#### DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850



## **CENTER FOR MEDICARE**

**DATE:** May 15, 2025

**TO:** Drug Manufacturers, Dispensing Entities, and Other Interested Parties

**FROM:** Christina Ritter, Director

Medicare Drug Rebate and Negotiations Group

**SUBJECT:** New Operational Documents Available for the Medicare Transaction

Facilitator (MTF): MTF ICR, MTF User Agreements, MTF Technical FAQs

CMS has published a new collection of operational documents related to the ongoing development and implementation of the Medicare Transaction Facilitator, a key tool in effectuating the maximum fair prices negotiated under the Medicare Drug Price Negotiation Program. Please see below for more details.

# Information Collection Request (ICR) for the Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)

The ICR for the Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) is now available. This ICR previously underwent a 60-day public comment period, concluding on December 27, 2024 and a 30-day comment period, concluding on May 1, 2025; CMS revised this ICR based on public comments and is releasing the final documents for publication. Respondents to the forms included in this ICR included manufacturers of drugs covered under Part D selected for negotiation under the Medicare Drug Price Negotiation Program for the initial price applicability years 2026 and 2027 and the dispensing entities that dispense the selected drugs to MFP-eligible individuals, as well as other interested parties. The final ICR is available for viewing on OMB's website. Click "all" to see full details.

## **Medicare Transaction Facilitator User Agreements**

Following a public feedback period, CMS has finalized the MTF User Agreements. The final MTF agreements are now available on <u>CMS' Medicare Drug Price Negotiation Program website</u>. These final MTF agreements reflect input received from interested parties regarding terms and conditions for using the MTF Data Module and, if applicable, the MTF Payment Module, which support implementation of the Medicare Drug Price Negotiation Program. CMS thanks all commenters for their feedback.

In June 2025, CMS will begin onboarding dispensing entities (including their third-party support entities) and Primary Manufacturers in the MTF Data Module (and the MTF Payment Module for participating Primary Manufacturers that choose to opt in) to prepare for January 1, 2026, the date that the negotiated maximum fair prices (MFPs) for the first ten drugs selected for the Medicare Drug Price Negotiation Program and covered under Part D go into effect. The final MTF agreements are being made available for preview in advance of June 2025 and should be electronically signed by an authorized individual from each enrolling dispensing entity and Primary Manufacturer during the MTF onboarding process.

## **Medicare Transaction Facilitator Technical FAQs**

CMS has published a new Frequently Asked Questions (FAQ) resource to our <u>Medicare Drug Price Negotiation</u> webpage. This FAQ resource addresses inquiries that CMS has received from Primary Manufacturers participating in the Medicare Drug Price Negotiation Program. CMS intends to provide further information on manufacturer-initiated claims reversals, the credit/debit ledger system, and other operational details in forthcoming FAQs and technical instructions.