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

CENTER FOR MEDICARE

DATE: July 12, 2024

TO: PACE Organizations

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

SUBJECT: Prescription Drug Event Submission Certification Requirements for 2025 for
               PACE Organizations

As described in previously published HPMS memoranda, CMS will require <u>all Part D sponsors,</u>
<u>including PACE organizations,</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 PACE organizations will
begin on September 1, 2024 and is the subject of this memorandum. Certification testing for non-
PACE Part D sponsors began on July 1, 2024. The 2025 PDE Testing and Certification Protocol
for PACE organizations is posted at www.csscoperations.com → Topics → EDI Onboarding and
Connectivity → Submitter Onboarding Information. PACE testing and certification files should
not be submitted prior to September 1, 2024. Certification status must be achieved prior to
submitting PDEs in production beginning on January 1, 2025.

In response to the 2025 testing and certification of PDE submission files, the Prescription Drug
Front-end System (PDFS) will return a 1000-byte Transaction Validation Detail Report. CSSC

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[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 website.
[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.

Operations will perform outreach to Connect:Direct submitters to confirm appropriate datasets are established to receive response files in the new 1000-byte format.

PACE organizations may receive PDE Edits 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. PACE organizations may refer to the current PDE Edit Spreadsheet, posted here, to interpret existing edits that PACE organizations may encounter in the testing and certification environment. Additionally, CMS issued an HPMS memo titled "Additional Information Regarding Prescription Drug Event Submission Certification for 2025" on June 28, 2024 that provides additional information on edit modifications and newly established edits that will be applied to PDEs with Dates of Service on or after January 1, 2025. The edits discussed in that memo apply to both non-PACE and PACE submitters with the following exceptions and additions:

- Edits 655 and 656, which evaluate the validity of the Beginning and Ending Benefit Phases, do not apply to PACE organizations because PACE organizations do not submit these values on the PDE record.
- Edit 779 indicates that the submitting plan cannot submit NPP for the covered Part D drug. This edit does not apply to Medicare-only PACE plans.
- Edit 803 indicates an invalid LICS amount. For DOS >= 01/01/2025, LICS amount must = $0 for Medicare-only PACE plans, and for DOS <= 12/31/2024, LICS amount must = $0 for all PACE plans.
- Edit 821 indicates an invalid NPP amount. NPP must be >= $0 on PDEs submitted by Medicare-only PACE plans.

An updated DDPS Edit Spreadsheet will be made available prior to implementation of edit changes into the production environment effective January 1, 2025.

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.