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**July 3, 2023**

Centers for Medicare & Medicaid Services

Attention: OMB Control Number 0938–0982, CMS PRA CMS–10174 Collection of Prescription Drug Data from MA–PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments; RE: New 2025 Prescription Drug Event (PDE) File Layouts (FINAL)

CMS, Office of Strategic Operations and Regulatory Affairs,  
Division of Regulations Development,  
Attention: Document Identifier/OMB Control Number 0938–0982: Room C4–26–05,  
7500 Security Boulevard, Baltimore,  
Maryland 21244–1850

**Re: Feedback on the Prescription Drug Event (PDE) File Layout**


Dear Mr. William N. Parham, III,

CVS Health appreciates the opportunity to comment on the HPMS memo New 2025 Prescription Drug Event (PDE) File Layouts (FINAL) published on April 18, 2023, and the accompanying file layouts, as per the notice in the Federal Register on May 3, 2023. The changes detailed in these documents accommodate future business needs, including but not limited to, the anticipated updates to the National Council for Prescription Drug Programs (NCPDP) Telecommunications standard, recommendations from various NCPDP task groups, and changes related to the implementation of the Inflation Reduction Act (IRA) of 2022.

CVS Health serves millions of people through our local presence, digital channels, and our nearly 300,000 dedicated colleagues – including more than 40,000 physicians, pharmacists, nurses, and nurse practitioners. Our unique health care model gives us an unparalleled perspective on how systems can be better designed to help consumers navigate the health care system – and their personal health care – by improving access, lowering costs, and being a trusted partner for every meaningful moment of health. And we do it all with heart, each and every day.

A detailed discussion of our feedback is provided in the attached appendix. Thank you for considering our recommendations and comments. We welcome the opportunity to further engage with CMS on the updates to the PDE file layout to help accommodate the business needs of the future.

Sincerely,



Elizabeth Ross  
Lead Director, Regulatory Affairs, Medicare  
CVS Health

**Appendix:**  
**FEEDBACK – 2025 Prescription Drug Event (PDE) File Layout**

The feedback that CVS Health submitted in June of 2022 for in response to the CMS memo “Proposed Updates to the Prescription Drug Event (PDE) File Layout; Seeking Feedback” as published in an HPMS memo on May 31, 2022, was predicated on:

- The assumption that the changes to the HIPAA regulation requirements to upgrade from National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Version D.0 to Version F6 would be effective, at the earliest, in January 2025
- That most of the changes were related to converting to Version F6, and many of the other proposed fields were related to recommendations from several of NCPDP’s task groups.

Additionally, our prior recommendations predated Congress passing the Inflation Reduction Act (IRA) into law, which has initiated massive changes to the Medicare programs.

Much has changed since our initial recommendations. We now know that the move from NCPDP Telecommunication Standard Version D.0 to Version F6 will not likely happen until 2026, or later, as the rule has not yet been finalized, and is not anticipated to be finalized until near year end. Additionally, there are significant changes being made to the Medicare Part D program related to the passing of the IRA, the majority of which are effectuating between now and 2025, which did not enter into the formulation of our prior feedback.

Considering the enormity of the work ahead for every entity that provides, receives, or uses the Medicare Part D Prescription Drug Event (PDE) data, as well as those working on the implementation of the IRA changes, often using the same limited resources, we would like to propose a modification to the PDE file layout changes deliverable by January 1, 2025.

We ask that CMS consider altering their approach to this work and to the timeline for implementation. In short, we propose that CMS implement the PDE file layout changes in two stages. The first stage would be to keep the existing file layout format adding the minimal number of fields needed, using existing filler fields, or to repurpose existing fields that become obsolete due to the changes related to implementation of the IRA. The second stage would be to add the remaining new fields and the field size expansions which are largely related to the implementation of NCPDP Telecommunication Standard Version F6.

What follows is a detailed explanation on how this could be accomplished for each field that is changing or being added for the end result.

**Recommendations for new PDE fields that CMS requires for the administration of the IRA:**

Field Name	Requirement Change for IRA	Recommendation
Government Pay Subsidy (Inbound/Outbound)	New Field	<ul style="list-style-type: none"> <li>In support of the IRA, locate in existing Filler field, (inbound file field 60 positions 398-408/outbound file field 80 positions 501-511, using 11-byte, format S9(9)V99), for plan year 2025.</li> <li>Relocate field after implementation of the IRA.</li> </ul>
Reported Manufacturer Discount (Inbound/Outbound)	New Field	<p>Repurpose the <u>existing</u> field Reported Gap Discount (inbound file field 50, positions 367-374/Outbound file field 50, positions 367-374, using 8 bytes, format S9(6)V99), with the following rules, for plan year 2025:</p> <ul style="list-style-type: none"> <li>Dates of service &lt;=12/31/2024 submit reported gap discount</li> <li>Dates of service &gt;=1/1/2025 submit reported manufacturer discount</li> <li>Implement new/separate field, expand field to 11 bytes, &amp; relocate fields after implementation of the IRA.</li> </ul>

Field Name	Requirement Change for IRA	Recommendation
CMS Calculated Manufacturer Discount (outbound only)	New Field For PDEs with a DOS >= 01/01/2011 and a DOS <= 12/31/2024, the Gap Discount Amount calculated by CMS during on-line PDE editing based on data reported in the PDE.	Repurpose the <u>existing</u> field CMS Calculated Gap Discount (outbound file field positions 408-415, using 8 bytes. format S9(6)V99) with the following rules, for plan year 2025: <ul style="list-style-type: none"> <li>Dates of service &lt;=12/31/2024 submit reported gap discount</li> <li>Dates of service &gt;=1/1/2025 submit reported manufacturer discount</li> <li>Implement new/separate field, and field expansion to 11 bytes after implementation of the IRA.</li> </ul>
Deductible Accumulator (Inbound/Outbound)	New field Sum of the beneficiary's deductible amount for the benefit year known immediately prior to adjudicating the claim. Required for PDEs with a DOS >= 01/01/2025. On PDEs with a DOS < 01/01/2025, must be zero.	<ul style="list-style-type: none"> <li>If not required for successful implementation of the IRA, hold until after the implementation of the IRA.</li> <li>If needed for successful implementation of the IRA, locate in existing Filler field, format to 8 bytes S9(6)V99 (inbound file field 60, positions 409-416/outbound file field 60, positions 398-405 – or alternatively, add additional length to the outbound file and for inbound, use additional spaces to accommodate the full 11 bytes), for plan year 2025.</li> <li>Relocate and expand field after implementation of the IRA.</li> </ul>

Field Name	Requirement Change for IRA	Recommendation
Applicable Discount Percentage for Specified Small Manufacturer Drugs (outbound only)	New field For PDEs with a DOS >= 01/01/2025, 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.	<ul style="list-style-type: none"> <li>• Locate in existing Filler field, (field 11, outbound positions 128-129), for plan year 2025.</li> <li>• Relocate field after implementation of the IRA.</li> </ul>
Applicable Discount Percentage for Specified Manufacturer Drugs Dispensed to LIS Beneficiaries (outbound only)	New field For PDEs with a DOS >= 01/01/2025, 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.	<ul style="list-style-type: none"> <li>• Locate in existing Filler field, (field 15, outbound positions 166-167), for plan year 2025.</li> <li>• Relocate field after implementation of the IRA.</li> </ul>

### Recommendations for existing PDE fields that CMS requires changes related to the administration of the IRA:

Field Name	Requirement Change for IRA	Recommendation
Other TrOOP Amount (Inbound/Outbound)	This field records all third-party payments that contribute to a beneficiary's TrOOP except LICs, Patient Pay Amount, and the Reported Gap Discount (for PDEs with a DOS < 01/01/2025) or Manufacturer Discount (for PDEs with a DOS >= 01/01/2025)	<ul style="list-style-type: none"> <li>Change the rule as described in the memo and file layout, for plan year 2025 in support of the implementation of the IRA.</li> <li>Hold on the field size expansion until after implementation of the IRA.</li> </ul>
Reported Gap Discount (Inbound/Outbound)	Required on PDEs with a DOS >= 01/01/2011 and a DOS <= 12/31/2024. On PDEs with a DOS < 01/01/2011 or PDEs with a DOS >= 01/01/2025, must be zero.	<p>Repurpose existing field Reported Gap Discount – field 50 - (also see recommendation for field Reported Manufacturer Discount above) with the following rules, in support of the implementation of the IRA, for plan year 2025:</p> <ul style="list-style-type: none"> <li>Dates of service &lt;=12/31/2024 submit reported gap discount</li> <li>Dates of service &gt;=1/1/2025 submit reported manufacturer discount</li> </ul>
Beginning Benefit Phase (Inbound/Outbound)	For PDEs with a DOS >= 01/01/2025, the value of G no longer applies, and will not be accepted.	<ul style="list-style-type: none"> <li>Proceed with the rule change for plan year 2025.</li> <li>Hold on the field size expansion until after implementation of the IRA.</li> </ul>
Ending Benefit Phase (Inbound/Outbound)	or PDEs with a DOS >= 01/01/2025, the value of G no longer applies, and will not be accepted.	<ul style="list-style-type: none"> <li>Proceed with the rule change for plan year 2025.</li> <li>Hold on the field size expansion until after implementation of the IRA.</li> </ul>

### Recommendations for other changes that are not related to the implementation of the IRA regulation.

Field Name	Reason for change	Recommendation
All dollar fields expansions (Inbound/Outbound)	Related to implementation of NCPDP Telecommunication Standard Version F6	<ul style="list-style-type: none"> <li>Hold on the field size expansion until after implementation of the IRA.</li> </ul>
Product Service ID (Inbound/Outbound)	Expansion from 19 to 40 bytes	<ul style="list-style-type: none"> <li>Hold for implementation until after implementation of the IRA.</li> </ul>
All new filler fields (Inbound/Outbound)	For future use	<ul style="list-style-type: none"> <li>Hold these for implementation until after implementation of the IRA.</li> </ul>
Relocation of existing fields (Inbound/Outbound)	Rearrangement of fields and field size expansions	<ul style="list-style-type: none"> <li>Hold these for implementation until after implementation of the IRA.</li> </ul>
LTPAC Dispensing Frequency (Inbound/Outbound)	Related to implementation of NCPDP Telecommunication Standard Version F6	<ul style="list-style-type: none"> <li>Hold for implementation until after implementation of the IRA.</li> </ul>
Submission Type Code fields (1-5) (Inbound/Outbound)	Related to implementation of NCPDP Telecommunication Standard Version F6	<ul style="list-style-type: none"> <li>Hold these for implementation until after implementation of the IRA.</li> </ul>
Submission Clarification Code field 1 (Allowing any valid NCPDP value for Dates of Service >= 1/1/2025) (Inbound/Outbound)	Recommended by NCPDP Expansion from 2 to 3 bytes	<ul style="list-style-type: none"> <li>Proceed with the rule change for plan year 2025 using the existing field location.</li> <li>Implement the new field location and field size expansion after implementation of the IRA.</li> </ul>
Submission Clarification Code fields 2 & 3 (Inbound/Outbound)	Recommended by NCPDP	<ul style="list-style-type: none"> <li>Hold for implementation until after implementation of the IRA.</li> </ul>
Adjustment Reason Code Qualifier (change of valid values for before & after 1/1/2025) (Inbound/Outbound)	Administrative change	<ul style="list-style-type: none"> <li>Hold for implementation until after implementation of the IRA.</li> </ul>
Adjustment Reason Code (change of valid values for before & after 1/1/2025) (Inbound/Outbound)	Administrative change	<ul style="list-style-type: none"> <li>Hold for implementation until after implementation of the IRA.</li> </ul>
Pharmacy Price Concession (Inbound/Outbound)	Align with NCPDP guidance for reporting at POS	<ul style="list-style-type: none"> <li>Hold for implementation until after implementation of the IRA.</li> </ul>
Estimated Remuneration at POS Amount (ERPOSA) (Inbound/Outbound)	Clarification of use for DOS >=1/1/2025 vs. <=1/1/2024	<ul style="list-style-type: none"> <li>Continue to use existing ERPOSA field and location for plan year 2025.</li> <li>Hold the field relocation for implementation after implementation of the IRA.</li> </ul>

Field Name	Reason for change	Recommendation
Originally Prescribed Quantity (Inbound/Outbound)	Compliance monitoring	<ul style="list-style-type: none"><li>• Hold for implementation after implementation of the IRA.</li></ul>
Prescriber ID (Inbound/Outbound)	Expansion from 15 to 35 bytes	<ul style="list-style-type: none"><li>• Hold for implementation after implementation of the IRA.</li></ul>
OAP Indicator (Inbound/Outbound)	Removed from layout, not used	<ul style="list-style-type: none"><li>• Hold for implementation after implementation of the IRA.</li></ul>

Additionally, although this has not been done in the past, we would like to recommend that CMS add an additional column to the Outbound file layout, to designate whether the field is NCPDP, CMS, or PDFS Defined field, as is done with the Inbound file layout. This will make it easier for development staff to understand the sourcing of each field and aligns better with the Inbound file layout.

Lastly, we request the CMS provide plans with the details of any DDPS editing that CMS is planning to put into place for the IRA related fields. This will assist all plans to be better able to ensure our systems are in alignment with CMS' expectations.