



CENTER FOR MEDICARE

DATE: October 20, 2023

TO: All Drug Manufacturers

FROM: Dr. Meena Seshamani, MD, PhD
Deputy Administrator and Director of the Center for Medicare

SUBJECT: NOTICE: October Drug Manufacturer Call on Implementation of IRA Medicare Provisions

The purpose of this memorandum is to notify drug manufacturers that the Centers for Medicare & Medicaid Services (CMS), Center for Medicare hosts monthly calls on implementation of the Medicare provisions of the Inflation Reduction Act of 2022 (Public Law 117-169). The October call will be held on Monday, October 30, at 1:30 pm ET.

CMS is committed to engaging our partners and the communities we serve throughout the policymaking and implementation process, including the implementation of the Inflation Reduction Act. Aligned with our strategic pillar, CMS created this forum to provide drug manufacturers the opportunity to ask questions and provide feedback to CMS on issues related to the implementation of the Medicare provisions of the new law. The October 30 call will focus on a released Request for Information (RFI) seeking public input on the availability and potential technical ability of healthcare-related organizations to provide Medicare Transaction Facilitator (MTF) services in support of the Medicare Drug Price Negotiation Program (Negotiation Program).

Under the Negotiation Program established by the Inflation Reduction Act of 2022, manufacturers of drugs selected for the first cycle of negotiations that choose to participate must provide access to any negotiated Maximum Fair Prices (MFPs) for selected drugs to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers beginning January 1, 2026. CMS indicated in its [revised guidance](#) for the first cycle of negotiations, released on June 30, 2023, that it intends to contract with an MTF to facilitate the exchange of data and potentially payment between manufacturers, pharmacies, and other pharmaceutical supply chain entities. This RFI begins that process. The feedback from the RFI may be used to develop a future Request for Proposals for MTF services.

The RFI solicits input on a range of questions regarding the capabilities that the MTF should include, such as maintaining databases, sending and receiving data, collecting prescription claims for beneficiaries eligible for MFP drugs, providing for the adequate protection of data,

facilitating HIPAA compliance, calculating reimbursement amounts, and providing secure electronic payments. The RFI also asks healthcare-related organizations to share their experience with similar functionality needs. CMS hopes that a wide variety of stakeholders including pharmacies and other dispensers, providers and suppliers, patient organizations, and other impacted healthcare organizations also will respond to questions about desired functionalities. The RFI is available [here](#). Public comments are due by November 13.

Registered participants will have the opportunity to share feedback and ask questions about the RFI. This does not replace or stand in the place of providing responses to the RFI, so CMS encourages registered participants to also share input through the formal RFI process. CMS also welcomes submitted questions in advance of the call, which can be emailed to IRAREbateandNegotiation@cms.hhs.gov, indicating “10/30 Discussion Question” in the [subject line](#).

[To register for the October 30 call, please click here.](#) Registration will close at 5:00 pm ET on Thursday, October 26. The zoom link and an agenda with additional details will be sent to registrants in advance of the meeting. Please allow for some time to receive the e-mail with this information; zoom links will not be sent automatically after registering.

Please note that the registration link for this event is associated with one email address and device.

Note, this call is limited to drug manufacturers. Manufacturers that participate in the Medicare Coverage Gap Discount Program (CGDP) should use their P# (i.e., HPMS Contract ID) to register for this call. Manufacturers having issue accessing HPMS or recalling their P# can reach out to the HPMS Access Help Desk (hpms_access@cms.hhs.gov) for assistance. Manufacturers who wish to join this call but are currently not participating in the CGDP should reach out to IRAREbateandNegotiation@cms.hhs.gov to request access.