DEPARTMENT OF HEALTH & HUMAN SERVICES

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



CENTER FOR MEDICARE

DATE: May 10, 2024

TO: All Part D Plan Sponsors

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

SUBJECT: Prescription Drug Event Submission Certification Requirements for 2025

As described in previously published HPMS memoranda, CMS will require <u>all Part D sponsors</u> to recertify in order to submit Prescription Drug Event (PDE) data beginning January 1, 2025.^{1, 2, 3, 4} 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).⁵

Certification testing will occur in two phases. Certification testing for non-PACE Part D sponsors will begin on July 1, 2024, and is the subject of this memorandum. The 2025 PDE Testing and Certification Protocol for non-PACE Part D sponsors is posted at www.csscoperations.com → Topics → EDI Onboarding and Connectivity → Submitter Onboarding Information. Non-PACE testing and certification files should not be submitted prior to July 1, 2024.

The second phase of certification testing, which is only for PACE submitters, will begin on September 1, 2024. The PACE-specific 2025 PDE Testing and Certification Protocol will be released at a later date, and PACE organizations will receive additional communication when it is available. PACE testing and certification files should not be submitted prior to September 1, 2024.

¹ See "New 2025 Prescription Drug Event (PDE) File Layouts (FINAL)," April 18, 2023

² See "New 2025 Prescription Drug Event (PDE) FINAL File Layouts - FIELD UPDATES" October 31, 2023

³ See HPMS memorandum, "2025 Prescription Drug Event (PDE) File Layout Updates for all Part D Plan Sponsors, and Additional 2025 Changes to PDE Reporting for PACE Organization," March 8, 2024

⁴ Additional information about the PDE record can be found on the PDE Inbound File Layout which is located on the Customer Service and Support Center (CSSC) Operations <u>website</u>.

⁵ See "Medicare Part D Manufacturer Discount Program Final Guidance" released through HPMS on November 17, 2023 for a detailed discussion of the implementation of the Discount Program in 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. CSSC Operations will perform outreach to Connect:Direct submitters to confirm appropriate datasets are established to receive response files in the new 1000-byte format.

Upon successful completion of certification testing, CSSC Operations will formally notify the submitter and make the appropriate updates in the Prescription Drug Front-end System (PDFS) to accept production PDE file transmissions.

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.