Submitted July 1, 2022 electronically at: PDE-Operations@cms.hhs.gov

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

RE: FEEDBACK – Proposed Updates to the Prescription Drug Event (PDE) File Layout

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 who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies 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 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 Proposed Updates to the Prescription Drug Event (PDE) File Layout.

CERT Testing and Proposed Timeline

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 time to implement these changes into your systems, please explain how much longer you might need, and why."

NCPDP Comment: NCPDP requests the revised file layout be released by the end of March 2023. Plans will need adequate time to perform coding which cannot begin until the layout is available. NCPDP also requests additional information on other PDE-related reports that may

have layout changes and when those changes would be effective (i.e., P2P Phase 3 Report and Potential Exclusion Warning Report). NCPDP requests CMS indicate how to handle new fields for PDEs for dates of service prior to the implementation date.

"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."

NCPDP Comment: There are concerns about the timeline for CERT testing occurring during the annual open enrollment period and concerns regarding the short window for CERT testing. NCPDP requests six months of CERT testing be allowed (July-December 2024).

New Fields

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."

NCPDP Comment: NCPDP requests edit applicability for standard type PDEs only. NCPDP would like to note that Quantity Prescribed is a required field for electronically submitted claims and manual and/or batch claims will often not have Quantity Prescribed included. NCPDP requests the PDE requirement be limited to Schedule II product(s) only for a non-standard format code of blank, (indicating it was an electronically transmitted claim). NCPDP recommends this field be optional for any date of service prior to the effective date of the new layout.

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."

NCPDP Comment: NCPDP requests clarification on which has more significance in the proposed new PLRE field. Is it the breakdown of the dollars that CMS is interested in obtaining, or the acknowledgment that the claim is not fully payable by EGWP Other Health Insurance (OHI) coverage when a claim is entering catastrophic? If the latter, NCPDP recommends not creating the new PLRE field and alternatively utilizing the existing Catastrophic Coverage Code PDE field including a new value indicating if the PLRO amount includes both EGWP OHI and other Patient Liability Reduced by Other payer (PLRO) dollars. This would allow CMS to update their editing logic for reject edit 671 simplifying the solution for the industry.

If the requirement is to separate the EGWP OHI from other PLRO dollars, additional technical guidance is necessary as determining when and why to recalculate and to report PLRE versus PLRO will be complex.

- PLRO is calculated as an aggregate, and it is challenging to solely break out and report only the EGWP OHI components separately, especially during retroactive reprocessing.
- PLRO is currently used to sum other amounts that are not broken out on the PDE (e.g., Other Payer Amount Recognized amounts, supplemental payer payments due to Information Reporting (Nx) transactions).
- Audit considerations are needed. For example, some PDEs may have PLRE, PLRO or both values depending on CMS guidance on effective dates for resubmitted PDEs.

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."

NCPDP Comment: NCPDP requests additional information on the following: how this field will be used on PDE, the value of having this field on the PDE if the negotiated price already contains this amount and if the field can be left blank if there is no price concession. 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. One concern NCPDP would like addressed is if something that is known at POS changes (if the claim is adjusted and/or the pharmacy price concession changes), will the PDE need to be updated to reflect this change. Without clarification and a better understanding on how this field is intended to work, NCPDP is unable to make a recommendation.

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)."

NCPDP Comment: NCPDP recommends the Submission Clarification Code (420-DK) field not be discontinued. The values for LTPAC Dispensing Frequency in the Telecommunication Standard Version F6 do not completely replace all the Submission Clarification Code (SCC) values designated for short-cycle dispensing identification. There are still valid SCC values (16, 21 and 36) for short-cycle claims.

Updates to Existing Fields

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."

NCPDP Comment: NCPDP has no comments on the update to the Product Service ID field.

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."

NCPDP Comment: NCPDP has no comments on the update to the Prescriber ID field.

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."

NCPDP Comment: Additional clarification and technical guidance are needed on how this field is expected to be used for the claim transaction response and for PDE editing and/or balancing. NCPDP is also seeking more information on the use of the words "estimated" and "POS" in the field title. At any point, does the remuneration transition from "estimated" to "final," and if so, does the PDE need to be updated to reflect this change?

Dependent on the response to the above clarification, NCPDP may recommend a new field be created rather than repurposing an existing field, because the "Estimated Rebate at POS" field is currently in use and indicates an amount that was used to reduce the patient responsibility. It is our understanding that any additional pharmacy remuneration paid by the plan would never affect the patient responsibility.

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."

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

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)*
- *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"*

NCPDP Comment: NCPDP requests all pricing fields be a consistent length, even if the expanded length is not necessary.

10) Additional Request for Feedback

"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."

NCPDP Comment: NCPDP would like to provide additional comments on Submission Clarification Code (SCC) field (420-DK). 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. 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.

NCPDP recommends adding the new field Submission Type Code (D17-K8) to the PDE layout and allow for five (5) instances of the field on the record to align with future versions of the Telecommunication Standard. Some values currently being submitted in the SCC field (e.g., for 340B, split bill and encounters) will be submitted in the Submission Type Code field under the new version of the Telecommunication Standard.

NCPDP requests the addition of Level of Service (418-DI) to recommended fields. 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. Currently, there is no specific guidance from CMS and/or Medicare Part D regarding LTC-at-home. This field exists in the current Telecommunication Standard.

NCPDP proposes CMS create a methodology 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.

NCPDP recommends field number 53 – Gap Discount Plan Override Code – be removed from the PDE layout if CMS does not intend to utilize this field.

NCPDP recommends adding two new fields introduced in the Telecommunication Standard Version F6 to the PDE based on the plan's response pricing: "Regulatory Fee Amount Paid (558-AW)" and "Regulatory Fee Type Code (D61-RL)". The Regulatory Fee Amount Paid is 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 thanks CMS for the opportunity to comment on the Proposed Updates to the Prescription Drug Event (PDE) File Layout 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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President & CEO
National Council for Prescription Drug Programs (NCPDP)