roundtable events may share their preferences for certain attributes of a drug used to treat their condition(s), such as dosing frequency, or they may share their preferences for treatment outcomes, such as avoidance of certain side effects, which may allow for greater engagement with family or hobbies.

**Question:** What type of information may CMS obtain from the town hall meeting?

**Response:** CMS expects to obtain a range of information from the town hall meeting. For example, participants in the town hall meeting may share their experience prescribing and/or managing treatment with the selected drug or therapeutic alternatives, information related to the goals of the treatment for the condition(s) treated by the selected drug, or considerations that drive treatment choice among the selected drug and therapeutic alternatives.

**Question:** How does CMS intend to use the information provided at public engagement events?

**Response:** CMS will use the information shared during the roundtable events to better understand patients’ experiences with the conditions and diseases treated by the selected drugs and patients’ experiences with the selected drugs themselves. CMS will use the information shared during the town hall meeting to better understand clinicians’ experiences prescribing and/or managing treatment with the selected drugs or therapeutic alternatives and clinicians’ considerations that drive treatment choice between the selected drugs and therapeutic alternatives. The information shared during both the town hall meeting and the roundtable events will also inform CMS’ identification of therapeutic alternatives, key outcomes, and adjustment of the starting point to develop the initial offer in negotiating with manufacturers of selected drugs. For example, patient input on their preferences for treatment outcomes, such as avoidance of certain side effects, and clinician input on the considerations that drive treatment choice among the selected drug and therapeutic alternatives may help CMS understand different perspectives regarding how the selected drug compares to therapeutic alternatives or addresses an unmet need. CMS also addresses this question in section 60.4.1 of the [final guidance for](#)

## Registration Process

**Question:** Who should register for the public engagement events?

**Response:** CMS encourages patients, patient advocacy organizations, and caregivers to register for the opportunity to speak at the roundtable events. CMS encourages practicing clinicians and researchers, as well as other interested parties, to register for the opportunity to speak at the town hall meeting. All stakeholders are welcome to attend and listen to the town hall meeting, which will be livestreamed.

**Question:** How long is registration open?

**Response:** Registration will be open through March 19, 2025.

**Question:** How do I register for a public engagement event?

**Response:** Registration for the roundtable events and town hall meeting is available at the [CMS IRA website](#).

**Question:** Can I register one time for the opportunity to speak at more than one event?

**Response:** To register for the opportunity to speak at multiple events, individuals will need to complete a separate registration form for the roundtable events and the town hall meeting. The registration forms for the roundtable events and the town hall meeting allow individuals to select up to three drugs they wish to speak about, including their second and third choices if they are not selected to speak about their first choice.

**Question:** When registering for a public engagement event, may participants select more than one participant type?

**Response:** Registrants may select only one participant type when registering for the town hall meeting. Registrants may select more than one participant type when registering for the roundtable events. Please select the participant type(s) that best aligns with the perspectives you plan to share during the event. This reflects CMS' approach to understanding if patient registrants for the roundtable events have experience with the selected drug, the condition(s) treated by the selected drug, other treatment(s) similar to the selected drug for those condition(s), or a combination thereof.

**Question:** Will the public engagement events be livestreamed? Do I need to register as a listener for the town hall meeting?

**Answer:** The town hall meeting will be livestreamed, and you do not need to register as a listener for the livestream. CMS notes that roundtable events will not be available to listen to via livestream.

**Question:** Why are the date and time listed on the confirmation message I received after registration different from my preferred session date and time?

**Answer:** The confirmation message registrants receive is a default message and does not reflect the registrant's specific session preferences. Selected participants will receive a detailed confirmation email during the week of March 24, 2025, that will include the date and time of the event they are confirmed to speak at. If selected to speak at the event for which they registered, participants will have four days

from the receipt of the confirmation email to confirm their availability for the assigned event date and time.

## Participant Selection

**Question:** If an individual does not submit a response to [Section I of the Negotiation Data Elements and Drug Price Negotiation Process Information Collection Request \(ICR\) \(OMB Control Number 0938-1452\)](#), are they less likely to be selected as a participant in a public engagement event?

**Response:** No, submitting a response to the ICR will not impact whether an individual is selected to participate in the public engagement events.

## Participant Requirements

**Question:** Will participants be required to submit a Health Insurance Portability and Accountability Act of 1996 (HIPAA) authorization form and, if so, will the form be available in a user-friendly format?

**Response:** Patients, caregivers, and representatives of a patient advocacy organization will be required to submit to CMS a completed HIPAA authorization form. CMS also reminds speakers who furnish health care services to individuals of their obligations under the [HIPAA Privacy Rule](#). CMS aims to provide a user-friendly format, to the extent feasible, for any required forms.

**Question:** Will other consent forms be required?

**Response:** Participants will also be required to submit to CMS a completed image release form. This form gives CMS permission to use recordings of the events for internal use and to livestream the town hall meeting. CMS will not post recordings or photographs publicly.

**Question:** Will CMS require participants to report conflicts of interest? If so, what types of conflicts of interest will be required to be reported?

**Response:** Yes, CMS is requiring individuals who are registering for the opportunity to speak at a roundtable event or the town hall meeting to report potential conflicts of interest (COI). Specifically, reported COI should include:

- Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a health care company (e.g., drug company, health plan) or related association with direct or indirect interest in the Negotiation Program, in excess of \$10,000 by you, your spouse, or an immediate family member.
- Direct assistance preparing your remarks from someone who is not a family member, caregiver, friend, or your health care provider.
- You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of \$10,000 in a health care company (e.g., drug company, health plan) or related association with direct or indirect interest in the Negotiation Program.
- Any other personal or professional relationship or interaction with a health care company (e.g., drug company, health plan) or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest.

Transparent disclosure of COI helps CMS and other stakeholders understand possible influences on remarks made during the meeting. Disclosure of a potential COI does not disqualify you from consideration as a speaker. COI will be disclosed alongside remarks made during the events.

## Preparing for the Events

**Question:** Given the short window of time between the opening of event registration and the events, how should interested parties prepare?

**Response:** Interested parties can review the patient-focused questions in the [Negotiation Data Elements and Drug Price Negotiation Process ICR \(OMB Control Number 0938-1452\)](#) to get a sense of the information CMS plans to seek during the roundtable events. Additionally, interested parties can review the clinical-focused and research-focused questions in that ICR to get a sense of the information CMS plans to seek during the town hall meeting.

**Question:** Will CMS share the discussion questions for the roundtable events in advance?

**Response:** CMS does not plan to share specific discussion questions with participants in advance. CMS expects the roundtable events will discuss topics and questions similar to those in the [Negotiation Data Elements and Drug Price Negotiation Process ICR \(OMB Control Number 0938-1452\)](#) and refers interested parties to the questions in that ICR for topics that may be covered.

## After the Events

**Question:** Does CMS intend to follow up with speakers after the public engagement events?

**Response:** No, CMS does not intend to ask additional questions of participants outside of or after the public engagement events.

**Question:** What information does CMS plan to publish after the public engagement events?

**Response:** CMS will release redacted transcripts of the roundtable events and town hall meeting after the events have concluded. Redacted transcripts will omit names and other identifying information for patients according to the Safe Harbor de-identification method under the HIPAA Privacy Rule, as well as omit names and other identifying information for all participants.

**Question:** Are patients, caregivers, patient advocacy organizations, and other interested parties able to provide additional supporting information about selected drugs and/or therapeutic alternatives to CMS after the public engagement events?

**Response:** Interested parties may submit questions and information via the CMS IRA mailbox ([IRAREbateandNegotiation@cms.hhs.gov](mailto:IRAREbateandNegotiation@cms.hhs.gov)) at any time. However, CMS strongly encourages interested parties to share relevant information about selected drugs and/or therapeutic alternatives in a [Negotiation Data Elements and Drug Price Negotiation Process ICR](#) submission or during the public engagement events.