

## Report in Brief

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Report No. A-03-17-00001

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**



### Why OIG Did This Audit

Every time a beneficiary fills a prescription covered under Medicare Part D, the Part D sponsor must submit a summary record called a prescription drug event (PDE) record to the Centers for Medicare & Medicaid Services (CMS). To offer a drug plan, a sponsor submits a bid that must receive CMS approval. Amounts reported in PDE records are used in formulating these sponsor bids. In 2016, a CMS-contracted audit found that a Part D sponsor (Sponsor) included, within the Part D total allowed dollars in several of its Part D bids, a margin for prescriptions from pharmacies wholly owned by the Sponsor.

The objective of this audit was to determine whether the Sponsor complied with Federal requirements for reporting PDE information during calendar year 2015 that supported cost information included in its 2017 Medicare Part D bid.

### How OIG Did This Audit

We conducted an audit of the PDE amounts the Sponsor reported in its 2017 bid submission. Our audit covered drug ingredient costs the Sponsor reported for its pharmacies in its PDE records for 2015. We obtained an understanding of the methodology the Sponsor used to calculate the ingredient cost and dispensing fees. From information provided by the Sponsor, we determined the cost of the drugs dispensed to beneficiaries during 2015 to identify the differences between the costs to the Sponsor and the amounts reported to CMS.

## CMS Should Strengthen Its Prescription Drug Event Guidance To Clarify Reporting of Sponsor Margin for Medicare Part D Bids

### What OIG Found

We found that the Sponsor complied with CMS's PDE reporting requirements. However, we also found that CMS's PDE reporting guidance does not adequately address a sponsor service delivery model in which a sponsor owns the pharmacy it uses and does not have a negotiated contract with the pharmacy. CMS clarified that it does not consider pharmacy margin to be sponsor margin, and CMS's current guidance allows pharmacy margin but not sponsor margin to be included in the PDE record. However, in this type of integrated service delivery model, the margin included in the ingredient costs in the PDE record for wholly owned pharmacies goes to the sponsor. Any sponsor margin included in the PDE record cannot be identified and separated from pharmacy costs. Ingredient costs in the PDE records are the basis for drug costs reported in the Part D bidding process. Ingredient costs in the PDE record for any one year impact the Part D bidding process in a future year. In sponsors' Part D bid submissions, sponsor margin is reported separately from ingredient costs. Any sponsor margin included in PDE records may not be evaluated during the bid review.

Because of the lack of clarity surrounding margin in the PDE records for sponsors with an integrated service delivery model, the inclusion of margin in ingredient costs prevents CMS from being able to readily identify and evaluate all margin that accrues to such sponsors in future years' Part D bids. Therefore, CMS cannot readily determine whether the amounts included in those Part D bids are reasonable.

### What OIG Recommends and CMS Comments

We recommend that CMS update its PDE guidance to address margin under sponsor delivery models in which a sponsor owns a pharmacy. We are not making any recommendations to the Sponsor because it followed PDE guidance for the period we audited.

CMS did not concur with our recommendation but agreed that it is important for sponsor-owned pharmacies' margins to be clearly reported and stated that it is open to exploring other avenues to achieve this. We are pleased that CMS agrees that it is important for sponsor-owned pharmacies' margins to be clearly reported but disagree with CMS's statement that current guidance is sufficient. We maintain that further guidance is necessary to address margin under sponsor delivery models in which a sponsor owns a pharmacy.

The full report can be found at <https://oig.hhs.gov/oas/reports/region3/31700001.asp>.

*This report contains restricted, sensitive information, such as confidential proprietary material with a high potential for misuse. All such information has been redacted from the final report posted on the Internet.*