

DEPARTMENT OF HEALTH & HUMAN
SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



CENTER FOR MEDICARE

DATE: February 29, 2024

TO: All Drug Manufacturers and Other Interested Parties

FROM: Meena Seshamani, MD, PhD
Centers for Medicare & Medicaid Services Deputy Administrator and Director of
the Center for Medicare

SUBJECT: NOTICE: Monthly Manufacturer Call Status, Current Open Comment
Opportunities

The purpose of this memorandum is to notify drug manufacturers that the monthly Inflation Reduction Act (IRA) technical calls will be shifting to an ad hoc schedule. Moving forward, CMS will host these calls on an ad hoc basis dependent on the calendar of implementation activities and as needed to address questions from manufacturers regarding implementation. Manufacturers will be notified of any scheduled IRA technical calls through the Health Plan Management System (HPMS) and will undergo the same registration process that has been used for these calls in the past.

Stakeholders with interest in meeting with CMS in between the ad hoc scheduled calls should contact the following email inboxes, depending on the nature of your interests:

Medicare Drug Price Negotiation Program/Medicare Inflation Rebate Program:
IRAREbateandNegotiation@cms.hhs.gov

Manufacturer Discount Program: PartDManufacturerDiscountProgram@cms.hhs.gov

Part D Redesign and Medicare Prescription Payment Plan:
PartDPaymentPolicy@cms.hhs.gov

Cost Sharing for Part B Drugs for Medicare Advantage and Section 1876 Cost Plans: <https://mabenefitsmailbox.lmi.org/MABenefitsMailbox>

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 (IRA). As a reminder, CMS has several open comment opportunities that are detailed below.

[Draft Calendar Year \(CY\) 2025 Part D Redesign Program Instructions](#) provides draft guidance related to CY 2025 IRA-related changes made by sections 11201(a) and (b) to the Part D benefit, certain CY 2025 changes made by sections 11201(c) and (e), as well as guidance for CY 2023 Medical Loss Ratio (MLR) reporting related to the Inflation Reduction Act Subsidy Amount (IRASA). CMS is voluntarily soliciting comments on the draft program instructions. Please send comments about the draft program instructions to PartDRedesignPI@cms.hhs.gov with the subject line “Draft CY 2025 Part D Redesign Program Instructions.” Comments on the Draft Calendar Year (CY) 2025 Part D Redesign Program Instructions *must be submitted to PartDRedesignPI@cms.hhs.gov (this email address is only for submission of comments on the Draft CY 2025 Part D Redesign Program Instructions) by 6:00 PM Eastern time on March 1, 2024.*

Please note the draft program instructions are being published concurrently with the [CY 2025 Advance Notice](#) that, among other things, announces updates to Part D benefit parameters, some of which are impacted by provisions in the IRA. To submit comments or questions electronically related to the CY 2025 Advanced Notice, go to www.regulations.gov, enter the docket number “CMS-2024-0006” in the “search” field, and follow the instructions for “submitting a comment.” In order to receive consideration prior to the release of the Rate Announcement, CMS must receive comments on this Advance Notice by 6:00 PM Eastern Time on Friday, March 1, 2024.

[Part 2 Draft Guidance for the Medicare Prescription Payment Plan](#) provides draft guidance on Part D sponsor obligations on enrollee education, outreach, pharmacy processes, and operational considerations related to the Medicare Prescription Payment Plan. This draft guidance builds on the Draft Part One guidance that was issued on August 21, 2023 through an HPMS memo titled “Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments,” and the July 17, 2023 HPMS memo titled “Technical Memorandum on the Calculation of the Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans.” CMS is voluntarily soliciting comments; please send comments pertaining to this draft guidance to PartDPaymentPolicy@cms.hhs.gov with the subject line “Medicare Prescription Payment Plan Guidance – Part Two.” *Comments must be received by **March 16, 2024.***

Information Collection Requests (ICR):

[Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Advantage Prescription Drug \(MARx\) System Updates for the Medicare Prescription Payment Plan Program](#) is an ICR regarding the proposal to require Part D plans to submit beneficiary-level data elements into the MARx system via a program-specific transaction (separate from the enrollment file). This information will be used to monitor the requirement that MA Organizations offering Part D coverage and Part D sponsors offer enrollees the option to pay their Part D cost sharing in monthly amounts spread out over the plan year. Full text of the ICR can also be found on [CMS's PRA](#)

[Listing website](#). This ICR has a sixty-day comment period. *Comments must be received by **March 26, 2024**, and can be submitted at this [comment submission link](#).*

[Rebate Reduction Request](#) is an ICR regarding the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program and the process for manufacturers to submit requests for a rebate reduction for either a drug that has experienced a severe supply chain disruption or is likely to be in shortage. The full text of the ICR can also be found on [CMS's PRA Listing website](#). This ICR has a sixty-day comment period. *Comments must be received by **March 29, 2024**, and can be submitted at this [comment submission link](#).*

[2025 Medicare Part D Reporting Requirements](#) is an ICR outlining the Medicare Part D Reporting Requirements, including information for oversight, monitoring, compliance, and auditing. The ICR also includes information regarding the implementation the Medicare Prescription Payment Plan, which requires all Medicare Part D sponsors to offer their Part D enrollees the option to pay their out-of-pocket Part D drug costs through monthly payments over the course of the plan year. The full text of the ICR can be found on [CMS's PRA Listing website](#). This ICR has a sixty-day comment period. *Comments must be received by **April 2, 2024**, and can be submitted at this [comment submission link](#).*

[Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents](#) is an ICR outlining the model materials developed for beneficiary outreach and education on the Medicare Prescription Payment Plan. The full text of the ICR can be found on [CMS's PRA Listing website](#). This ICR has a sixty-day comment period. *Comments must be received by **April 29, 2024**, and can be submitted at this [comment submission link](#).*