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CENTER FOR MEDICARE

DATE: April 18, 2023
TO: All Part D Plan Sponsors
FROM: Jennifer R. Shapiro, Director, Medicare Plan Payment Group
SUBJECT: New 2025 Prescription Drug Event (PDE) File Layouts (FINAL)

The purpose of this memo is to share the new 2025 Prescription Drug Event (PDE) Final File Layouts, “PDE Inbound File Layout Final_20250101.xlsx” and “PDE Outbound File Layout Final_20250101.xlsx,” which will become effective on January 1, 2025. On May 31, 2022, CMS released a memo, “Proposed Updates to the Prescription Drug Event (PDE) File Layout; Seeking Feedback,”¹ requesting Part D sponsor feedback on the Centers for Medicare & Medicaid Services’ (CMS’) anticipated updates to the PDE expanded file size and layouts. On November 1, 2022, CMS released a second memo, “New 2025 Prescription Drug Event (PDE) File Layouts (draft); Seeking Feedback,”² requesting Part D sponsor feedback on the anticipated updates to the PDE Inbound and Outbound Draft File Layouts. CMS 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 is now sharing the finalized 2025 PDE File Layouts.

Timing

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. Beginning January 1, 2025, Part D sponsors must use the new 2025 PDE Inbound File Layout to submit PDE records (PDEs) 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.

All Part D sponsors will be required to submit certification (CERT) test files prior to submitting

¹ May 31, 2022 HPMS memorandum, *Proposed Updates to the Prescription Drug Event (PDE) File Layout; Seeking Feedback*, available [here](#).

² November 1, 2022 HPMS memorandum, *New 2025 Prescription Drug Event (PDE) File Layouts (draft); Seeking Feedback*, available [here](#).

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

CMS will also publish specific operational PDE reporting guidance and information on related updated edits at a later date. Please note that CMS will issue separate guidance regarding the operational implementation of the Inflation Reduction Act (IRA),³ which may include additional PDE File Layout updates.

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 is expanding the PDE File Layouts from their current 512-byte length to 1000 bytes, 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) Telecommunication Standard, as well as to operationally implement Federal legislation. In addition, the lengths of some of the existing fields on the PDE File Layouts are increasing, requiring an overall reorganization of the fields within the PDE File Layouts.

Part D sponsors will notice the reorganization of fields into logical groupings in the attached final 2025 PDE File Layouts, 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 thanks Part D sponsors for their feedback to the prior requests regarding CMS' anticipated updates to the PDE file size and file layouts; CMS has incorporated stakeholders' suggestions into the final PDE File Layouts, as applicable.

New Fields

As part of CMS' effort to assist Medicare Part D sponsors in submitting complete and accurate data for payment, to be compliant with Federal legislation and CMS regulations, and based on the feedback received from stakeholders, CMS is adding the following *new* fields to the 2025 PDE File Layouts:

1) Originally Prescribed Quantity

CMS is adding a new 10-position field, "Originally Prescribed Quantity," to enable more accurate identification of incrementally filled Schedule II products and to monitor for compliance. Editing will be applied to ensure that the "Quantity Dispensed" does not exceed the "Originally Prescribed Quantity."

³ INFLATION REDUCTION ACT OF 2022, PL 117-169, August 16, 2022, available [here](#).

Beginning January 1, 2025, Part D sponsors must report the “Originally Prescribed Quantity” for Schedule II drugs that are reported on standard, electronically-submitted PDEs.

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

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)⁴ (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 #8 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 #10 below. Beginning January 1, 2025, Part D sponsors must report pharmacy price concessions at the POS in this field, which must be a positive dollar value (the value may never be negative), or may be \$0 when there is no price concession applied at the POS. For PDEs with a DOS prior to January 1, 2025, the value reported must be zero.

3) Submission Type Code 1-5

CMS is adding 5 new “Submission Type Code” fields that will allow Part D sponsors to report up to 5 instances of codes that identify specific types of claims on the PDE record, to align with future versions of the NCPDP Telecommunication Standard. Note: If an updated NCPDP Telecommunication Standard has not yet become effective as of January 1, 2025, that includes the “Submission Type Code” field, the values of these fields on the PDE are optional and may be spaces until the effective date of the new NCPDP Telecommunication Standard.

The 5 new PDE fields will have a format of X(2). Valid values that CMS will accept are included in the PDE File Layouts’ Definition/Values column.

4) LTPAC Dispense Frequency

CMS is adding a new “LTPAC Dispense Frequency” field that will be used to identify long-term and post-acute care short-cycle (LTPAC) dispensing PDEs. Currently, LTPAC dispensing is reported in the existing “Submission Clarification Code” field on the PDE. Beginning January 1, 2025, this information 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 become effective as of January 1, 2025, that includes the

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

“LTPAC Dispense Frequency” field, the value of this field on the PDE is optional and may be spaces until the effective date of the new NCPDP Telecommunication Standard. The short-cycle dispensing codes may continue to be reported in the “Submission Clarification Code” fields on the PDE until the new NCPDP Telecommunication Standard becomes effective.

The new PDE field will have a format of X(2). Valid values that CMS will accept are included in the PDE File Layouts’ Definition/Values column.

5) Inflation Reduction Act Fields

To operationally implement the applicable provisions of the IRA, CMS is adding new IRA-related fields to the PDE File Layouts. Please note that CMS will publish specific operational PDE reporting guidance and information on related updated edits regarding the following new PDE fields at a later date.

PDE Inbound Layout

a) Government Pay Subsidy

CMS is adding a new dollar amount field, “Government Pay Subsidy”. Beginning January 1, 2025, Part D sponsors must report the government pay selected drug subsidy amount in this field.

This new field will have a format of S9(9)V99, consistent with the expanded dollar amount fields, as described in #10 below. This field must be a positive dollar value (the value may never be negative), or may be \$0 when there is no government pay selected drug subsidy to report. For PDEs with a DOS prior to January 1, 2025, the value reported must be zero.

b) Reported Manufacturer Discount

CMS is adding a new dollar amount field, “Reported Manufacturer Discount”. Beginning January 1, 2025, Part D sponsors must report the amount that the plan sponsor advanced at the point of sale for the Manufacturer Discount for applicable drugs.

This new field will have a format of S9(9)V99, consistent with the expanded dollar amount fields, as described in #10 below. This field must be a positive dollar value (the value may never be negative), or may be \$0 when there is no Manufacturer Discount to report. For PDEs with a DOS prior to January 1, 2025, the value reported must be zero. This amount will not increment the True Out-of-Pocket Accumulator amount.

c) Deductible Accumulator

CMS is adding a new dollar amount field, “Deductible Accumulator”. Beginning January 1, 2025, Part D sponsors must report the sum of the beneficiary's deductible amount for the benefit year that is known immediately prior to adjudicating the claim.

This new field will have a format of S9(9)V99, consistent with the expanded dollar amount fields, as described in #10 below. This field must be a positive dollar value (the value may never be negative), or may be \$0 when there is no cumulative deductible to report. For PDEs with a DOS prior to January 1, 2025, the value reported must be zero.

PDE Outbound Layout

Please note that all of the new IRA-related fields added to the PDE Inbound Layout will also be added to the PDE Outbound Layout, with the following additions:

d) CMS Calculated Manufacturer Discount

CMS is adding a new dollar amount field, “CMS Calculated Manufacturer Discount”. Beginning January 1, 2025, this field will contain the Manufacturer Discount amount calculated by CMS during on-line PDE editing based on data reported by the Part D sponsor on the PDE.

This new field will have a format of S9(9)V99, consistent with the expanded dollar amount fields, as described in #10 below. For PDEs with a DOS prior to January 1, 2025, the value reported will be zero

e) Applicable Discount Percentage for Specified Small Manufacturer Drugs

CMS is adding a new field, “Applicable Discount Percentage for Specified Small Manufacturer Drugs”. Beginning January 1, 2025, this field will contain the phased-in Manufacturer Discount percentage that applies for the benefit year of the PDE for specified small manufacturer drugs, as provided by the statute.

This new field will have a format of X(2). For PDEs with a DOS provided by the statute prior to January 1, 2025, the value reported will be spaces.

f) Applicable Discount Percentage for Specified Manufacturer Drugs Dispensed to LIS Beneficiaries

CMS is adding a new field, “Applicable Discount Percentage for Specified Manufacturer Drugs Dispensed to LIS Beneficiaries”. Beginning January 1, 2025, this field will contain the phased-in Manufacturer Discount percentage that applies for the benefit year of the PDE for specified manufacturer drugs dispensed to Low Income Subsidy (LIS) eligible beneficiaries, as provided by the statute.

This new field will have a format of X(2). For PDEs with a DOS prior to January 1, 2025, the value reported will be spaces.

Updates to Existing Fields

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

6) Product Service ID

CMS is expanding the existing “Product Service ID” field from its current 19-character length to

40 characters; i.e., from a format of X(19) to the new format of X(40), consistent with future versions of the NCPDP Telecommunication Standard. This change will become effective on January 1, 2025. Direction on how to populate this field is included in the PDE File Layouts' Definition/Values column.

7) Prescriber ID

CMS is expanding the existing "Prescriber ID" field from its current 15-character length to 35 characters; i.e., from a format of X(15) to the new format of X(35), consistent with future versions of the NCPDP Telecommunication Standard. This change will become effective on January 1, 2025. Direction on how to populate this field is included in the PDE File Layouts' Definition/Values column.

8) 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. Until January 1, 2025, the ERPOSA field (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. For detailed PDE reporting instructions, please see the October 14, 2022 HPMS memorandum entitled, "Reporting Estimated Remuneration Applied to the Point-of-Sale Price."⁵

For PDEs with a Date of Service (DOS) before January 1, 2024, this field must contain the estimated amount of rebates and/or other price concessions that the plan 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.

For PDEs with a DOS between January 1, 2024 and December 31, 2024, this estimate must reflect the maximum amount of any contingent payments or adjustments that the plan sponsor might receive from a network pharmacy that would serve to decrease the total amount that the plan sponsor pays for the drug, i.e., all pharmacy price concessions. This estimate must *also* reflect the rebate or other price concession amount that the plan sponsor expects to receive from a pharmaceutical manufacturer or other non-pharmacy entity and has elected to apply to the negotiated price.

Beginning January 1, 2025, Part D sponsors must 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. This estimate includes the rebate or other price concession amount that the plan sponsor expects to receive from a pharmaceutical manufacturer or other non-pharmacy entity and has elected to apply to the negotiated price. Beginning January 1, 2025, the ERPOSA field must *not* include pharmacy price concessions. Rather, as described in #2 above, when the PDE File Layouts are expanded on January 1, 2025, CMS is adding the new "Pharmacy Price

⁵ October 14, 2022 HPMS memorandum, *Reporting Estimated Remuneration Applied to the Point-of-Sale Price*, available [here](#).

Concessions at POS” dollar amount field where pharmacy price concessions will be separately reported.

When there is no rebate or price concession made available to the beneficiary at the POS, this field may be \$0. This field must contain a positive dollar amount; the field may never be negative.

9) Submission Clarification Code 1-5

CMS is expanding the one existing “Submission Clarification Code” field to 5 “Submission Clarification Code” fields that will allow Part D sponsors to report up to 5 instances of clarification codes on the PDE record, to align with future versions of the NCPDP Telecommunication Standard.

CMS is also expanding the 5 “Submission Clarification Code” fields from the current 2-character length to 3 characters; i.e., from a format of X(2) to the new format of X(3), consistent with future versions of the NCPDP Telecommunication Standard. Beginning January 1, 2025, a numeric value or spaces may be reported in these fields; if an LTC-related value is reported, Patient Residence must be "03". This change will become effective on January 1, 2025. Valid values that CMS will accept are included in the PDE File Layouts’ Definition/Values column.

10) Dollar Amount fields

CMS is expanding all dollar amount fields to accommodate future potential million-dollar claims. The size of these fields is expanding 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 become effective 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 (GDCEB)
- 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)
- **New** Government Pay Subsidy
- **New** Reported Manufacturer Discount
- Reported Gap Discount
- Total Gross Covered Drug Cost (TG CDC) Accumulator
- True Out-Of-Pocket (TrOOP) Accumulator
- **New** Deductible Accumulator

- CMS Calculated Gap Discount (*PDE Outbound Layout only*)
- **New** CMS Calculated Manufacturer Discount (*PDE Outbound Layout only*)

Updated Reports

The following list of existing reports containing PDE data will be updated to reflect the PDE Layouts updates. The timeframes in which the impacted reports will be distributed with a new report layout are also included in the table below. Please note that CMS will publish the updated report file layouts at a later date.

Report Name	Frequency	Date file will be distributed in new layout
DDPS PDE Response File	Daily	01/01/2025
Report 4COV Non-PACE	Monthly	Mid-February 2025 (no later than 2/15/25)
Report 4ENH Non-PACE	Monthly	Mid-February 2025 (no later than 2/15/25)
Report 4OTC Non-PACE	Monthly	Mid-February 2025 (no later than 2/15/25)
Report 4 LI NET	Monthly	Mid-February 2025 (no later than 2/15/25)
Report 4COV PACE	Monthly	Mid-February 2025 (no later than 2/15/25)
Report 4ENH PACE	Monthly	Mid-February 2025 (no later than 2/15/25)
Report 4OTC PACE	Monthly	Mid-February 2025 (no later than 2/15/25)
Report 40COV	Monthly	Mid-February 2025 (no later than 2/15/25)
Report 40ENH	Monthly	Mid-February 2025 (no later than 2/15/25)
Report 40OTC	Monthly	Mid-February 2025 (no later than 2/15/25)
Report 41COV	Monthly	Mid-February 2025 (no later than 2/15/25)
Report 42COV	Monthly	Mid-February 2025 (no later than 2/15/25)
Report 43COV	Monthly	Mid-February 2025 (no later than 2/15/25)
Report 44	Monthly	Mid-February 2025 (no later than 2/15/25)
Contract Data Report	Quarterly	April 2025
Coverage Gap Tracking Report	Quarterly	April 2025
Upheld Dispute CNTRCT Detail	Annually	July 2025
Contract Dispute Disposition File	Quarterly	August 2025
Potential Exclusion Warning Report	Annually	January 2026

Exclusion from Reconciliation Report	Annually	October 2026
PDE Recon Inputs Report to Plans	Annually	November 2026
PDE Recon Results Report to Plans	Annually	November 2026
LINET Recon Inputs Report to Plans	Annually	November 2026
LINET Recon Results Report to Plans	Annually	November 2026

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

Thank you.

2 Attachments