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

CENTER FOR MEDICARE

DATE: June 28, 2024

TO: All Part D Plan Sponsors

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

SUBJECT: Additional Information Regarding Prescription Drug Event Submission Certification for 2025

As described in previously published HPMS memoranda, CMS will require all Part D sponsors to recertify in order to submit Prescription Drug Event (PDE) data beginning January 1, 2025.[1] This program-wide recertification is necessary due to upcoming PDE changes, including the PDE File Layout expansion and the introduction of new financial fields on the PDE record in support of the Manufacturer Discount Program (Discount Program).[2] Further information on the procedure for testing and certification, as well as the test case matrix, can be found at www.csscoperations.com → Topics → EDI Onboarding and Connectivity → Submitter Onboarding Information. Certification testing for non-PACE Part D sponsors begins on July 1, 2024, and must be completed before production PDE files can be submitted in the new format beginning on January 1, 2025.

In response to the 2025 testing and certification PDE submission files, the Prescription Drug Front End System (PDFES) will return a 1000-byte Transaction Validation Detail Report. CMS is releasing additional information regarding PDE Edits that sponsors may receive in the testing and certification environment on the Transaction Validation Detail Report that are modified or new for PDE submissions in the new 1000-byte layout on or after January 1, 2025. An updated DDPS Edit Spreadsheet will be made available prior to implementation of edit changes into the production environment effective January 1, 2025.

---

[1] *See* HPMS memorandum, "Prescription Drug Event Submission Certification Requirements for 2025," May 10, 2024

[2] For a detailed discussion of the implementation of the Discount Program in 2025, *see* HPMS memorandum, "Medicare Part D Manufacturer Discount Program Final Guidance," November 17, 2023.

The following previously established edits are modified for PDE submissions on or after January 1, 2025:

Edit	Description
641	Filler fields must be <SPACE>. For PDE submissions >= 01/01/2025, filler field positions are 168-197, 217, 240-242, 290-314, 382-436, 558-623, 635-636, 648-660, 746-1000.
655	The Beginning Benefit Phase is missing or invalid. For DOS >= 01/01/2011 and <= 12/31/2024, valid values are D, N, G or C. For DOS >= 01/01/2025, valid values are D, N or C.
656	The Ending Benefit Phase is missing or invalid. For DOS >= 01/01/2011 and <= 12/31/2024, valid values are D, N, G or C. For DOS >= 01/01/2025, valid values are D, N or C.
657	The Reported Gap Discount Amount is missing or invalid. Required on PDEs with DOS >= 01/01/2011 and DOS <= 12/31/2024. On PDEs with a DOS < 01/01/2011 or PDEs with a DOS >= 01/01/2025, must = $0.
671	For DOS between 01/01/2011 and 12/31/2023, if TrOOP Accumulator + Delta TrOOP <= OOP Threshold, GDCA must = $0. For DOS >= 01/01/2024 if TrOOP Accumulator + Delta TrOOP < OOP Threshold, GDCA must = $0. For DOS <= 12/31/2024, Delta TrOOP is calculated as [Patient Pay + Other TrOOP Amount + LICS + Reported Gap Discount]. For DOS >= 01/01/2025, Delta TrOOP is calculated as [Patient Pay + Other TrOOP Amount + LICS + (NPP if >$0)].
779	Submitting plan cannot report NPP for Covered Part D Drug. This edit is bypassed for PDEs submitted by EGWPs for DOS <= 12/31/2013 and for DOS >= 01/01/2025.
881	For DOS >= 01/01/2024, TrOOP Accumulator + Delta TrOOP exceeds the annual Out of Pocket threshold. For DOS <= 12/31/2024, Delta TrOOP is calculated as [Patient Pay + Other TrOOP Amount + LICS + Reported Gap Discount]. For DOS >= 01/01/2025, Delta TrOOP is calculated as [Patient Pay + Other TrOOP Amount + LICS + (NPP if >$0)].

The following edits are new for PDE submissions on or after January 1, 2025.

Edit	Description
748	Effective for DOS >= 01/01/2025, this drug is not covered under Part D because the FDA-assigned Marketing Category is NDA or BLA, and no MDP agreement is on file for the manufacturer responsible for this labeler code.
749	Quantity Dispensed exceeds Quantity Prescribed.
931	MSP and COB claims are not eligible to receive a manufacturer discount.

Edit	Description
932	The FDA does not designate this drug as NDA or BLA and is not eligible to receive a manufacturer discount.
933	The Reported Manufacturer Discount must = $0 when Service Provider ID Qualifier = 99.
934	Manufacturer Discount does not apply.
935	Reported Manufacturer Discount <> CMS Calculated Manufacturer Discount +/- $0.05.
936	Reported Manufacturer Discount exceeds amount estimated by CMS + $0.05.
937	Reported Manufacturer Discount is <= amount estimated by CMS. (Informational)
940	Compound drugs are not eligible to receive a manufacturer discount.
961	Pharmacy Price Concessions at POS is missing or invalid. Effective for DOS >= 01/01/2025, amount must be >= $0. For DOS < 01/01/2025, amount must = $0.
962	Submission Type Code 1 – 5 field(s) invalid.
963	LTPAC Dispense Frequency is missing or invalid.
965	Medicare Prescription Payment Plan Indicator is missing or invalid.
966	The Reported Manufacturer Discount is missing or invalid.
981	If Drug Coverage Status Code is E or O, then the Reported Manufacturer Discount must = $0.
982	If Drug Coverage Status Code = E or O, then the Medicare Prescription Payment Plan Indicator must be <SPACE>.
986	Quantity Prescribed is missing or invalid.

Please contact CSSC Operations at 1-877-534-2772 (option 2) or by email at https://www.csscoperations.com with questions regarding the PDE submission certification process.

Thank you.