

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**CMS SHOULD STRENGTHEN ITS  
PRESCRIPTION DRUG EVENT GUIDANCE  
TO CLARIFY REPORTING OF SPONSOR  
MARGIN FOR MEDICARE PART D BIDS**

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Principal  
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November 2021  
A-03-17-00001

# ***Office of Inspector General***

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## Report in Brief

Date: November 2021

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>.

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## INTRODUCTION

### WHY WE 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). PDE records contain prescription drug cost and payment data that enable CMS to make payments to plans and otherwise administer the Part D benefit. For each drug plan that the sponsor offers, the sponsor submits to CMS a bid detailing the plan's expected cost of providing drug coverage. Each bid must receive CMS approval. Amounts reported in PDE records are used in formulating these sponsor bids.

In 2016, a CMS-contracted audit<sup>1</sup> found that a Part D sponsor (Sponsor) included, within the total allowed dollars in several of its Part D bids, a margin<sup>2</sup> for prescriptions dispensed from pharmacies wholly owned by the Sponsor. This finding pertained to the Part D sponsor bids and not to the PDE records used in formulating these bids. We reviewed the Sponsor's 2017 Part D bids as well as the PDE records used in formulating those bids to determine whether this Sponsor continued to include a margin in the total allowed dollars in its Part D bids.

### OBJECTIVE

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.

### BACKGROUND

#### Medicare Part D Program

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social Security Act by establishing the Medicare Part D prescription drug program. Medicare Part D is an optional program to help Medicare beneficiaries pay for prescription drugs. Under Part D, which began on January 1, 2006, individuals entitled to benefits under Part A or enrolled in Part B may obtain drug coverage.<sup>3</sup>

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<sup>1</sup> The contracted independent audit firm audited the Sponsor and prepared an Examination Report for the Medicare Advantage Organization and Prescription Drug Plan's Financial Information for Contract Year 2012.

<sup>2</sup> Margin, called gain/loss margin in the Part D bid instructions, refers to the additional revenue requirement beyond allowed prescription drug costs and nonbenefit expenses.

<sup>3</sup> Medicare Part A provides inpatient hospital insurance benefits and coverage for extended care services for patients after discharge. Medicare Part B provides supplementary insurance for medical and other health services, including coverage of outpatient hospital services.

To provide prescription drug benefits under Part D, CMS contracts with private entities called sponsors that act as payers and insurers. Sponsors provide a minimum set of prescription benefits through a standalone prescription drug plan or as part of a managed care plan known as a Medicare Advantage prescription drug plan. Medicare beneficiaries enrolled in a standalone or Medicare Advantage prescription drug plan are sometimes referred to as plan members.

### *Prescription Drug Event Records*

Every time a beneficiary fills a prescription covered under Part D, the sponsor must submit a PDE record to CMS. The PDE record contains a data field for the ingredient cost, which is the amount a sponsor paid to the pharmacy for the drug.<sup>4</sup> Dispensing fees or other costs should not be included in the amount reported in the PDE “ingredient cost” field.

Generally, the amount paid to the pharmacy for each drug is negotiated between the sponsor and the pharmacy. If a pharmacy can purchase a drug for a price lower than the negotiated ingredient cost amount, the difference represents a margin for the pharmacy. The pharmacy margin is permissible in and of itself and is included in the amount reported in the PDE ingredient cost field. The distinction between *pharmacy margin*, as defined above, and *sponsor margin*, which is margin that accrues to the sponsor itself, is central to this audit report. Moreover, ingredient costs in the PDE records are the basis for drug costs reported in the Part D bidding process.

### *Part D Sponsor Bidding Process*

For a sponsor to offer a drug plan, the sponsor must submit a bid to CMS. CMS publishes bid instructions that each sponsor must follow when preparing its bid and must approve the bid submission before the beginning of the plan year. CMS uses the amounts in the bid to determine the amount it will pay prospectively to the plan sponsor.

In general, the beneficiary pays a percentage of the bid amount through premium payments, and CMS pays a percentage of the bid amount through subsidy payments.

A sponsor’s bid submission includes the bid-pricing tool, which consists of spreadsheets that sponsors use to develop and submit prices for the components of Medicare plan bids, and the plan benefit package, which provides a description of the plan benefits, premiums, and cost sharing. The bid-pricing tool calculates a plan sponsor’s per-member, per-month revenue requirements using base-period experience from a previous year to develop projected

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<sup>4</sup> The PDE record also includes a “dispensing fee paid” field that should contain the amount paid to the pharmacy for dispensing medication. The sponsor may negotiate each plan’s dispensing fees with pharmacies, and this may result in fees that are higher than the pharmacy’s actual cost of dispensing the medication. For purposes of this audit, we focused on the margin included in the ingredient cost field.

allowable costs for the next plan year.<sup>5</sup> Specifically, this tool calculates the bid amount after taking into account the total allowed dollar amount for prescriptions filled for plan members, nonbenefit expenses such as administrative expenses associated with the operation of the prescription drug plan during the base period, and the amount of any sponsor margin.

For 2017, the total allowed dollar amount was defined as the ingredient cost plus the dispensing fee, vaccine administration fees, and sales tax, as applicable, before the application of rebates recovered after the point of sale. This total allowed dollar amount is reported in the Part D claims experience section of the Part D bid. The basis for the total allowed dollar amount is the PDE record, which contains prescription drug cost and payment data.

CMS's bid instructions provide further guidance related to sponsor margins, and this guidance allows sponsors flexibility to achieve pricing targets, provided that the sponsor's overall margin meets the requirements in the guidance and that anticompetitive practices are not used.

As part of its bid approval process, CMS evaluates the bid components, including the sponsor's margin, to ensure that the amounts meet specific requirements. The bid instructions also require that data from the base period must reconcile in an auditable manner to both the PDE data submitted to CMS and the Part D sponsor's audited financial statements.

#### *Year-End Reconciliation*

Among other uses, the prescription drug cost and payment data in the PDE record enable CMS to make payments to plans and otherwise administer the Part D benefit. After the close of the plan year, CMS is responsible for calculating the final payment amount for each Part D plan by reconciling the prospective payments to the actual allowable costs (42 CFR § 423.343). Total prospective payments include certain CMS subsidy payments and beneficiary premiums minus administrative costs. Actual allowable costs are generally the payments that the sponsor makes for covered drugs less reported direct and indirect remuneration (DIR).<sup>6</sup>

#### **The Sponsor's Integrated Delivery Model**

The Sponsor owns the retail and mail-order pharmacies (Sponsor-owned pharmacies) that dispense drugs to its members.<sup>7</sup> These integrated pharmacies are part of a pharmacy department that is not a separate legal entity from the Sponsor. Under the Sponsor's integrated Part D service delivery model, pharmacies are considered an operational department of the Sponsor. The Sponsor performs most of the functions along the entire drug distribution and supply chain for drugs it dispenses to beneficiaries. The Sponsor negotiates

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<sup>5</sup> For 2017 bids, the base-period experience used 2015 data.

<sup>6</sup> DIR consists of any rebates, subsidies, or other price concessions (from any source) that decrease the costs that a sponsor incurs under the Part D plan (42 CFR § 423.308).

<sup>7</sup> The Sponsor also uses a pharmacy benefit manager to provide a pharmacy network for cases in which a beneficiary cannot use a Sponsor-owned pharmacy.

directly with drug manufacturers for most of its drugs and handles storage and distribution of the drugs.

There is no contract between the Sponsor and its pharmacies, and the Sponsor and its pharmacies have the same employer identification number (EIN). Because the Sponsor and Sponsor-owned pharmacies operate under the same EIN, they report data to the Internal Revenue Service, are audited, and present financial statements as a single entity.

## **HOW WE CONDUCTED THIS AUDIT**

We conducted an audit of the PDE amounts the Sponsor reported in its 2017 bid submission. Specifically, our audit covered approximately [REDACTED] in drug ingredient costs the Sponsor reported for its pharmacies in its PDE records for 2015.<sup>8</sup>

To conduct this audit, we obtained an understanding of the methodology the Sponsor used to calculate the ingredient costs and dispensing fees it reported on its PDE records and submitted to CMS during 2015. We selected and reviewed a judgmental sample of [REDACTED] manufacturer contracts<sup>9</sup> to obtain information related to purchase discounts and rebates. From information provided by the Sponsor, we determined the costs of the drugs dispensed to beneficiaries during 2015 to identify the differences between the costs to the Sponsor and the amounts reported to CMS in the PDE records. We discussed our findings with the Sponsor and CMS.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A describes our audit scope and methodology.

## **FINDING**

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. This is the type of integrated service delivery model that the

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<sup>8</sup> We provided an initial draft report copy to the Sponsor and requested that the Sponsor comment on the validity of the facts. The Sponsor requested that certain confidential and proprietary information be redacted from the report on the grounds that it is likely to jeopardize the Sponsor's anonymity and cause foreseeable competitive harm to the Sponsor. This information, which is highlighted, is redacted in the final report posted on the OIG website.

<sup>9</sup> A sponsor may negotiate with drug manufacturers to provide the sponsor with discounts or rebates for drug purchases. The terms of these discounts and rebates are documented in contracts between the sponsor and the drug manufacturer.



Sponsor used. In other types of sponsor-pharmacy arrangements, pharmacy margin constitutes an expense for the sponsor. However, if a sponsor has this type of integrated service delivery model, any margin from wholly owned pharmacies functions as margin, not expense, for the sponsor.

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, because of the type of integrated service delivery model in question, the margin included in the ingredient costs in the PDE record for wholly owned pharmacies goes to the sponsor and not to a separate pharmacy. Accordingly, margin included in the ingredient cost ultimately accrues to the sponsor in an integrated service delivery model. In addition, because there is nothing in the PDE record to indicate which portion of the ingredient costs constitutes pharmacy costs and which portion is margin, any margin included in the PDE record cannot be identified and separated from actual pharmacy costs.

This is important because the ingredient costs in the PDE records are the basis for drug costs reported in the Part D bidding process. For instance, the Sponsor's 2015 PDE records were the basis for the drug costs reported in the Sponsor's 2017 Part D bids. Therefore, the ingredient costs in the PDE record for any one year impact the Part D bidding process in a future year.

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. In sponsors' Part D bid submissions, sponsor margin is reported (and subsequently evaluated by CMS) separately from ingredient costs. If any margin in the PDE record accrues to a sponsor, it is not reported as sponsor margin and therefore may not be evaluated during the bid reviews. Because it is not transparent to CMS whether any margin in ingredient costs accrued to the sponsor, CMS might approve a bid that otherwise might not have approved if it had complete information. Additionally, this lack of transparency could affect approved bid pricing and the amounts paid by beneficiaries and the Federal Government. Specifically, the entire ingredient cost would appear to CMS to be an expense to the sponsor instead of a partial expense and a partial margin to the sponsor, and CMS would evaluate it as an expense, not a margin, during the bidding process.

## **THE SPONSOR COMPLIED WITH REQUIREMENTS, BUT PRESCRIPTION DRUG EVENT GUIDANCE WAS NOT ADEQUATE TO ENSURE THAT ALL MARGIN THAT ACCRUED TO THE SPONSOR COULD BE EVALUATED DURING THE PART D BIDDING PROCESS**

### **Federal Requirements and CMS Guidance**

As defined at 42 CFR section 423.100 (2015), "negotiated prices" are covered Part D drug prices that: (1) the Part D sponsor or intermediary contracting organization and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount the dispensing entity will receive for a particular drug; (2) are reduced by discounts, direct or

indirect subsidies, rebates, other price concessions, or DIR that the Part D sponsor elects to pass through to Part D enrollees at the point of sale; and (3) include dispensing fees.<sup>10</sup>

The negotiated price may include a pharmacy's margin in addition to its direct and indirect costs of dispensing the prescriptions. The January 28, 2005, Final Rule implementing the Part D program states that "we expect Part D plans and pharmacies to account for pharmacy profit as part of negotiated prices—either as part of overhead costs accounted for in dispensing fees or in the reimbursement rates for ingredient costs negotiated with pharmacies" (70 Fed. Reg. 4194, 4236). CMS indicated that this policy applies even in the case of pharmacies owned and operated by the Part D plan sponsor or pharmacy benefit manager.

In a response to a comment in the January 2005 Part D Final Rule, CMS stated that it believed that it addressed instances in which a sponsor uses an integrated pharmacy business model. In explaining the response to us, CMS stated that the same rules regarding allowable pharmacy costs in the negotiated price apply irrespective of whether the pharmacy is owned by the sponsor (i.e., there are no additional restrictions on sponsors that own and operate their own pharmacies). CMS also stated that any additional information needed to verify plan costs would be collected through the bid review and audit processes. In response to our questions, CMS stated that "sponsors are not permitted to include in the negotiated price reported on a PDE any plan or [pharmacy benefit manager] margin . . . . CMS does not consider the pharmacy margin, or in this case, the difference between the pharmacy's acquisition cost and the price reported on the PDE, to be sponsor margin."

### **The Sponsor Complied With Requirements, but Current Prescription Drug Event Guidance Does Not Allow CMS To Readily Evaluate All Margin That Accrued to the Sponsor**

We found that the Sponsor complied with Federal requirements for reporting negotiated prices in 2015 PDEs, but those requirements did not require that the PDE record contain the information necessary for CMS to be able to readily view and consider all margin when assessing the Sponsor's 2017 Part D bid.

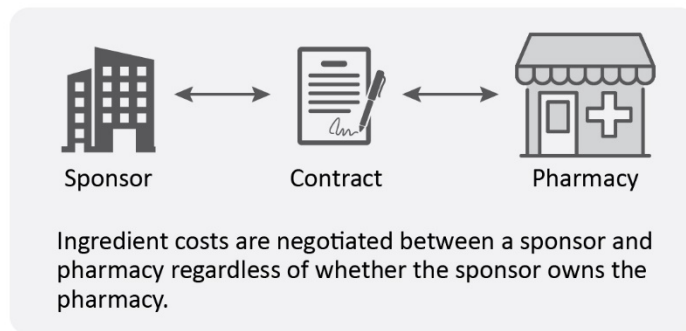
CMS does not consider the pharmacy's margin to be the sponsor's margin, which is not permitted to be included in the PDE record even in the case of an integrated delivery model. However, under the Sponsor's integrated delivery model, any margin built into the ingredient costs functions as sponsor margin because the Sponsor and pharmacy operate as a single legal entity. (See Figure 1.)

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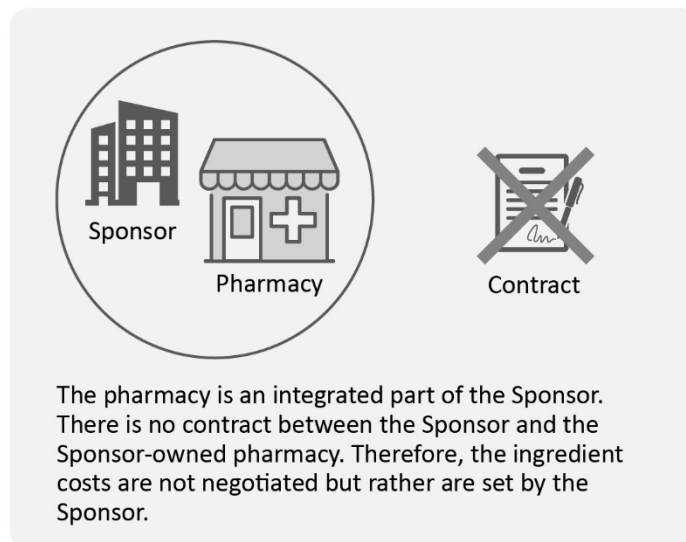
<sup>10</sup> After the audit period, the definition of negotiated prices was clarified to include all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point of sale.

**Figure 1: CMS Negotiated Cost Expectations and the Sponsor's Delivery Model**

**What CMS Expects**



**The Sponsor's Delivery Model**



For 2015, the Sponsor reported ingredient costs of approximately [REDACTED] on its PDE records. However, during our audit, the Sponsor provided documentation that showed that the cost to acquire these drugs was approximately [REDACTED]. We therefore calculated a [REDACTED] difference between the amount the Sponsor paid to purchase Part D drugs (i.e., its acquisition costs) and the amount it reported as ingredient costs in its PDE records.

According to the Sponsor, this [REDACTED] difference consisted of direct and indirect pharmacy costs and margin. There was nothing in the PDE records to indicate to CMS how much of the [REDACTED] represented actual pharmacy costs and how much was margin. The Sponsor stated that it did not have a breakdown of the individual direct and indirect pharmacy costs and the margin amounts, but other documents the Sponsor provided indicated that the Sponsor estimated its margin was [REDACTED] percent of the amount reported on the PDE. If the Sponsor did not have an integrated delivery model, the [REDACTED] would have been paid to the pharmacy. However, because the Sponsor owned the pharmacy, the entire difference, including any margin, accrued to the Sponsor. This margin was included in the ingredient costs reported on

PDE records in accordance with CMS guidance. These PDE records were submitted to CMS for 2015 payment calculations and were used in preparing 2017 Part D bids.

CMS's current PDE guidance related to pharmacy margin primarily exists in the preamble to the Part D Final Rule and has not been updated since the Part D program was established. The guidance states that CMS expects Part D plans to account for pharmacy margin as part of negotiated prices—either as a part of the overhead costs accounted for in dispensing fees or in the reimbursement rate for ingredient costs negotiated with pharmacies. Sponsors report these negotiated prices on the PDE record each time a drug is dispensed, including from sponsor-owned pharmacies. However, if a sponsor included margins for sponsor-owned pharmacies in the PDE record (as the Sponsor did) rather than as part of the sponsor's margin on the plan's bid, CMS may not be able to readily evaluate the true margin amount that accrued to the sponsor. Because of this lack of clarity in the information provided in the plan's bid, CMS may only become aware that margin that accrued to the sponsor may be included in the ingredient costs if that margin is found during an audit or is reported by the sponsor.

### **Current Prescription Drug Event Guidance May Affect CMS's Ability To Assess Part D Plan Bids**

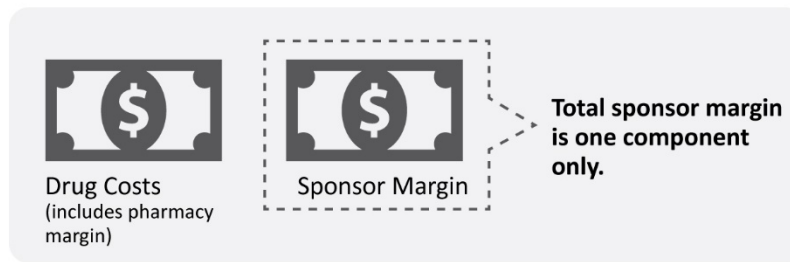
Drug costs<sup>11</sup> and sponsor margin are two components that CMS reviews when assessing Part D bids for future plan years. Sponsors use PDE records from a previous year to determine drug costs used in developing the next year's bid, and CMS expects pharmacy margin to be built into the drug costs as part of the prices negotiated between sponsors and pharmacies. Sponsor margin is considered separately in the bidding process, and CMS does not expect it to be included in the drug costs. (See Figure 2 on the following page.)

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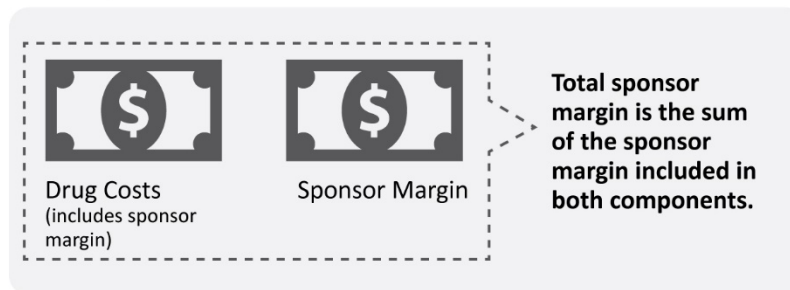
<sup>11</sup> Drug costs are entered in the Part D bid in the Part D claims experience section as the total allowed dollars. For 2017, total allowed dollars were defined as the ingredient cost plus the dispensing fee, vaccine administration fees, and sales tax, as applicable, before the application of rebates recovered after the point of sale. The experience data for the 2017 Part D bids were based on 2015 data. Experience data must reconcile in an auditable manner to the PDE data submitted to CMS.

**Figure 2: Margin in 2017 Bid Submissions**

**How Margin Appears in Bids**



**Actual Location of Margin for a Sponsor With an Integrated Delivery Model**



CMS does not expect sponsor margin to appear in the drug costs and does not expect to evaluate drug costs for any included sponsor margin.

For its Sponsor-owned pharmacies, the Sponsor did not include the margin in the drug costs in the separately evaluated sponsor margin section of the bid. If a sponsor does not include this margin in the sponsor margin section of the bid, CMS cannot readily assess all of the sponsor's margin when evaluating a bid submission, and the sponsor's margin could appear to be less than it actually is. If CMS does not assess all of a sponsor's margin, CMS might approve a bid that it otherwise might not have approved if it had complete information. Additionally, this lack of transparency could affect approved bid pricing and the amounts paid by beneficiaries and the Federal Government.

**RECOMMENDATION**

We recommend that the Centers for Medicare & Medicaid Services 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 COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

### **CMS Comments**

CMS did not concur with our recommendation to update its PDE guidance to address margin under sponsor delivery models in which a sponsor owns a pharmacy. However, CMS agreed that it is important for sponsor-owned pharmacies' margins to be clearly reported and is open to exploring other avenues to achieve this.

CMS commented that the amount paid to a pharmacy for each drug is negotiated between the sponsor and the pharmacy and that it audits the accuracy of the plan's PDEs used in reconciliation and verifies the drug costs. CMS stated that the main objective of the audits is to verify that the prices reflected in the PDE are in accordance with contractual terms between the plan sponsor and its contracted pharmacies.

CMS stated that current PDE guidance is sufficient for the purpose of addressing proper reporting of margins to calculate plan payments. CMS further stated that due to the complexity and volume of PDE reporting, adding a field to the PDE record when that granularity of data is unnecessary to review plan bids would be a tremendous operational burden for the vast majority of plan sponsors.

CMS stated it believes that there are more appropriate and less burdensome vehicles for clarifying margin reported by sponsor-owned pharmacies.

CMS's comments are included in their entirety as Appendix B.

### **Office of Inspector General Response**

We are pleased that CMS agrees that it is important for sponsor-owned pharmacies' margins to be clearly reported. We agree that the typical sponsor arrangement would establish a negotiated price between the sponsor and the pharmacy. However, there is no negotiated price when a sponsor with an integrated service delivery model, such as the one the Sponsor has, does not have a contract between itself and the pharmacy it owns. We do not know how CMS can audit the PDE when there is no contract.

Furthermore, we disagree with CMS's statement that current guidance is sufficient to address how a sponsor with an integrated service delivery model and no negotiated price should report sponsor margin. Specifically, if there is no negotiated price between the sponsor and pharmacy, the difference between the amount reported on the PDE and the amount the pharmacy paid for the drug functions as margin for the sponsor, not expense. We maintain that further PDE guidance is necessary to address margin under this type of sponsor delivery model since such margin could affect approved bid pricing and the amounts paid by beneficiaries and the Federal Government. Addressing margin under this type of sponsor delivery model would increase transparency in the bid pricing process and provide a way for CMS to be able to audit the PDE when there is no contract.

We neither agree nor disagree with CMS's statement that adding a field to the PDE record would be a tremendous burden but point out that our recommendation does not prescribe changing the PDE record. Finally, we look forward to CMS's alternative suggestions to address margin under sponsor delivery models in which a sponsor owns a pharmacy.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

We reviewed the Sponsor's 2015 PDEs and 2017 Medicare Part D bids to determine whether the Sponsor complied with Federal requirements for reporting 2015 PDE information that was used as support for cost information included in the Sponsor's 2017 Medicare Part D bids. We selected a judgmental sample of ■ manufacturer contracts that represented each type of contract (e.g., specialty pharmacy contract or Medicare contract) that the Sponsor had and that covered the sampled drugs to determine the contract terms and verify the ingredient costs on PDEs submitted to CMS. We limited our audit to determining whether the Sponsor complied with Federal requirements for reporting 2015 PDE information that was used as support for cost information included in its 2017 Medicare Part D bid.

We did not review the Sponsor's overall internal control structure. Rather, we reviewed only those internal controls related to our objective.

We performed our audit work from February 2017 through October 2020, including fieldwork conducted in February 2017 at the Sponsor's offices.

### METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance pertaining to Part D bids and PDEs;
- held discussions with CMS officials to obtain their views on how Medicare Part D bid and PDE information should be prepared and submitted when a Medicare Part D sponsor owns the pharmacy it uses;
- met with the Sponsor to obtain information about its delivery model, process for preparing and submitting Medicare Part D bids, process for contracting with manufacturers, and process for developing drug prices included on PDE records submitted to CMS;
- reviewed the Sponsor's policies and procedures for calculating the amounts reported as ingredient costs in the PDE records submitted to CMS;
- reviewed the contracts between the Sponsor and ■ drug manufacturers to obtain information related to purchase discounts and rebates;
- selected a judgmental sample of 50 national drug codes, applied the Sponsor's pricing algorithm to the cost, and compared the result to PDEs submitted to CMS;
- obtained and reviewed Medicare Part D bids submitted by the Sponsor for 2017; and



- determined the 2015 total allowed dollars for the Sponsor's Part D claim experience in its 2017 Part D bids.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## APPENDIX B: CMS COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

*Administrator*  
Washington, DC 20201

DATE: July 20, 2021

TO: Christi Grimm  
Inspector General

FROM: Chiquita Brooks-LaSure *Chiquita LaS*  
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: CMS Should Strengthen Its Prescription Drug Event Guidance to Clarify Reporting of Sponsor Profit for Medicare Part D Bids (A-03-17-00001)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the OIG's draft report regarding Prescription Drug Event (PDE) guidance for Part D sponsors. CMS takes seriously its role in ensuring Medicare Part D sponsors comply with Federal requirements for reporting PDE information. As OIG noted in their report, the sponsor reviewed for this audit complied with all Federal requirements for PDE reporting.

To provide prescription drug benefits under Part D, CMS contracts with private entities called sponsors. These sponsors provide a minimum set of prescription benefits through either a standalone prescription drug plan or as part of a managed care plan. Pursuant to 42 CFR § 423.505(i), the sponsor maintains ultimate responsibility for complying with its contract with CMS.

As part of its bid approval process to offer a drug plan under Part D, CMS evaluates the bid components, including the sponsor's margin. The bid instructions also provide that bid amounts reconcile to the PDE data submitted to CMS and the Part D sponsor's audited financial statements. Having margin information at the PDE level is not necessary to evaluate plan bids.

When a beneficiary fills a prescription covered under Part D, the sponsor must submit a PDE record to CMS. Submitted PDE records enable CMS to reconcile payments to the sponsor and otherwise administer the Part D benefit. Among other things, the PDE record includes a "dispensing fee paid" field that should contain the amount paid to the pharmacy for dispensing medication. Pursuant to 42 CFR § 423.505(k), the sponsor must provide certification as to the accuracy, completeness, and truthfulness of the claims data submitted for payment purposes.

The amount paid to a pharmacy for each drug is negotiated between the sponsor and the pharmacy. The negotiated price may include, as OIG acknowledges, a profit margin, in addition to its direct and indirect costs to dispense the prescriptions. In the initial rulemaking to implement the Part D program (70 FR 4194), CMS stated that it expects Part D plans and pharmacies to account for pharmacy profit as part of negotiated prices—either as part of overhead costs accounted for in dispensing fees, or in the reimbursement rates for ingredient costs negotiated with pharmacies (70 CFR 4236). CMS further stated that in the case of

pharmacies owned and operated by a health plan, dispensing fees are understood to be the equivalent of all reasonable pharmacy costs included in the definition (those related to the transfer of possession of a covered Part D drug to a Part D plan enrollee), including the salaries of pharmacists and other pharmacy workers as well of the costs associated with maintaining the pharmacy facility and equipment necessary to operate the pharmacy (70 FR 4245). Current Part D statute and regulations do not prohibit a Part D sponsor from including a mark-up to reflect profit in the negotiated price for its sponsor-operated pharmacies.

CMS also audits the accuracy of the plan's PDEs used in reconciliation. Part of the review involves verifying that the drug costs (ingredient costs and dispensing fee fields) reported on the PDE records reflect prices actually paid to pharmacies and other dispensing providers. The main objective is to verify that the prices reflected in the PDE are in accordance with contractual terms between the plan sponsor and its contracted pharmacies.

CMS appreciates the OIG's review in this area. The OIG's recommendation and CMS's response are below.

**OIG Recommendation**

We recommend that the Centers for Medicare & Medicaid Services update its PDE guidance to address margin under sponsor delivery models in which a sponsor owns a pharmacy.

**CMS Response**

CMS agrees that it is important for sponsor-owned pharmacies' margins to be clearly reported and is open to exploring other avenues to achieve this. However, current PDE guidance is sufficient for the purpose of addressing proper reporting of margins to calculate plan payments. Due to the complexity and volume of PDE reporting, adding a field to the PDE record when that granularity of data is unnecessary to review plan bids would be a tremendous operational burden for the vast majority of plan sponsors. CMS believes that there are more appropriate and less burdensome vehicles for clarifying margin reported by sponsor-owned pharmacies. Therefore, CMS does not concur with this recommendation in its current form.