REPORT HIGHLIGHTS

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CMS Oversight Did Not Prevent Medicare Part D Sponsors From Making $587.7 Million in Ineligible Payments to Pharmacies for Drugs Available Over the Counter but Labeled as Prescription-Only

Why OIG Did This Audit

- CMS contracts with Medicare Advantage organizations and private prescription drug plans (collectively referred to as "sponsors" in this report) to offer Part D managed care benefits to eligible Medicare enrollees. Medicare Part D does not cover products that may be purchased without a prescription (e.g., over-the-counter [OTC] drugs).
- In 2022, a drug manufacturer agreed to pay $7.9 million for causing the submission of false claims to Medicare Part D sponsors by continuing to sell three generic drugs under obsolete prescription-only (Rx-only) labeling after the brand-name drugs were switched to OTC. We conducted this nationwide audit to determine whether CMS oversight of Medicare Part D sponsors ensured compliance with Federal requirements for preventing payment for OTC drugs sold under obsolete Rx-only labeling.

What OIG Found

CMS oversight of Medicare Part D sponsors did not prevent payments to pharmacies for some OTC drugs sold under obsolete Rx-only labeling.

- Part D sponsors made payments for five drugs associated with obsolete Rx-only labeling more than 1 year after the brand-name drugs were switched to OTC use. For calendar years (CYs) 2021 through 2023, Part D sponsors made $587.7 million in ineligible payments associated with the five drugs.
- The ineligible payments occurred because CMS: (1) updated its Part D Formulary Reference File using obsolete FDA data on Rx-only drugs and (2) did not set a timeframe for Part D sponsors to reject payments for OTC drugs sold under obsolete Rx-only labeling.
- Before we issued our draft report, FDA issued a policy in December 2025 requiring generic drug manufacturers to update their labeling "at the earliest time possible and within 6 months" after FDA approves an associated brand-name drug's switch from Rx-only to OTC use.

What OIG Recommends

We recommend that CMS issue guidance on timeframes for Part D sponsors to reject payments for OTC drugs sold under obsolete Rx-only labeling after an Rx-to-OTC switch. This step could have helped to prevent $587.7 million in ineligible payments for CYs 2021 through 2023.

CMS concurred with our recommendation.