# DEPARTMENT OF HEALTH & HUMAN **SERVICES**

Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850



#### MEDICARE PLAN PAYMENT GROUP

May 16, 2025 **DATE:** 

TO: All Part D Sponsors

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

**SUBJECT:** May 2025 Updates to the Drug Data Processing System (DDPS)

The Centers for Medicare & Medicaid Services (CMS) is announcing upcoming changes to the Drug Data Processing System (DDPS), effective May 19, 2025. CMS is posting an updated DDPS Edit Spreadsheet reflecting these updates on the Customer Service Support Center (CSSC) Operations website (available here) concurrent with the release of this memo.

### DDPS Edit Modifications consistent with the definition of a "Covered Insulin Product"

Section 11406 of the Inflation Reduction Act of 2022 (IRA) amended the Social Security Act (the Act) to require that, effective for plan years beginning on or after January 1, 2023, covered insulin products are not subject to a deductible, and Part D cost-sharing for a 1-month supply must not exceed the statutorily defined "applicable copayment amount." A covered insulin product, by definition under section 1860D-2(b)(9)(C) of the Act, must be approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act. The definition includes FDA-licensed biological products that are a combination of more than one type of insulin or both insulin and non-insulin drugs or biological products. However, compounded drugs, defined at 42 CFR § 423.120(d), do not meet the definition of a covered insulin product as those products are not FDA-licensed. Accordingly, CMS is making the following updates to exclude compounded insulins from DDPS edits that take into consideration National Drug Codes (NDCs) for covered insulin products.

### DDPS Edit 787: Modification to Bypass Condition for Compounded Insulin

Edit 787 is an informational edit that fires when the Beginning and Ending Benefit Phase combination does not align with the Total Gross Covered Drug Cost (TGCDC) and/or True Out-of-Pocket (TrOOP) Accumulator. This edit is bypassed for Advisory Committee on Immunization Practices (ACIP)-recommended adult vaccines or covered insulin products that would otherwise fall in the Deductible Phase based on accumulator values because the deductible does not apply. Effective May 19, 2025, the bypass condition is being modified to exclude insulin NDCs with

<sup>&</sup>lt;sup>1</sup> For more information about the definition of a "covered insulin product," see the CMS final rule, *Medicare and* Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 90 FR 15792, 15802 (April 15, 2025).

Compound Code = '2' because compounded drugs containing insulin are not considered covered insulin products and, therefore, the Deductible Phase may be reported and the bypass to this edit is not necessary.

### DDPS Edit 900: Modification to Bypass Condition for Compounded Insulin

Edit 900 is a reject edit that fires when the Other TrOOP Amount Indicator = 'B' or 'S' and the NDC is not an ACIP-recommended adult vaccine or a covered insulin product. Effective May 19, 2025, for Prescription Drug Event (PDE) records with a Date of Service (DOS) between 01/01/2023 and 12/31/2023, the bypass condition is being modified to exclude insulin NDCs with Compound Code = '2' because compounded drugs containing insulin are not considered covered insulin products.

## DDPS Edit 904: Addition of Bypass Condition for Compounded Insulin

Edit 904 is an informational edit that fires when the Patient Pay Amount exceeds the statutory maximum for a covered insulin product. Effective May 19, 2025, a bypass condition is being added to exclude insulin NDCs with Compound Code = '2' because compounded drugs containing insulin are not considered covered insulin products.

#### DDPS Edit 906: Addition of Bypass Condition for Compounded Insulin

Edit 906 is a reject edit that fires when the Beginning and/or Ending Benefit Phase is reported as 'D' for covered insulin products. Effective May 19, 2025, a bypass condition is being added for insulin NDCs with Compound Code = '2' because compounded drugs containing insulin are not considered covered insulin products. PDEs that have been previously rejected with Edit 906 falling under this scenario may be resubmitted on or after May 19, 2025.

### DDPS Edit 908: Addition of Bypass Condition for Compounded Insulin

Edit 908 is a reject edit that fires if a PDE for a covered insulin product (excluding Medicare-Medicaid Plans (MMPs)) reports dollars in the Non Covered Plan Paid Amount (NPP) field. Effective May 19, 2025, a bypass condition is being added for insulin NDCs with Compound Code = '2' because compounded drugs containing insulin are not considered covered insulin products. PDEs that have been previously rejected with Edit 908 falling under this scenario may be resubmitted on or after May 19, 2025.

#### Additional DDPS Edit Modifications

### DDPS Edit 879: Modification to Bypass Condition

Edit 879 is a reject edit that fires when the Reported Gap Discount = \$0.00 for an applicable drug in the Coverage Gap Phase and the Covered D Plan Paid Amount (CPP) field reflects generic costsharing. This edit is bypassed when the sum of cost fields = \$0.00. Effective May 19, 2025, the bypass condition is being modified to include PDEs where the sum of Ingredient Cost Paid and Total Amount Attributed to Sales Tax is  $\le \$0.02$ . PDEs that have been previously rejected with Edit 879 falling under this scenario may be resubmitted on or after May 19, 2025.

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