

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
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**Audits and Vulnerabilities Group**

Date: December 18, 2023

To: All Medicare Advantage Prescription Drug (MA-PD) and Prescription Drug Plan Sponsors (PDPs)

From: Jennifer Dupee, Director

Subject: Upcoming National Audit - Analysis of Prescription Drug Event (PDE) Records for Medical Supplies Associated with the Delivery of Insulin for Beneficiaries with No Evidence of Insulin Use in Medicare Parts B, C, or D

The Centers for Medicare & Medicaid Services (CMS), in collaboration with the Plan Program Integrity Medicare Drug Integrity Contractor (PPI MEDIC), will conduct a National Audit of Medicare Part D payments for medical supplies associated with the delivery of insulin for beneficiaries with no evidence of insulin use in Medicare Parts B, C, or D. The National Audit is expected to start February 2024.

As stated in 42 CFR 423.100 and Chapter 6 section 10.1 of the *Medicare Prescription Drug Benefit Manual*, the definition of a Part D drug includes medical supplies associated with the injection of insulin.<sup>1</sup> These supplies include syringes, needles, alcohol swabs, and gauze. If these medical supplies are used for purposes other than the delivery of insulin to the body, they do not meet the definition of a Medicare Part D drug and are not payable under the Part D benefit. Both the PPI MEDIC and Investigations MEDIC (I-MEDIC) have identified these medical supplies, specifically gauze, alcohol wipes and cotton balls, as sources of potential fraud, waste, and abuse.

A preliminary analysis of Medicare Part D payments for medical supplies associated with the delivery of insulin for beneficiaries with no evidence of insulin use in Medicare Parts B, C, or D identified potentially improper PDE records for medical supplies associated with the delivery of

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<sup>1</sup> Centers for Medicare & Medicaid Services, US Department of Health & Human Services. General. In: Medicare Prescription Drug Manual. Chapter 6, Section 10.1. Revised January 15, 2016. Effective January 15, 2016. Accessed November 28, 2023. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/part-d-benefits-manual-Chapter-6.pdf>.

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insulin for beneficiaries with no evidence of insulin use. Based upon the results of this analysis, CMS and the PPI MEDIC will conduct a National Audit of Medicare Advantage Prescription Drug (MA-PD) and stand-alone Prescription Drug Plan (PDP) sponsors that have submitted potentially improper Medicare Part D PDE records for medical supplies associated with the delivery of insulin for beneficiaries with no evidence of insulin use in Medicare Parts B, C, or D. This audit will cover PDE records for cotton balls, alcohol swabs and gauze with dates of service from January 1, 2020, through December 31, 2022.

Due to the large number of PDE records for medical supplies associated with the delivery of insulin for beneficiaries with no evidence of insulin use in Medicare Parts B, C, or D, CMS will employ a sampling strategy for this national audit. The sampling will be conducted at the beneficiary level and will limit the initial audit universe to 5% of the total beneficiaries identified in the full universe. All PDE records associated with the selected sample beneficiaries between January 1, 2020 and December 31, 2022 are included in this sample audit universe. Additional PDEs may be subject to future audit, depending on the findings of this initial sample.

If you are selected for this audit, you will receive additional communication regarding the audit and next steps. The Payment Recovery Information System Medicare Parts C & D Plan Portal (PRIS Plan Portal) will be used for all data transmissions between CMS and organizations selected for audit. For additional information, please refer to the Health Plan Management System (HPMS) memo released September 8, 2021, subject: “Payment Recovery Information System Medicare Parts C & D Plan Portal (PRIS Plan Portal) Launch.” Your organization remains accountable to ensure the designated PRIS Plan Portal contact(s) is available and is responsible for all data transmissions and monitoring of the system. The PRIS Plan Portal can be accessed via the web at <https://pmpp.cms.gov>.

If you have any questions related to this memo, please send your inquiry to [CPIMedicarePartD\\_Data@cms.hhs.gov](mailto:CPIMedicarePartD_Data@cms.hhs.gov) with “Medical Supplies Associated with the Delivery of Insulin National Audit 2023” in the subject line.

If you have any questions/issues related to the PRIS Plan Portal, please send your inquiry to [PRIS\\_PMPP\\_Support@cms.hhs.gov](mailto:PRIS_PMPP_Support@cms.hhs.gov).

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