



CENTER FOR MEDICARE

DATE: May 31, 2022

TO: All Part D Plan Sponsors

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

SUBJECT: Proposed Updates to the Prescription Drug Event (PDE) File Layout; Seeking Feedback

The purpose of this memo is to seek plan feedback regarding anticipated updates to the Prescription Drug Event (PDE) file size and layout. 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 file length is available on the PDE file layout to add new fields and/or to expand existing fields. As we look ahead to the future, the Centers for Medicare & Medicaid Services (CMS) is planning to expand the PDE file layout from its current 512-byte length to 1000 bytes.

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 layout will be increased, which will require a reorganization of the overall PDE file layout; i.e., some of the existing fields on the PDE file layout will move to a different record location on the layout than their current locations. CMS recognizes the significance of this change, and requests plan feedback on the following:

- a. The current PDE file layout will be accepted until the implementation date of the expanded new PDE file layout. CMS is considering an implementation date of 1/1/2025, at which time the Drug Data Processing System (DDPS) will reject PDEs submitted in the current ("old") format. All plans will be required to submit certification (CERT) test files prior to submitting production PDE files on 1/1/2025.
 - 1) We plan to share the revised final PDE file layout in early 2023. While we believe that this timeline allows for implementation before the planned CERT start date, if you believe that this is not an adequate amount of time to implement these changes into your systems, please explain how much longer you might need, and why.
 - 2) We plan to open CERT testing on 10/1/2024. While we believe the three months allowed under this timeline is sufficient to test your PDE file submissions with the new file layout, if you believe that is not an adequate amount of time, please explain how much longer you might need, and why.

- b. When the PDE file layout is expanded, CMS will group related fields together and add filler space after each grouping of related fields to allow for future field expansions and/or additions. We will also add filler at the end of the PDE file record for the addition of new unrelated fields.

New Fields

As part of our effort to assist Medicare Part D plan sponsors in submitting complete and accurate data for payment, and based on feedback from our stakeholders, CMS plans to add the following new fields to the PDE file layout, and requests plan feedback:

1) Original Quantity Prescribed

CMS plans to add a new 10-position field, “Original Quantity Prescribed,” so that CMS and auditors can more accurately identify incrementally filled Schedule II products and monitor for compliance. Some editing will need to be applied to ensure that the “Quantity Dispensed” does not exceed the “Original Quantity Prescribed.” This new field will have a format of 9(7)V999.

2) Patient Liability Reduction due to EGWP (PLRE)

CMS plans to add a new field, “Patient Liability Reduction due to EGWP (PLRE),” for plans to report Patient Liability Reduction Due to Other Payer amounts when the other payer is an Employer Group Waiver Plan (EGWP). The new PLRE field will provide CMS with additional transparency and clarity of the EGWP supplemental benefit when there are other non-EGWP, non-TrOOP eligible payers present on a PDE. Reporting payment amounts attributed to EGWP additional coverage in the new PLRE field, separate from those that are non-EGWP and not TrOOP eligible reported in the existing PLRO field, will allow for the Drug Data Processing System (DDPS) editing logic to differentiate between the two amounts, and will reduce rejects. Further, this new field will allow applicable PDEs to be resubmitted. This new field will have a format of S9(9)V99, consistent with the expanded dollar amount fields, as described in #9 below.

CMS is interested in plan feedback regarding the following:

- a. Where Part D sponsors of EGWPs plan to resubmit previously-rejected PDEs, whether you prefer to resubmit *all* Calendar Year (CY) and non-CY EGWP PDEs, versus resubmitting the PDEs that are exclusively impacted for the years prior to the new PLRE field implementation date, and the reasoning for resubmitting all PDEs from a year;
- b. Feedback regarding the resubmission of *all* claims for any beneficiary with at least one PDE resubmitted with PLRE < 0;
- c. The effectiveness of resolving CY EGWP PDEs with an additional non-EGWP OHI payer that are currently receiving reject edit code 671; and
- d. Any other implications, adverse or constructive, of the proposed updates.

3) 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)¹ (hereinafter referred to as the “pharmacy price concessions final rule”), and the future PDE file expansion, CMS will add a new dollar amount field, “Pharmacy Price Concessions at POS,” to allow plans to report pharmacy price concessions that were accounted for in the Negotiated Price. Plans will report pharmacy price concessions at the Point of Sale (POS) in the new “Pharmacy Price Concessions at POS” field, and separately report all other estimated remuneration at the POS in the existing “Estimated *Remuneration* at POS” (ERPOSA) field. This 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.

4) LTPAC Dispense Frequency

Depending on updates to the National Council for Prescription Drug Programs (NCPDP) Telecommunications standard, CMS may add a new 2-character field, “LTPAC Dispensing Frequency,” to be used for long-term and post-acute care short-cycle (LTPAC) dispensing. Currently, short cycle dispensing is defined using the existing “Submission Clarification Code” field on the PDE file layout. With the addition of this new field, the use of the “Submission Clarification Code” field may be discontinued and replaced with this new field. The new field will have a format of X(2).

Updated Existing Fields

In addition, CMS plans to make updates to the following existing fields on the PDE file layout:

5) Product Service ID

The United States Food & Drug Administration (FDA) is proposing future expansion to the Labeler Code, which makes up part of the existing “Product Service ID” field’s value. In addition, the FDA is considering the accommodation of a 14-digit Unique Device Identification (UDI) for use for some devices in place of the National Drug Code (NDC).² To accommodate both potential future changes, at the time that the PDE file layout is expanded CMS plans to expand the existing “Product Service ID” on the PDE file layout 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). While we are planning to increase the field length in the expanded PDE layout, any updates to edits of the NDC field will be made when the FDA’s changes are finalized, and according to the mandated effective date, which will be announced separately.

6) Prescriber ID

At the time that the PDE file layout is expanded, CMS plans to expand the field length of the existing “Prescriber ID” field on the PDE file layout from the current 15 characters to 35 characters, i.e., from the existing format of X(15) to a new format of X(35) for consistency with future versions of the NCPDP Telecommunications standard.

¹ 87 FR 27704, 27833 (May 9, 2022), available [here](#).

² 83 FR 38666, 38669 (August 7, 2018), available [here](#).

7) Estimated *Remuneration* at POS (ERPOSA)

CMS will change the name of the existing “Estimated Rebate at POS” field to “Estimated *Remuneration* at POS (ERPOSA).” This change will be implemented prior to the January 1, 2024 applicability date of the pharmacy price concessions final rule.³

In addition, as described in #3 above, at the time that the PDE file layout is expanded, CMS will add a new “Pharmacy Price Concessions at POS” dollar amount field. At that time, CMS proposes that plans will report pharmacy price concessions at the Point of Sale (POS) in the new “Pharmacy Price Concessions at POS” field, and separately report all other estimated remuneration applied at the POS in the existing “Estimated *Remuneration* at POS (ERPOSA)” field.

8) 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. To account for this use of the field, CMS will change the name of the field from “Vaccine Administration Fee” to “Vaccine Administration Fee or *Additional Dispensing Fee*,” to be implemented along with the 2023 annual DDPS system changes, on or about December 31, 2022.

9) Dollar Amount fields

At the time that the PDE file layout is expanded, CMS plans to expand the following dollar amount fields on the PDE file layout 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:

- Ingredient Cost Paid
- Dispensing Fee Paid
- Total Amount Attributed to Sales Tax
- 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)
- Estimated *Remuneration* at Point of Sale (ERPOSA)

³ 87 FR 27704, 27835 (May 9, 2022), available [here](#).

- Vaccine Administration Fee *or Additional Dispensing Fee*
- Total Gross Covered Drug Cost (TGCDC) Accumulator
- True Out-Of-Pocket (TrOOP) Accumulator
- Reported Gap Discount
- CMS Calculated Gap Discount

Additional Request for Feedback

10) In addition, an updated NCPDP Telecommunications standard will allow plans to capture additional information on claims. CMS is also interested in hearing from plans which, if any, of the potential future new Telecommunications standard fields might be of interest to CMS, and why.

Please submit any feedback regarding this memo to PDE-Operations@cms.hhs.gov with the subject line “FEEDBACK - Proposed Updates to the Prescription Drug Event (PDE) File Layout” no later than July 1, 2022. Thank you.