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**DATE:** November 1, 2022

**TO:** All Part D Plan Sponsors

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

**SUBJECT:** New 2025 Prescription Drug Event (PDE) File Layouts (draft); Seeking Feedback

The purpose of this memo is to seek Part D sponsor feedback regarding the new 2025 Prescription Drug Event (PDE) File Layout drafts for your review, as “PDE Inbound File Layout Draft 20250101.xlsx” and “PDE Outbound File Layout Draft 20250101.xlsx.” On May 31, 2022, we released a memo, “Proposed Updates to the Prescription Drug Event (PDE) File Layout; Seeking Feedback,” requesting Part D sponsor feedback on the Centers for Medicare & Medicaid Services’ (CMS’) anticipated updates to the Prescription Drug Event (PDE) expanded file size and layouts. We carefully considered the feedback received on the addition of new fields, changes to existing fields, file format, and timing of implementation of the new file layouts, and we are now presenting these File Layout drafts for comment. As described in more detail at the end of this memo, feedback must be submitted by December 15, 2022 to be eligible for our consideration as we finalize the PDE File Layouts.

**Timing**

The finalized 2025 PDE File Layouts are planned to be published, along with a list of impacted reports, in April of 2023. Until January 1, 2025, Part D sponsors should continue to use the current PDE Inbound File Layout published on the [Customer Service and Support Center \(CSSC\) Operations website](#) to submit their PDEs. Part D sponsors must start using the new 2025 PDE Inbound File Layout to submit their PDEs on January 1, 2025.

All Part D sponsors will be required to submit certification (CERT) test files prior to submitting production PDE files on January 1, 2025. CERT Testing is planned to begin on July 1, 2024. CMS will provide requirements in advance. We will also publish specific operational guidance and related updated edits at a later date. Please note that CMS will issue separate guidance regarding the operational implementation of the Inflation Reduction Act,<sup>1</sup> which may include additional PDE File Layout updates.

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<sup>1</sup> INFLATION REDUCTION ACT OF 2022, PL 117-169, August 16, 2022, available [here](#).

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 Drug Data Processing System (DDPS) will reject PDEs submitted in the existing (“old”) format.

## **Background**

The expansion of the PDE file is the first increase in file length since the PDE file structure was implemented in 2006. Currently less than 5% of the file length is available on the PDE file layouts to add new fields and/or to expand existing fields. As we look ahead to the future, CMS will expand the PDE file layouts from their current 512-byte length to 1000 bytes, to be implemented effective January 1, 2025.

This expansion is being implemented to accommodate future business needs, including but not limited to, anticipated updates to the National Council for Prescription Drug Programs (NCPDP) Telecommunications Standard. In addition, the lengths of some of the existing fields on the PDE file layouts will be increased, which requires a reorganization of the overall PDE file layouts. You will notice this reorganization of fields into logical groupings in the attached 2025 PDE File Layout drafts, including the addition of Filler within each grouping to allow for future field expansions and/or additions. Filler is also added at the end of the PDE file record to accommodate the addition of future new unrelated fields. CMS recognizes the significance of this change, and requests technical feedback from Part D sponsors’ information technology staff on the 2025 PDE File Layout drafts.

We thank Part D sponsors for their feedback to our prior request on CMS’ anticipated updates to the Prescription Drug Event (PDE) file size and layout; we have incorporated many of the suggestions into our draft File Layouts and will consider other suggestions for future changes.

## **New Fields**

As part of our effort to assist Medicare Part D sponsors in submitting complete and accurate data for payment, to be compliant with CMS regulations, and based on the feedback received from our stakeholders, CMS will add the following *new* fields to the 2025 PDE file layouts:

### **1) Original Quantity Prescribed**

CMS is adding a new 10-position field, “Original Quantity Prescribed,” so that CMS can more accurately identify incrementally filled Schedule II products and monitor for compliance. Editing will be applied to ensure that the “Quantity Dispensed” does not exceed the “Original Quantity Prescribed.”

Beginning January 1, 2025, Part D sponsors must report the original quantity prescribed for Schedule II drugs that are reported on standard, electronically-submitted PDEs in the new “Original Quantity Prescribed” field.

The new “Original Quantity Prescribed” field will have a format of 9(7)V999. For PDEs with a Date of Service (DOS) prior to January 1, 2025 or for non-Schedule II PDEs, the value reported must be 0.

## **2) Pharmacy Price Concessions at POS**

In light of the changes to the treatment of pharmacy price concessions, codified in the CY 2023 Medicare Advantage and Part D Final Rule (CMS-4192-F)<sup>2</sup> (hereinafter referred to as the “pharmacy price concessions final rule”), CMS is adding a new dollar amount field, “Pharmacy Price Concessions at POS.”

Beginning January 1, 2025, Part D sponsors must report in this field the maximum amount of any contingent payments or adjustments that the Part D sponsor might receive from a network pharmacy that would serve to decrease the total amount that the Part D sponsor pays for the drug, i.e., all pharmacy price concessions. All other estimated remuneration applied at the point of sale (POS) must be reported in the existing “Estimated Remuneration at POS Amount (ERPOSA)” field, as described in #7 below.

The new “Pharmacy Price Concessions at POS” field will have a format of S9(9)V99, consistent with the expanded dollar amount fields, as described in #9 below. For PDEs with a Date of Service (DOS) prior to January 1, 2025 or for PDEs with no pharmacy price concessions to report, the value reported must be \$0.

## **3) LTPAC Dispense Frequency**

The new “LTPAC Dispense Frequency” field will be used for long-term and post-acute care short-cycle (LTPAC) dispensing. Currently, short-cycle dispensing is reported using the existing “Submission Clarification Code” field on the PDE file layouts, but will be reported via the “LTPAC Dispense Frequency” field to align with future versions of the NCPDP Telecommunication Standard. Note: If an updated NCPDP Telecommunication Standard has not yet been implemented as of January 1, 2025 that includes this field, the value of the field on the PDE may be blank until the effective date of a new NCPDP Telecommunication Standard.

The new PDE field will have a format of X(2). Valid values will be published following future updates to the NCPDP Telecommunication Standard.

## **4) Submission Type Code**

The new “Submission Type Code” field will allow for 5 instances of codes on the PDE record to align with future versions of the Telecommunication Standard. Some values currently reported in the existing NCPDP Telecommunication Standard “Submission Clarification Code” (SCC) field (ex: indication of Section 340B claims) will be submitted in the new “Submission Type Code” field under the new version of the NCPDP Telecommunication Standard. Note: If an updated NCPDP Telecommunication Standard has not yet been implemented as of January 1, 2025 that includes this field, the value of the field on the PDE may be blank until the effective date of a new NCPDP Telecommunication Standard.

The 5 new PDE fields will have a format of X(2). Valid values will be published following future updates to the NCPDP Telecommunication Standard.

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<sup>2</sup> 87 FR 27704, 27833 (May 9, 2022), available [here](#).

## **Updates to Existing Fields**

In addition, CMS will make *updates* to the following existing fields on the 2025 PDE file layouts:

### **5) Product Service ID**

CMS is expanding the existing “Product Service ID” on the PDE file layouts from its current 19-character length to 40 characters; i.e., from the existing format of X(19) to a new format of X(40), consistent with future versions of the NCPDP Telecommunications Standard. This change will be made at the time that the PDE file layouts are expanded on January 1, 2025.

### **6) Prescriber ID**

CMS is expanding the field length of the existing “Prescriber ID” field on the PDE file layouts from the current 15 characters to 35 characters, i.e., from the existing format of X(15) to a new format of X(35), consistent with future versions of the NCPDP Telecommunications Standard. This change will be made at the time that the PDE file layouts are expanded on January 1, 2025.

### **7) Estimated Remuneration at POS Amount (*ERPOSA*)**

CMS is changing the name of the existing “Estimated Rebate at POS” field to “Estimated Remuneration at POS Amount (*ERPOSA*).” This field name change will be implemented prior to the January 1, 2024 applicability date of the pharmacy price concessions final rule.<sup>3</sup> Until January 1, 2025, ERPOSA (under its current name or under its new name) must include all remuneration applied at the POS, including any pharmacy price concessions applied at the POS.

Beginning January 1, 2025, CMS will direct Part D sponsors to report the estimated amount of remuneration that the Part D sponsor is required to apply, or has elected to apply, to the negotiated price as a reduction in the drug price made available to the beneficiary at the POS in the “Estimated Remuneration at POS Amount (*ERPOSA*)” field. Beginning January 1, 2025, ERPOSA must not include pharmacy price concessions. Rather, as described in #2 above, at the time that the PDE file layouts are expanded on January 1, 2025, CMS will add a new “Pharmacy Price Concessions at POS” dollar amount field where pharmacy price concessions will be reported.

### **8) Vaccine Administration Fee or Additional Dispensing Fee**

CMS is changing the name of the existing “Vaccine Administration Fee” field to “Vaccine Administration Fee or Additional Dispensing Fee.” The existing PDE field, “Vaccine Administration Fee,” has been used to report the amount of additional dispensing fees paid for Emergency Use Authorization (EUA) oral antiviral drugs procured by the U.S. Government, over and above what was reported in the “Dispensing Fee Paid” field. The field name is changing to account for this expanded usage of the field. This change will be implemented, along with the 2023 annual DDPS system changes, on or about December 31, 2022.

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<sup>3</sup> 87 FR 27704, 27833 (May 9, 2022), available [here](#).

## 9) Dollar Amount fields

CMS is expanding all dollar amount fields on the PDE file layouts to accommodate future potential million-dollar claims. The lengths of these fields will expand from 8 characters to 11 characters, i.e., from the existing format of S9(6)V99 to a new format of S9(9)V99. This change will be made at the time that the PDE file layouts are expanded on January 1, 2025.

- Ingredient Cost Paid
- Dispensing Fee Paid
- Total Amount Attributed to Sales Tax
- Estimated *Remuneration* at POS *Amount (ERPOSA)*
- *\*New\** Pharmacy Price Concessions at POS
- Vaccine Administration Fee *or Additional Dispensing Fee*
- Gross Drug Cost Below Out- Of-Pocket Threshold (GDCB)
- Gross Drug Cost Above Out-Of-Pocket Threshold (GDCA)
- Patient Pay Amount
- Other TrOOP Amount
- Low Income Cost Sharing Subsidy Amount (LICS)
- Patient Liability Reduction Due to Other Payer Amount (PLRO)
- Covered D Plan Paid Amount (CPP)
- Non-Covered Plan Paid Amount (NPP)
- Reported Gap Discount
- Total Gross Covered Drug Cost (TGCDC) Accumulator
- True Out-Of-Pocket (TrOOP) Accumulator
- CMS Calculated Gap Discount

CMS recommends that you share this memo and the 2025 PDE File Layout drafts with your information technology staff to solicit their technical feedback.

Please submit any feedback regarding this memo and the attached 2025 Prescription Drug Event (PDE) File Layout drafts to [PDE-Operations@cms.hhs.gov](mailto:PDE-Operations@cms.hhs.gov) with the subject line “FEEDBACK – New 2025 Prescription Drug Event (PDE) File Layouts (draft)” no later than December 15, 2022. Thank you.

2 Attachments