

DEPARTMENT OF HEALTH & HUMAN
SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: November 15, 2023
TO: All Part D Plan Sponsors
FROM: Jennifer R. Shapiro, Director, Medicare Plan Payment Group
SUBJECT: Updates to the Drug Data Processing System (DDPS) for Benefit Year 2024

The Centers for Medicare & Medicaid Services (CMS) is announcing upcoming changes to Prescription Drug Event (PDE) data validation edits in the Drug Data Processing System (DDPS) effective January 1, 2024. Data validation edits are applied against PDE data submitted to DDPS by Part D sponsors to ensure the information accepted by the system is in accordance with published statute, regulation, program instruction, and program guidance. Changes being announced include modifications to data edits, the addition of new reject edits and other new edits, and inclusion of end dates to certain existing edits. These changes reflect the 2024 Part D benefit design mandated by the Inflation Reduction Act of 2022 (IRA), and additional changes to the Part D program effective in 2024, which require DDPS system modifications and conforming updates to field descriptions on the inbound and outbound 2024 PDE file layouts. These include:

- The elimination of beneficiary cost-sharing in the Catastrophic Phase of the Part D benefit.
- The expansion of the full Low-Income Subsidy (LIS) benefit to low-income beneficiaries that previously qualified for the partial LIS benefit. The IRA changes the eligibility requirements for the full LIS benefit, resulting in the beneficiaries who would have been eligible for the partial LIS benefit absent the enactment of the IRA to be eligible for the full LIS benefit.
- The temporary retrospective subsidy paid to Part D sponsors for the reduction in cost-sharing and elimination of the deductible for Advisory Committee on Immunization Practices (ACIP) recommended vaccines and covered insulin products was limited to the 2023 plan year. Therefore, covered insulin products and ACIP-recommended vaccines are no longer eligible for the Inflation Reduction Act Subsidy Amount (IRASA). Part D sponsors must account for these costs as part of the Part D Defined Standard benefit.

- The Part D Senior Savings (PDSS) Model, which provided beneficiaries with Part D sponsors that offer a one-month supply insulin at no more than \$35, ends on December 31, 2023.¹

The reporting of all pharmacy price concessions that were incorporated into the negotiated price of the drug at the point of sale as required by regulation.² The Prescription Drug Event (PDE) Edit Code Listing spreadsheet and the inbound and outbound 2024 PDE file layouts reflecting these updates is posted on the CSSC Operations [website](#).

Please submit questions regarding these updates to PDE-Operations@cms.hhs.gov.

¹ February 10, 2023 HPMS memorandum, Part D Senior Savings (PDSS) Model Status Update, available [here](#).

² See CMS-4192-F (Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency).

Catastrophic Cost-Sharing

Modification to DDPS Edit 671

DDPS Edit 671 is a reject edit that occurs when the True Out-of-Pocket (TrOOP) Accumulator + Delta TrOOP \leq the Out-of-Pocket (OOP) Threshold, and Gross Drug Cost Above Out-of-Pocket Threshold (GDCA) $>$ zero. This edit ensures that the beneficiary has accumulated enough TrOOP for a PDE to be reported with gross drug costs in the Catastrophic Phase. Beginning in 2024, beneficiary cost-sharing in the Catastrophic Phase is eliminated and Delta TrOOP should no longer be reported in the Catastrophic Phase. Therefore, effective January 1, 2024, for PDE records with a Date of Service (DOS) on or after 1/1/2024, Edit 671 will be modified to no longer occur when the TrOOP Accumulator + Delta TrOOP = the OOP Threshold, and GDCA $>$ zero.

New Reject DDPS Edit 903

Beginning in 2024, beneficiary cost-sharing in the Catastrophic Phase is eliminated. Therefore, effective January 1, 2024, for PDE records with a DOS on or after 1/1/2024, DDPS will issue new reject Edit 903 if a PDE is fully in the Catastrophic Phase and reports payment fields, other than Covered D Plan Paid Amount (CPP), greater than zero. Reject Edit 903 will be bypassed for Medicare as Secondary Payer (MSP) PDE records when Patient Liability Reduction due to Other Payer Amount (PLRO) $>$ zero.

Low Income Cost-Sharing

Modification to DDPS Edit 675

DDPS Edit 675 is a reject edit that occurs when a PDE with Low Income Cost-Sharing Subsidy Amount (LICS) $>$ zero straddles from the Coverage Gap Phase to the Catastrophic Phase, and CPP $<$ 95% of GDCA. Beginning in 2024, beneficiary cost-sharing in the Catastrophic Phase is eliminated and the entire amount falling in the Catastrophic Phase is covered by CPP. Therefore, effective January 1, 2024, for PDE records with a DOS in 2024, Edit 675 will be modified to occur when CPP $<$ 100% of GDCA.

End Date DDPS Edit 719

DDPS Edit 719 is an informational edit that occurs when beneficiary liability for a Low Income Category 4 beneficiary exceeds the statutorily defined cost-sharing maximum between the Deductible and Catastrophic Phases. Beginning in 2024, eligibility is expanded for the full benefit to include beneficiaries who would have been eligible for the partial LIS benefit absent the enactment of the IRA. As a result, beginning in 2024, Low Income Category 4 will no longer apply. In accordance with this, effective January 1, 2024, for PDE records with a DOS on or after 1/1/2024, Edit 719 will no longer occur.

End Date DDPS Edit 720

DDPS Edit 720 is a reject edit that occurs when beneficiary liability exceeds the statutorily defined cost-sharing maximum in the Catastrophic Phase for a Low Income Category 1 or Category 2 beneficiary. Beginning in 2024, cost-sharing for all Part D beneficiaries is eliminated in the Catastrophic Phase of the Part D benefit. In accordance with this, effective January 1, 2024, for PDE records with a DOS on or after 1/1/2024, Edit 720 will no longer occur.

End Date DDPS Edit 721

DDPS Edit 721 is a reject edit that occurs when beneficiary liability exceeds the statutorily defined cost-sharing maximum in the Catastrophic Phase for a Low Income Category 4 beneficiary who has reached the OOP Threshold. As stated above, beginning in 2024, Low Income Category 4 will no longer apply and cost-sharing for all Part D beneficiaries is eliminated in the Catastrophic Phase of the Part D benefit. In accordance with this, effective January 1, 2024, for PDE records with a DOS on or after 1/1/2024, Edit 721 will no longer occur.

Insulin and ACIP-Recommended Vaccine Reporting

Modification to DDPS Edit 787

DDPS Edit 787 is an informational edit that occurs when the benefit phase indicators do not match the TrOOP and Total Gross Covered Drug Cost (TGDC) Accumulators reported on the PDE record. Beginning in 2024, PDE records for insulin products and ACIP-recommended vaccines may have a TGDC Accumulator that is less than or equal to the Part D plan's deductible, and the PDE correctly reports the Beginning Benefit Phase indicator as "N" (Initial Coverage Phase), since these drugs are not subject to a deductible beginning in 2024. Effective January 1, 2024, for PDE records with a DOS on or after 1/1/2024, DDPS Edit 787 will be bypassed for covered insulin products and ACIP-recommended vaccines when the Beginning Benefit Phase = N, the Ending Benefit Phase = N, G (Gap Phase), or C (Catastrophic Phase), and the TGDC Accumulator is less than or equal to the plan deductible so that DDPS Edit 787 is not triggered inappropriately.

New Informational DDPS Edit 905

As part of the Defined Standard benefit, beginning in 2024, ACIP-recommended vaccines are not subject to a deductible. In accordance with this, effective January 1, 2024, for PDE records with a DOS on or after 1/1/2024, DDPS will issue informational Edit 905 if an ACIP-recommended vaccine PDE reports a Beginning and/or Ending Benefit Phase indicator = D (Deductible Phase). This edit will be informational only so as not to inappropriately reject a PDE when an ACIP-recommended vaccine is given outside the parameters of the ACIP recommendation (for example, a vaccine with an age-specific recommendation that is given to a beneficiary outside of that age range) while in the Deductible Phase.

New Reject DDPS Edit 906

As part of the Defined Standard benefit, beginning in 2024, covered insulin products are not subject to a deductible. In accordance with this, effective January 1, 2024, for PDE records with a DOS on or after 1/1/2024, DDPS will issue reject Edit 906 if a PDE for a covered insulin product reports a Beginning and/or Ending Benefit Phase indicator = D.

New Informational DDPS Edit 907

ACIP-recommended vaccines must be offered with no beneficiary cost-sharing. Since there is no cost-sharing under the Defined Standard benefit, there is no additional supplemental benefit that can be offered by an Enhanced Alternative plan. Therefore, effective January 1, 2024, for PDE records with a DOS on or after 1/1/2024, DDPS will issue informational Edit 907 if a PDE for an ACIP-recommended vaccine reports Non-Covered Plan Paid Amount (NPP) > 0. This edit will be informational only to accommodate limited circumstances where an ACIP-recommended vaccine is given outside the parameters of the ACIP recommendation so cost-sharing would be allowed and the Enhanced Alternative plan offers an enhanced benefit to reduce such cost-sharing.

New Reject DDPS Edit 908

Covered insulin products must be offered with beneficiary cost-sharing of no more than \$35 for a one-month supply. Since the cost-sharing under the Defined Standard benefit is defined as a range from \$35 down to \$0, there is no additional supplemental benefit that can be offered by an Enhanced Alternative plan. Therefore, effective January 1, 2024, for PDE records with a DOS on or after 1/1/2024, DDPS will issue reject Edit 908 if a PDE for a covered insulin product reports NPP > 0.

Part D Senior Savings Model

The Part D Senior Savings Model is ending on December 31, 2023. Beginning in 2024, CMS will be modifying the DDPS logic for the following edit codes by adding a 12/31/2023 end date.

End Date DDPS Edit 676

The modified edit verbiage will state “For DOS between 1/1/2022 and **12/31/2023**, if True Out-of-Pocket Accumulator = OOP Threshold, Part D Model Indicator cannot be '07' (Part D Senior Savings Model).”

End Date DDPS Edit 723

The modified edit verbiage will state “For DOS between 1/1/2022 and **12/31/2023**, Part D Model Indicator cannot be '07' (Part D Senior Savings Model). Beneficiary is eligible for LICS subsidy.”

End Date DDPS Edit 733

The modified edit verbiage will state “For DOS between 1/1/2022 and **12/31/2023**, the Submitting Contract/PBP is not a participant in the Part D Senior Savings Model on Date of Service.”

Modification to DDPS Edit 845

The modified edit verbiage will state “The Part D Model Indicator is invalid. For DOS prior to 1/1/2017 must be blank. For DOS on or after 1/1/2017, must be blank or a numeric value of 01. For DOS between 1/1/2022 and **12/31/2023**, must be blank or a numeric value of 01 or 07.”

Inbound and Outbound 2024 PDE File Layout Updates

Update to the Definition/Values for the Part D Model Indicator Field

CMS is modifying the verbiage in the Definition/Values column for the Part D Model Indicator field on the inbound and outbound 2024 PDE file layout to reflect the end date of the Part D Senior Savings Model (PDSS) of December 31, 2023. For PDSS model eligible PDEs submitted by Plans participating in the PDSS Model, this field is required to be populated with 07 on PDEs with a DOS \geq 1/1/2022 **and a DOS \leq 12/31/2023**.

Update to the Field Name and Definition/Values for the Estimated Remuneration at POS Amount (ERPOSA)

CMS is changing the name of the existing “Estimated Rebate at POS” field to “Estimated Remuneration at POS Amount (ERPOSA).” Until January 1, 2025, the ERPOSA field must include all remuneration applied at the POS, including any pharmacy price concessions applied at the POS. For detailed PDE reporting instructions, please see the October 14, 2022 HPMS memorandum entitled, “Reporting Estimated Remuneration Applied to the Point-of-Sale Price.”

For PDEs with a DOS before January 1, 2024, this field must contain the estimated amount of rebates and/or other price concessions that the plan 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.

For PDEs with a DOS between January 1, 2024 and December 31, 2024, this estimate must reflect the maximum amount of any contingent payments or adjustments that the plan sponsor might receive from a network pharmacy that would serve to decrease the total amount that the plan sponsor pays for the drug, i.e., all pharmacy price concessions. This estimate must *also* reflect the rebate or other price concession amount that the plan sponsor expects to receive from a pharmaceutical manufacturer or other non-pharmacy entity and has elected to apply to the negotiated price.