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CENTER FOR MEDICARE

DATE: March 8, 2024

TO: All Part D Plan Sponsors, including Programs of All-inclusive Care for the Elderly (PACE) Organizations

FROM: Jennifer R. Shapiro, Director, Medicare Plan Payment Group

SUBJECT: 2025 Prescription Drug Event (PDE) File Layout Updates for all Part D Plan Sponsors, and Additional 2025 Changes to PDE Reporting for PACE Organizations

The purpose of this memo is to share three updates to the 2025 Prescription Drug Event (PDE) Final File Layouts that will be effective on January 1, 2025. The first two updates are applicable to all Part D sponsors, while the last update is applicable only to PACE organizations.

The first update, applicable to all Part D sponsors, modifies the description of the “Vaccine Administration Fee or Additional Dispensing Fee” field on both the 2025 PDE Inbound and Outbound File Layouts to conform to recently announced changes applied to the 2024 PDE File Layouts.¹ As a reminder, this update removed reference to Emergency Use Authorization (EUA) status of oral antiviral drugs to reflect the distribution of government-procured antivirals that can now include antivirals approved by the Food and Drug Administration under a New Drug Application (NDA).²

The second update, also applicable to all Part D sponsors, defines an additional field, titled “Drug Status Indicator,” on the 2025 PDE Outbound File Layout only. For PDE records with a DOS \geq 01/01/2025, this field will be populated by CMS with the corresponding value identifying whether CMS’ Drug Data Processing System (DDPS) determines that the National Drug Code (NDC) submitted on the PDE was an applicable drug or non-applicable drug at the time of PDE processing. Additionally, the ability to designate an NDC as “selected” in this field will become effective for DOS \geq 01/01/2026. The determination returned in the “Drug Status Indicator” field will be used to establish the Manufacturer Discount or Selected Drug Subsidy applicability, and the differential reinsurance calculations based on drug status. This field will be returned on covered Part D drugs only.

Lastly, this memo serves as notice to PACE organizations of the additional PDE fields that they must populate beginning with PDEs for Dates of Service (DOS) on or after January 1, 2025, as indicated in

¹ See CSSC Operations listserv, January 31, 2024, available at [https://www.csscoperations.com/internet/csscw3.nsf/DIDC/5STYLICW8P~ListServs~Prescription%20Drug%20Program%20\(Part%20D\)](https://www.csscoperations.com/internet/csscw3.nsf/DIDC/5STYLICW8P~ListServs~Prescription%20Drug%20Program%20(Part%20D))

² Additional information regarding government-procured, NDA-labeled antivirals can be found in the January 4, 2024, HPMS memorandum, “Introduction of Prescription Oral Antivirals for COVID-19 to the Commercial Market,”

the additional column added to the 2025 PDE Inbound Final File Layout. PACE organizations must submit this information in order to participate in the Manufacturer Discount Program (Discount Program) created by section 11201(c) of the Inflation Reduction Act of 2022 (IRA), and to conform with regulatory provisions and oversight activities, including the regulatory requirement to account for the maximum pharmacy price concession in the negotiated price.^{3,4} All other Part D sponsors, besides PACE organizations, already submit all of the information described in this section on PDE records. Only PACE organizations have been exempt from this reporting to date. The Appendix to this memo provides additional information on certain fields required for PACE organizations; however, PACE organizations should refer to the 2025 PDE Inbound File Layout for the complete list of required fields.

Concurrent with the release of this memo, the Centers for Medicare and Medicaid Services (CMS) is posting updated 2025 PDE Final File Layouts to the Customer Service and Support Center (CSSC) Operations website (www.csscoperations.com) → Prescription Drug Program → File and Report Layouts. CMS has also provided these layouts as attachments to this memo.

As a reminder, until January 1, 2025, Part D sponsors should continue to use the current PDE Inbound File Layout, published on the [CSSC Operations website](http://www.csscoperations.com), to submit PDE records. Beginning January 1, 2025, all Part D sponsors and PACE organizations must use the new 2025 PDE Inbound File Layout to submit PDE records for *all* Benefit Years and *all* DOS, including Benefit Years prior to 2025 and DOS prior to January 1, 2025. 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 Prescription Drug Front-end System (PDFS) will reject PDE submission files, regardless of the PDE's Benefit Year, submitted in the existing ("old") format.

CMS will require all Part D sponsors, including PACE organizations, to submit certification (CERT) test files prior to submitting production PDE files in the new layout on January 1, 2025. CERT Testing for 2025 is planned to begin on July 1, 2024 for non-PACE Part D sponsors. CERT Testing for 2025 for PACE organizations is planned to begin on September 1, 2024. CMS will provide CERT Testing requirements in advance.

CMS will publish specific operational 2025 PDE reporting guidance for Part D sponsors and separately for PACE organizations. CMS will also publish information on related edit updates that will be effective beginning January 1, 2025, at a later date.

Questions from non-PACE Part D sponsors regarding updates to the 2025 PDE Final File Layouts can be directed to PDE-Operations@cms.hhs.gov.

PACE organizations may submit questions regarding the 2025 PDE Final File Layouts and fields applicable to PACE to PACEDPartDPayment@cms.hhs.gov.

CMS strongly recommends that Part D sponsors, including PACE organizations, share this memo and the updated 2025 PDE Final File Layouts with their information technology staff for reference in

³ See final rule "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" (CMS-4192-F) (87 FR 27704), available at <https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf>, and the HPMS memorandum, "Application of Pharmacy Price Concessions to the Negotiated Price at the Point of Sale Beginning January 1, 2024," November 6, 2023, available at <https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-2-november-6-10>.

⁴ See HPMS memorandum, "PACE Participation in the Manufacturer Discount Program beginning January 1, 2025," January 26, 2024.

the implementation of these changes.

Thank you.

Appendix

Information for PACE Organizations on PDE Reporting Changes beginning January 1, 2025

As described above, the updated 2025 PDE Inbound File Layout includes a column indicating whether each field on the layout must be reported by PACE organizations. CMS is providing additional information on certain fields required for PACE organizations below; however, PACE organizations should refer to the 2025 PDE Inbound File Layout for the complete list of required fields.

Estimated Remuneration at POS Amount (ERPOSA): The value entered in the field for DOS on and after January 1, 2025, will contain the estimated remuneration amount (excluding pharmacy price concessions) the PACE organization is required to or elected to apply to the negotiated price as a reduction of the drug price made available at the point of sale (POS). (Note that previous PDE file layout versions used the different field name of *Estimated Rebate at POS Amount*.) The estimated remuneration amount includes the rebate or other price concession amount the PACE organization expects to receive from a pharmaceutical manufacturer or other non-pharmacy entity and elects to apply to the negotiated price. The estimated remuneration amount does not include pharmacy price concessions applied at POS, which is reported in the Pharmacy Price Concessions at POS field. PACE organizations must populate the ERPOSA field to ensure any applicable remuneration reduces the negotiated price. This field must contain a positive dollar amount or zero, but never a negative value. The field should report zero when no ERPOSA is applied at POS.

Pharmacy Price Concessions at POS: The value entered in the field for DOS on and after January 1, 2025, must report the maximum amount of any contingent payments or adjustments the PACE organization could receive from a network pharmacy that would decrease the total amount the PACE organization pays for the drug. PACE organizations must populate the Pharmacy Price Concessions at POS field to ensure any applicable pharmacy price concession reduces the negotiated drug price. This field must contain a positive dollar amount or zero, but never a negative value. The field should report zero when no pharmacy price concession is applied at POS or when the DOS is before January 1, 2025.

Patient Pay Amount: This field is used to report the amount paid at the POS by the PACE participant or by their family or friends. Because PACE participants have \$0 cost sharing, PACE organizations must populate the Patient Pay Amount field starting with DOS on and after January 1, 2025, and the field must contain zero.

Patient Liability Reduction Due to Other Payer Amount (PLRO): This field reports the amount by which patient liability is reduced due to payment by other payers that are not TrOOP-eligible and do not participate in Part D. Because the Low Income Cost Sharing Subsidy Amount (LICS), Enhanced Alternative (EA) plan supplemental benefits, and the PACE cost sharing add-on reduce patient liability so that PACE participants have \$0 cost sharing, there is no remaining patient liability to be further reduced. Therefore, PACE organizations must populate the PLRO field starting with DOS on and after January 1, 2025, and the field must contain zero.

Other TrOOP Amount: This field is used to report all third-party payments contributing to a participant's TrOOP, except for LICS and Patient Pay Amount. Payments reported in the Other TrOOP Amount field include other health insurance payments made by TrOOP-eligible payers, such as State Pharmaceutical Assistance Programs. Because LICS, EA plan supplemental benefits, and the PACE cost sharing add-on reduce patient liability so that PACE participants have \$0 cost sharing,

there is no remaining patient liability to be further reduced. Therefore, PACE organizations must populate the Other TrOOP Amount field starting with DOS on and after January 1, 2025, and the field must contain zero.

Other TrOOP Amount Indicator: PACE organizations must populate the Other TrOOP Amount Indicator field starting with DOS on and after January 1, 2025, and the field must contain spaces.

Selected Drug Subsidy: This field may contain a positive dollar amount or zero, but never a negative value. The field should report zero when there is no selected drug subsidy for the dispensed drug or when the DOS is before January 1, 2026. The reported subsidy amount will not increment the TrOOP Accumulator amount and the Selected Drug Subsidy field will report the amount the PACE organization advanced at POS for a selected drug in the Initial Coverage Phase.

Reported Manufacturer Discount: This field may contain a positive dollar amount or zero, but never a negative value. The field should report zero when there is no manufacturer discount for the dispensed drug or when the DOS is before January 1, 2025. The reported manufacturer discount will not increment the TrOOP Accumulator amount and the Reported Manufacturer Discount field will report the amount the PACE organization advanced at POS for the manufacturer discount for applicable drugs. PACE organizations must populate the Reported Manufacturer Discount field for appropriate implementation of the Discount Program.

Gross Drug Cost Below Out-of-pocket Threshold (GDCB): This field must contain a positive dollar amount or zero, but never a negative value. The value entered in the field reports the covered drug cost below the annual out-of-pocket threshold. Covered drug cost is the sum of the ingredient cost paid, dispensing fee paid, total amount attributed to sales tax, and vaccine administration fee or additional dispensing fee. Any amount of covered drug cost exceeding the annual out-of-pocket threshold is reported in the Gross Drug Cost Above Out-of-pocket Threshold (GDCA) field. PACE organizations must populate the GDCB field because the values provided in this field, in combination with other fields, indicate the necessity of an applicable manufacturer discount (if any).

Gross Drug Cost Above Out-of-pocket Threshold (GDCA): This field must contain a positive dollar amount or zero, but never a negative value. The value entered in the field reports the covered drug cost above the annual out-of-pocket threshold. Covered drug cost is the sum of the ingredient cost paid, dispensing fee paid, total amount attributed to sales tax, and vaccine administration fee or additional dispensing fee. PACE organizations must populate the GDCA field because the values provided in this field, in combination with other fields, indicate the necessity of an applicable manufacturer discount (if any).

Low Income Cost Sharing Subsidy Amount (LICS): This field must contain a positive dollar amount or zero, but never a negative value. The value entered in the field reports the amount the PACE organization advanced at POS due to the participant's low income status. PACE organizations must populate the LICS field for low income participants because this field increments the TrOOP Accumulator amount, which indicates the necessity of an applicable manufacturer discount (if any). This field should be zero for all Medicare-only participants of the PACE organization.

Non-covered Plan Paid Amount (NPP): Dual-eligible PACE plans must populate the NPP field starting with DOS on and after January 1, 2025, and the field must contain a zero. Medicare-only PACE plans must populate the NPP field starting with DOS on and after January 1, 2025, and the field must contain a numeric value. The NPP field reports the difference between the enrollee's cost sharing under the PACE organization's Enhanced Alternative (EA) benefit design (\$0 for PACE

enrollees) and what the enrollee would have paid under the Defined Standard benefit. Risk corridor calculations do not include amounts reported as NPP. PACE organizations must populate the NPP field because this field increments the TrOOP Accumulator amount, which indicates the necessity of an applicable manufacturer discount (if any).

The following non-financial fields are also a new requirement for PACE organizations beginning with DOS January 1, 2025:

Originally Prescribed Quantity: PACE organizations must populate the Originally Prescribed Quantity field on all standard, electronically submitted PDE records for Schedule II drugs starting with DOS on and after January 1, 2025, and the field must contain a numeric value greater than zero. This field must contain zero for PDE records for non-Schedule II drugs or for PDE records with DOS before January 1, 2025. PACE organizations must populate the Originally Prescribed Quantity field to comply with requirements for monitoring Schedule II drugs.

Part D Model Indicator: While this is a required field for PACE organizations, CMS expects this field to be populated with spaces because PACE organizations cannot offer any Part D Model plans.

Medicare Prescription Payment Plan Indicator: While this is a required field for PACE organizations, CMS expects this field to be populated with a space because PACE participants do not have cost sharing.