

We received comments from one entity in response to our collection of information, Collection of Prescription Drug Event Data From Contracted Part D Providers for Payment, CMS-10174, OMB 0938-0982.

COMMENT: The commenter stated that the comments it submitted in June 2022, in response to the CMS HPMS memorandum “Proposed Updates to the Prescription Drug Event (PDE) File Layout; Seeking Feedback,” May 31, 2022, were predicated on the commenter’s 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 in 2025, which the commenter believes is no longer the timeline for the effective date.

The commenter also stated that its comments to the CMS memorandum predated the passage of the Inflation Reduction Act (IRA),<sup>1</sup> which created significant changes to the Medicare Part D program. The IRA did not enter into the formulation of the commenter’s feedback on the CMS memorandum.

For those reasons, the commenter recommends that CMS alter the approach to this work and to the timeline for implementation. Specifically, the commenter recommends that CMS implement the PDE file layout changes in two stages. The first stage would be to keep the existing 512-byte file layout format adding the minimal number of fields needed, and the second stage would be to add the remaining new fields and expand the layout to the 1000-byte format.

RESPONSE: CMS is not commenting on the effective date of the implementation of the NCPDP Telecommunication Standard Version F6 (hereinafter referred to NCPDP F6) in this collection of information. However, in our April 18, 2023 HPMS memorandum finalizing the expansion of the PDE file layout changes for 2025, we acknowledge that certain PDE record layout fields may be optional and/or may be spaces until the effective date of NCPDP F6. See HPMS memorandum, “New 2025 Prescription Drug Event (PDE) File Layouts (FINAL),” April 18, 2023. In addition, we also stated that the expansion was being implemented not only to accommodate the anticipated updates to NCPDP F6 but also for other operational reasons. These reasons include implementation of the pharmacy price concession rule (effective in 2024),<sup>2</sup> with the addition of Pharmacy Price Concessions at POS field in the 2025 PDE file layout; expansion of all of the dollar fields' lengths by 3 characters each, which was not only done to align with NCPDP F6 but also necessary for high-cost drugs; future planned FDA expansion of the Product Service ID field length to accommodate a future 14-digit UPI (in place of NDC); and addition of the new Originally Prescribed Quantity field to support CMS' oversight of plan compliance for Schedule II drugs. In addition, the changes to the PDE file layout are necessary to operationalize the implementation of the IRA, which requires new IRA-related fields to support the implementation of the IRA Part D redesign.

Although, as the commenter states, the initial May 2022 memorandum (referenced in the comment above) was released prior to the passage of the IRA, CMS published a second memorandum requesting additional feedback, after the IRA was passed into law in August 2022. See HPMS memorandum, “New 2025 Prescription Drug Event (PDE) File Layouts (draft); Seeking Feedback,” Nov. 1, 2022. In that November 2022 memorandum, we indicated that implementation of the IRA may include additional PDE file layout updates. After thoughtful review of the comments received on the November 2022

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<sup>1</sup> INFLATION REDUCTION ACT OF 2022, PL 117-169, August 16, 2022.

<sup>2</sup> 87 FR 27704 (May 9, 2022)

memorandum, CMS published our memorandum finalizing the PDE file layout changes for 2025 on April 18, 2023. In the April 2023 memorandum, we announced IRA-related fields and stated that CMS would publish specific operational PDE reporting guidance regarding the new PDE fields at a later date. These new IRA-related fields are necessary to implement statutorily mandated changes to the Part D program that take effect January 1, 2025. As described in the memorandum, submission of test files from the Part D sponsors will begin July 1, 2024. Our timeline gives sponsors about 15 months from the date of the April 2023 memorandum to modify their systems to accommodate IRA-related changes that must take effect January 1, 2025. This timeline is responsive to feedback Part D plan sponsors have previously provided on the lead time needed to implement such changes.

For these reasons, we decline to accept the commenter's recommendations. No requirements or documents will be revised nor will any burden estimates be revised as a result of the comment.

COMMENT: The commenter requested that CMS add an additional column to the outbound file layout, to designate whether the field is a NCPDP, CMS, or PDFS defined field, as is done with the inbound file layout because it will make it easier for development staff to understand the sourcing of each field and aligns better with the inbound file layout.

RESPONSE: To clarify, the Part D sponsor only sends the inbound file to CMS. The outbound file is the response file that CMS sends back to the sponsor. As the outbound file is populated by CMS, the field designation is not relevant on that file, and all of the inbound fields are also included on the outbound PDE file layout, along with the addition of several CMS-populated fields (ex: Error/Edit Codes, CMS-calculated fields). Given that the outbound file layout changes that the commenter requested would not produce actual value, especially with respect to stakeholder burden, we decline to accept the commenter's recommendation. No requirements or documents will be revised nor will any burden estimates be revised as a result of the comment.

COMMENT: The commenter requested that CMS provide plans with the details of any PDE editing that CMS is planning to put into place for the IRA-related fields because it will assist all plans in ensuring that systems in alignment with CMS' expectations.

RESPONSE: The comment regarding PDE editing is out of scope of this information collection request related to the expansion of the PDE file layout for 2025. Therefore, no requirements or documents will be revised nor will any burden estimates be revised as a result of the comment. However, as with all PDE editing, and as stated in the April 2023 memorandum referenced above, CMS will publish specific operational PDE reporting guidance and information on related edits regarding the new PDE fields at a later date. Consistent with longstanding practice, we will provide such guidance through HPMS memoranda consistent with the current timeline for publishing upcoming plan year PDE reporting guidance.