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



CENTER FOR MEDICARE

DATE: October 31, 2023

TO: All Part D Plan Sponsors

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

SUBJECT: New 2025 Prescription Drug Event (PDE) FINAL File Layouts - FIELD UPDATES

The purpose of this memo is to share field updates to the new 2025 Prescription Drug Event (PDE) Final File Layouts, "PDE-Inbound-File-Layout-Final-20250101_Q4-2023.xlsx," and "PDE-Outbound-File-Layout-Final-20250101_Q4-2023.xlsx," which will become effective on January 1, 2025. On April 18, 2023, CMS released a memo, "New 2025 Prescription Drug Event (PDE) File Layouts (FINAL)," sharing the 2025 PDE Final File Layouts. In the April 2023 memo, it was noted that CMS would be issuing separate guidance regarding the operational implementation of the Inflation Reduction Act (IRA), which may include additional PDE File Layout updates. This memo describes one (1) new PDE field that we are adding, one (1) PDE field that we are updating, and three (3) PDE fields that we are removing in the attached updated 2025 PDE Final File Layouts. *Please note that the updates made to the 2025 PDE Final File Layouts since the April 18, 2023 publication, including updates to the Definition/Values column on both the HDR and DET tabs, are illustrated in the attachments as follows: 1) The updates that were made since April 18, 2023 which will become effective in 2025 are shown in red, bold, underlined text; and, 2) The updates that were made since April 18, 2023 which are currently in production are shown in black, bold, underlined text.

Timing (reiterated; no change)

Until January 1, 2025, Part D sponsors should continue to use the current PDE Inbound File Layout published on the <u>Customer Service and Support Center (CSSC) Operations website</u> to submit their PDEs. Beginning January 1, 2025, Part D sponsors must use the new 2025 PDE Inbound File Layout to submit PDE records for *all* Benefit Years and *all* Dates of Service (DOS), including Benefit Years prior to 2025 and DOS prior to January 1, 2025. The existing PDE Inbound File Layout will be accepted until the implementation date of the 2025 PDE Inbound File Layout on January 1, 2025, at which time the Prescription Drug Front-End System (PDFS) will reject PDE submission files, regardless of the PDE's Benefit Year, submitted in the existing ("old") format.

CMS will be requiring all Part D sponsors to submit certification (CERT) test files prior to

¹ April 18, 2023 HPMS memorandum, New 2025 Prescription Drug Event (PDE) File Layouts (FINAL), available here.

² INFLATION REDUCTION ACT OF 2022, PL 117-169, August 16, 2022, available here.

submitting production PDE files in the new layout on January 1, 2025. CERT Testing for 2025 is planned to begin on July 1, 2024. CMS will provide CERT Testing requirements in advance.

CMS will also publish specific operational 2025 PDE reporting guidance and information on related updated edits at a later date.

Updates to the 2025 PDE Final Inbound and Outbound File Layouts

New IRA Field

1) Medicare Prescription Payment Plan Indicator

To enable the identification of PDEs that are included in the Medicare Prescription Payment Plan, established by Section 11202 of the IRA as the *Maximum Monthly Cap on Cost-Sharing Payments Program*, and in alignment with the August 21, 2023 HPMS memo "Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments," CMS is adding a new 1-position field, "Medicare Prescription Payment Plan Indicator."

This new field will have a format of X(1), and will be added to position 289 of the 2025 PDE Final File Layouts. For PDEs with DOS beginning January 1, 2025 and following, Part D sponsors must report a value of "Y" in this field for a PDE that is included in the Medicare Prescription Payment Plan. For a PDE that is not included in the Medicare Prescription Payment Plan, and for PDEs with a DOS prior to January 1, 2025, the value reported must be a space.

Updates to IRA Fields

2) Selected Drug Subsidy (name change; formerly known as "Government Pay Subsidy")

For increased clarity, CMS is renaming the previously published "Government Pay Subsidy" field (in positions 525-535 of the 2025 PDE Final File Layouts) to "Selected Drug Subsidy".

For PDEs with DOS beginning January 1, 2026 and following (*please note the year update), Part D sponsors must report the subsidy amount that the plan sponsor advanced at the point of sale for a Selected Drug in the Initial Coverage Period in this field. This amount will not increment the True Out-of-Pocket Accumulator amount. This field must be a positive dollar value (the value may never be negative), or may be \$0 when there is no Selected Drug subsidy to report. For PDEs with a DOS prior to January 1, 2026, the value reported must be zero.

3) Deductible Accumulator (removed)

CMS has determined that the "Deductible Accumulator" field on the PDE is not necessary. CMS is removing this field from positions 650-660 on the previously published version of the

³August 21, 2023 HPMS memorandum, *Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments*, available here.

2025 PDE Final File Layouts, and reclaiming the space as Filler.

Updates to Existing PDE Fields

4) Dispensing Status (removed)

The "Dispensing Status" field on the PDE has not been used since 2010. Beginning January 1, 2025, CMS is removing this field from the PDE File Layouts (position 168 on the current PDE File Layouts; position 217 on the previously published version of the 2025 PDE Final File Layouts), and reclaiming the space as Filler.

5) Other Authorized Provider (OAP) Indicator (removed)

The "OAP Indicator" field on the PDE, established in 2016, has never been used; i.e. Part D sponsors have been directed to populate this field with a space. Beginning January 1, 2025, CMS is removing this field from the 2025 PDE Final File Layouts (position 377 on the current PDE File Layouts), and reclaiming the space as Filler.

CMS strongly recommends that Part D sponsors share this memo and the updated 2025 PDE Final File Layouts with their information technology staff for reference in the implementation of these changes.

Thank you.

2 Attachments