

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



MEDICARE PLAN PAYMENT GROUP

DATE: December 22, 2025

TO: All Part D Sponsors

FROM: Jennifer R. Shapiro, Director, Medicare Plan Payment Group

SUBJECT: Reminder of Timely Submission and Other Requirements for Selected Drug Prescription Drug Event (PDE) Records

The Centers for Medicare & Medicaid Services (CMS) wishes to remind Part D sponsors of the PDE submission timeliness requirement for selected drugs under the Medicare Drug Price Negotiation Program. Pursuant to 42 C.F.R. § 423.325(b), Part D sponsors “must submit initial PDE records for selected drugs (as described at section 1192(c) of the Act) within 7 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim.” This requirement starts January 1, 2026, and is specifically for selected drugs (i.e., this requirement is distinct from the general 30-day PDE submission timeliness requirement that applies to other Part D drugs) to support timely maximum fair price (MFP) refund payments, when applicable, to dispensing entities. The seven-calendar day PDE submission rule applies to all PDE records for selected drugs, in both standard and non-standard formats, including PDE records associated with mail order and long-term care pharmacy claims.

CMS will closely monitor PDE submission of selected drugs by Part D sponsors¹, and outreach directly to Part D sponsors if needed. Sponsors are expected to immediately review and correct deficiencies in this area to ensure the effective and efficient administration of the Medicare Part D program. Failure to submit PDEs for selected drugs within seven days or review and correct deficiencies timely may result in compliance action.

CMS also reminds Part D sponsors that the [Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026](#),

¹ When determining compliance with the seven-calendar day PDE submission requirement, CMS considers the claim receipt date (i.e., DATE ORIGINAL CLAIM RECEIVED on the PDE record) to be Day Zero. The submission date will be determined using the transmission date that is populated by the submitter when they send the file to the Prescription Drug Front End System (PDFS) (i.e., the TRANS DATE on the PDE Inbound file). For example, if the DATE ORIGINAL CLAIM RECEIVED is January 1, 2026 (Day Zero), the PDE record would be considered timely if the TRANS DATE is on or before January 8, 2026 (Day Seven).

[2027, and 2028](#) (“final guidance”) provides policies for maximum fair price (MFP) effectuation and may be a helpful resource for Part D sponsors. For example, section 40.4.2.2 outlines CMS’ expectation that Part D sponsors include standard default refund amounts (SDRAs) on all Part D claims for selected drugs with a negotiated MFP in effect. The National Council for Prescription Drug Programs (NCPDP) provides instruction to Part D sponsors regarding this new message, which will furnish dispensing entities with an estimate of the manufacturer MFP refund amount equal to the SDRA as calculated by the plan sponsor. In addition, section 80.1 describes the policies for direct member reimbursements (DMRs) and access to the MFP for selected drugs in 2026, 2027, and 2028, including that Primary Manufacturers and Part D sponsors may establish a reimbursement process related to DMR requests for MFP-eligible claims as necessary to ensure MFP effectuation for these MFP-eligible individuals.