REPORT HIGHLIGHTS

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CMS Has Limited Oversight of Selected Compounded Drugs Prescribed to Medicare Part D Enrollees

Why OIG Did This Audit

- Qualified health care professionals create compounded drugs by combining, mixing, or altering ingredients to create a prescription drug for patients whose medical needs cannot be met by an available U.S. Food and Drug Administration (FDA)-approved drug. FDA does not approve compounded drugs and does not verify the safety, effectiveness, or quality of these drugs before they are marketed.
- Over the past several years, OIG has participated in an increasing number of fraud investigations related to compounded drugs.
- To gain an understanding of Medicare Part D program integrity as it relates to compounded drugs, we conducted an audit of CMS's oversight of compounded drugs covered by Part D.

What OIG Found

CMS's oversight of selected compounded drugs prescribed to Part D enrollees is limited because the data CMS routinely obtains from sponsors (private companies that contract with CMS to provide the prescription drug benefit) does not provide a complete picture of a compounded drug's ingredients. As a result, enrollees we selected for review were given:

- An FDA-approved reconstituted injectable drug that may have been incorrectly identified on Prescription Drug Event (PDE) records as a compounded drug. Further, we found the days' supply dispensed by pharmacies exceeded the amount of time, indicated on the prescribing information label, that may pass between when a drug is reconstituted and when it is administered.
- Compounded drugs that included a drug (gabapentin) that CMS has identified as subject to misuse and that is known to increase the effects of opioids at the same time the enrollees had a separate prescription for that same drug. Additionally, some enrollees also received an opioid in a separate prescription during the same period.
- Compounded drugs that included a controlled substance (ketamine) that was not listed on the PDE record. Some of these enrollees also received an opioid in a separate prescription during the same period.

Since CMS does not routinely review the ingredients included in compounded drugs, it is limited in its ability to oversee sponsor efforts to ensure that quality assurance programs identify potential medication errors and potential overutilization of certain drugs.

What OIG Recommends

We made three recommendations to CMS, including that it work with sponsors, as appropriate, to ensure sponsors' claims for Part D compounded drugs are accurately reported on PDE records consistent with CMS guidance. The full recommendations are in the report. CMS concurred with all three recommendations.