



Submitted December 19, 2022 electronically at: PDE-Operations@cms.hhs.gov

Jennifer Shapiro, Director
Medicare Plan Payment Group
Center for Medicare and Medicaid Services

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

Dear Ms. Shapiro,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

For over 40 years, NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting and other functions in the pharmacy services industry as named in Health Insurance Portability and Accountability Act (HIPAA). The NCPDP SCRIPT Standard and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in Medicare Modernization Act (MMA).

NCPDP submits the following comments in response to *New 2025 Prescription Drug Event (PDE) File Layouts (draft); Seeking Feedback*, released November 1, 2022.

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, which may include additional PDE File Layout updates. 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."

NCPDP Comment: NCPDP has no comments on the updating timing.

New Fields

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.

NCPDP Comment: NCPDP is requesting the field be named Originally Prescribed Quantity to align with the NCPDP field 446-EB in the Data Dictionary.

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) (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."

NCPDP Comment:

- NCPDP requests additional information on the following:
 - How will this field be used?
 - What is the value of having this field on the PDE if the negotiated price already contains this amount?
- NCPDP is also requesting clarification whether CMS will edit on this field, what the edits will entail and if it will be balanced with cost.
- NCPDP requests clarification regarding the term "at POS" in the field name. Guidance is needed for what is expected in this field if changes occur post-POS.

- Without clarification and a better understanding on how this field is intended to work, NCPDP is unable to make a recommendation.

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.”

NCPDP Comment: NCPDP would like to reiterate its prior request, submitted with comments on July 1, 2022, that CMS add the Level of Service (418-DI) to the PDE record layout. It is anticipated this new PDE record layout will be used for multiple years to come. Based on CMS’ December 15, 2021 memo entitled *Part D Dispensing Fees and Enrollees with Institutionalized Level of Care Needs*, patients with an institutionalized level of care at home have the same need as enrollees in a long-term care facility. As such, the Level of Service field would clearly communicate to CMS these patients are receiving long-term care pharmacy services. This data would be necessary for CMS to evaluate the effectiveness of these new services supplied to these institutional level of care patients. The Level of Service (418-DI), which is already available in the current version of the Telecommunication Standard, would fulfill this need and could be sent when present on the claim transaction.

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.”

NCPDP Comment: NCPDP is in support of this change and the alignment with the claim transaction field definitions and usage.

Updates to Existing Fields

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.”

NCPDP Comment: NCPDP is in support of this change and the alignment with the claim transaction field definitions and usage.

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.”

NCPDP Comment: NCPDP is in support of this change and the alignment with the claim transaction field definitions and usage.

7) Estimated Remuneration at POS (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, 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.”

NCPDP Comment: NCPDP has no comments on the Estimated Remuneration at POS (ERPOSA).

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.”

NCPDP Comment: NCPDP has no comments on the updates to the Vaccine Administration Fee or Additional Dispensing Fee field.

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 (TGDC) Accumulator*
- *True Out-Of-Pocket (TrOOP) Accumulator*
- *CMS Calculated Gap Discount*

NCPDP Comment: NCPDP is in support of this change and the alignment with claim transaction field definitions and usage.

Additional Comments

NCPDP Comment: NCPDP would like to provide additional comments on Submission Clarification Code (SCC) field (420-DK). In the Telecommunication Standard Version D.0, the SCC field is used for more than short-cycle claim identification, including values used for LTPAC specific use cases. In previous discussions, it was recommended up to three values be allowed in the SCC field. Telecommunication Versions F6 and above allow the SCC field to repeat five times, so NCPDP now recommends the PDE allow five values in the SCC field. The additional SCC values may help auditors as they look for information. The PDE should accommodate as many SCC values as the claim; if more than one SCC was sent on the claim, more than one SCC should be available to send on the PDE. Additionally, in response to Acumen's flagging of certain types of claims for duplication, plans regularly respond with the information that certain SCC values are used, and they are not duplicates. Allowing all SCC values from the claim to be submitted will allow Acumen to identify the information via the PDE rather than as a separate plan response.

NCPDP proposes CMS create a new field to allow Medicare Part D plan sponsors to submit information on the PDE to indicate the plan sponsor has reviewed and authorized a medically accepted indication for a drug that is normally not covered under Part D. The intent would be to use this new value to bypass a Part D non-coverable drug reject (i.e., PDE Edit 738) as occurs on the PDE today.

NCPDP recommends adding two new fields available in Telecommunication Standard Versions F6 and above to the PDE based on the plan's response pricing: Regulatory Fee Amount Paid (558-AW) and Regulatory Fee Type Code (D61-RL). The NCPDP Data Dictionary defines the Regulatory Fee Amount Paid as a pre-defined fixed value which is included in the Total Amount Paid (509-

F9). The Regulatory Fee Type Code indicates how the reimbursement amount was calculated for Regulatory Fee Amount Paid (558-AW). These values would provide more detailed and transparent pricing information to CMS regarding any regulatory fees that were included in the pricing. For example, the state of Louisiana has a mandatory Provider Fee of \$0.10 per claim that is currently sent in the Sales Tax field on the PDE. Since Louisiana state law specifically exempts Part D claims from sales tax, use of this new field would provide further clarity to CMS around any regulatory fees included in the cost of the drug.

NCPDP requests the addition of a PLRO amount indicator field with values to allow plan sponsors to indicate the following:

- Value to indicate only EGWP as OHI PLRO is applied
- Value to indicate only Non-EGWP as OHI PLRO is applied
- Value to indicate both EGWP as OHI and non-EGWP as OHI PLRO is applied


This indicator would allow CMS to bypass edit 671 when the PLRO amount contains either non-EGWP as OHI PLRO or both EGWP as OHI and non-EGWP as OHI PLRO, such as PLRO associated to another payer.

NCPDP thanks CMS for the opportunity to comment on the *New 2025 Prescription Drug Event (PDE) File Layouts (draft); Seeking Feedback* and for the consideration of our comments. NCPDP looks forward to continuing our work with CMS.

For direct inquiries or questions related to this letter, please contact:

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Respectfully,



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