

Submitted electronically via PDE-Operations@cms.hhs.gov

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Jennifer R. Shapiro
Director, Medicare Plan Payment Group
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

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

Director Shapiro,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide feedback to CMS' New 2025 Prescription Drug Event (PDE) File Layouts (draft). NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a \$78.5 billion healthcare marketplace, employ 240,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

Timing

CMS, as in its original draft, 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. As stated in the previous draft as well, all plans will be required to submit certification (CERT) test files prior to submitting production PDE files on 1/1/2025.

NCPA re-iterates its concerns from its July 1, 2022, comments on CMS' initial draft of the PDE file layouts. We seek clarity on why the implementation date is beyond the January 1, 2024 implementation date of the pharmacy price concessions final rule, and why these updates will be made after January 1, 2024.

NCPA thanks CMS for providing clarification on the lag time in PDE reporting. We originally asked if a prescription filled in calendar year 2024 would be reported in 2025 on the new PDE form. CMS has answered our question with this new draft: "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."

According to CMS, as the chart below indicates,¹ reporting lookback is 6 months, so PDE updates could apply to the second half of the coverage year.

Reporting timeline:

	Period 1	Period 2
Reporting Period	January 1 – June 30	July 1 – December 31
Data due to CMS/HPMS	Last Monday of August	Last Monday of February

Inflation Reduction Act Implementation. Additionally, CMS states that “CMS will issue separate guidance regarding the operational implementation of the Inflation Reduction Act.” NCPA requests clarity on what specific guidance this entails, when stakeholders can expect to see such guidance, and if there will be a notice and comment period associated with this guidance.

Proposed New Field #1: Original Quantity Prescribed (page 2)

In the proposed updates, 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. CMS maintains, as in the previous draft, that editing will be applied to ensure that the “Quantity Dispensed” does not exceed the “Original Quantity Prescribed,” and that this new field will have a format of 9(7)V999. **NCPA supports this update, as currently CMS treats incremental fills as synonymous with refills, which is an issue for pharmacists dispensing incremental fills of controlled substances.**

Proposed New Field # 2: Pharmacy Price Concessions at POS (page 3)

NCPA fully supports CMS adding 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.

However, NCPA does have concerns that there is currently no corresponding NCPDP data field for pharmacy price concessions at POS. CMS’ final rule states that: “We agree with commenters who pointed out that the pharmacy price concessions cannot be conveyed to downstream supplemental payers unless price concession values are conveyed in a dedicated cost field, which is not available under D.O.” **CMS needs to decide how to present this information to downstream payers, or at least to provide guidance to upstream payers as to how to convey this information. NCPA strongly urges CMS to work with NCPDP to ensure a dedicated field exists for pharmacy price concessions by the implementation date, even if it is a temporary workaround using an existing field until a new standard is named.**

NCPA is adamant that pharmacy price concessions at POS need to be transparent to the pharmacy and reflected in a financial field of the pricing formula in the NCPDP claim response, NOT an information field. Combing data from both field types is complicated and makes claims reconciliation more difficult than it should be when one goal of the Medicare Part D and DIR final

¹ See Medicare Part D Reporting Requirements, Effective January 1, 2022. *Centers for Medicare and Medicaid Services.* Available at: Part D Plan Reporting Requirements (cms.gov).

rule is to increase transparency of price concessions. NCPA requests that CMS crosswalk the new PDE file layout field to the NCPDP standard.

Proposed New Field #3: LTPAC Dispense Frequency (page 3)

CMS proposes that “[t]he 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.”

NCPA supports the addition of this new field. We believe that the addition of this new field will come in use for audits, as it will serve as a way to share as much information as possible regarding medication orders and dispensing up front, rather than for asking for Telecom claim submission detail after the fact.

However, NCPA cautions against the discontinuation of the Submission Clarification Code (SCC) field in the PDE file. There are still valid SCC values (i.e., 16, 21 and 36) for short-cycle claims, so the SCC field should not be discontinued. Additionally, the values for LTPAC Dispensing Frequency in Telecom Standard Version F6 do not completely replace all SCC values designated for short-cycle dispensing identification. Currently, the identification of short-cycle claim dispense frequency is used on the PDE to share information about medication orders, to provide transparency on dispensing and to facilitate the audit process. The Short Cycle Final Rule specifies that plans report dispensing methodology for each dispensing event, which is done by using a subset of SCC values in the SCC field.

Proposed Updated Existing Field #7: Estimated Remuneration at POS Amount (ERPOSA) (page 4)

CMS proposes the following: “CMS will change the name of the existing ‘Estimated Rebate at POS’ field to ‘Estimated Remuneration at POS Amount (ERPOSA).’ This 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.”

NCPA supports the separate reporting to CMS of both the pharmacy's lowest possible reimbursement and any pharmacy price concessions at POS. This pair of data points will facilitate transparent per-claim reporting to the pharmacy. NCPA also requests that CMS capture any post-POS price adjustments.

That said, NCPA requests clarification on the following:

- Community pharmacy owners are expecting that the Total Amount Paid in the pricing segment of a paid claim response will be the pharmacy's lowest possible reimbursement. **What is the relationship between the Total Amount Paid in the claim response and the "Estimated Remuneration at POS (ERPOSA)"?** NCPA recommends an alternate name to this PDE field: **"Lowest Possible Payment to Pharmacy."**
- **Is the patient copayment for the drug based off the "Estimated Remuneration at POS (ERPOSA)"? Can CMS confirm that this field can only indicate a positive number?**
- **NCPA requests CMS provide a crosswalk of the proposed field values of the PDE, namely the "Estimated Remuneration at POS (ERPOSA)" and the "Pharmacy Price Concessions at POS" with the values in the claim response and 835 remittance advice.** The data fields and coded values available in the NCPDP Telecommunication billing standard might not currently provide sufficient detail in the pricing formula to the pharmacy. It will be vital for all stakeholders in the Part D program to have transparent knowledge and understanding of these values in order to implement the pharmacy price concessions final rule.

Additional Request for Feedback:

Add Level of Service (418-DI)

NCPA requests that CMS add Level of Service (418-DI) to its list of recommended fields for addition to the PDE file layout. The addition of this field will allow the claim to be conveyed as LTC at Home and will increase identification of the level of service. This field exists in the current Telecommunication Standard. The Level of Service field currently has a value ("7") for LTC at Home (currently described in the ECL as Medical at Home). In the future, there may well be other use cases for which this field may prove useful in the PDE.

In December 2021, CMS issued guidance that clarified that Part D dispensing fees can include additional costs for specialized services typically provided in the institutional care setting, such as delivery and special packaging, for enrollees residing in their homes with institutionalized level of care needs. Adding Level of Service will facilitate uptake of the important practice of LTC pharmacies providing a higher level of pharmacy services to beneficiaries in a home setting who otherwise need institutionalized care. The Level of Service field would clearly communicate to CMS that 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 would fulfill this need and could be sent when present on the claim transaction.

Submission Clarification Code

NCPA would like to provide additional comments on the Submission Clarification Code (SCC) field. The SCC field is used for more than short-cycle claim identification, although there are specific SCC values used for LTPAC use cases. In previous discussions, it was recommended up to three values be allowed in the SCC field, as additional SCC values could 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.

Conclusion

NCPA thanks CMS for the opportunity to provide feedback, and we stand ready to work with CMS to offer possible solutions and ideas.

Should you have any questions or concerns, please feel free to contact me at ronna.hauser@ncpa.org.

Sincerely,

A handwritten signature in black ink that reads "Ronna B. Hauser". The signature is written in a cursive, flowing style.

Ronna B. Hauser, PharmD
Senior Vice President, Policy & Pharmacy Affairs