U.S. Department of Health and Human Services
Office of Inspector General
Issue Brief
December 2022, OEI-03-21-00390

CMS Should Bolster Its Oversight of Manufacturer-Submitted Average Sales Price Data To Ensure Accurate Part B Drug Payments

Why OIG Did This Review

Medicare and its enrollees spend nearly $40 billion annually to cover a limited number of Part B outpatient prescription drugs and biologicals. (Part B drugs are generally drugs that are injected or infused in physicians' offices or hospital outpatient settings.) The Centers for Medicare & Medicaid Services (CMS) uses manufacturer-reported average sales prices (ASPs)—which are based on manufacturers' actual quarterly drug sales—to calculate provider payment amounts for these drugs. When drug manufacturers' data are not accurate, Medicare and its enrollees may make inappropriate payments for these drugs. The Consolidated Appropriations Act, 2021, directed OIG to review manufacturer-reported ASP data. We conducted this evaluation to provide insight into CMS's oversight of ASP data, including assessing their accuracy before using them to calculate Medicare Part B payment amounts.

Key Takeaway

Gaps in CMS's oversight of manufacturer reported ASP data may continue to limit its ability to ensure the accuracy of ASP data and result in inaccurate Part B drug payment amounts.

How OIG Did This Review

To determine how CMS oversees the accuracy of manufacturer-submitted ASP data, we (1) collected and reviewed CMS's standard operating procedures for oversight of ASP data; and (2) interviewed CMS staff regarding CMS's oversight processes and challenges to conducting effective oversight. We reviewed 5 years of Medicare Part B ASP and drug payment data from the first quarter of 2016 to the fourth quarter of 2020. We determined the number of drug codes for which CMS calculated a payment amount using a payment methodology other than ASP because the ASP data were either unavailable or invalid (i.e., the ASP data were equal to or less than zero). We also identified the number of drugs that CMS categorized as having data values missing.

What OIG Found

While CMS has some oversight procedures in place to review ASP data (e.g., system edits in the ASP data collection system and CMS's internal reviews of manufacturer data), gaps exist in its oversight that allowed inaccurate data to impact Medicare Part B payment amounts. CMS's quality assurance procedures do not include checks to ensure the accuracy of manual processes it employs to analyze the data used to calculate Part B payment amounts. CMS also does not leverage its ASP data collection system to produce analytical reports that would monitor ASP data quality and maximize its oversight capabilities.

Because of invalid or missing ASP data, CMS could not calculate an ASP-based payment amount for 8 percent of drug codes at least once between 2016 and 2020. CMS was unable to calculate an ASP-based payment amount for several reasons, including that (1) the manufacturer reported a negative sales or ASP value; or (2) the manufacturer had no sales to report for that quarter. The

alternative payment methodology that CMS uses when ASP data are either unavailable or deemed invalid often results in higher drug payment amounts for Part B drugs. In total, we found that 24 percent of drug codes were missing ASP data for one or more specific drugs within that code in at least one quarter between 2016 and 2020. In addition, CMS reported that late ASP data submissions from manufacturers substantially hindered its ability to conduct effective oversight.

What OIG Recommends

To bolster its oversight of manufacturer-reported ASP data, we recommend that CMS build a strategy to strengthen its internal controls for ensuring the accuracy of Part B drug payments. CMS concurred with our recommendation.

BACKGROUND

Medicare and its enrollees spend nearly $40 billion annually on a limited number of Part B outpatient prescription drugs and biologicals. CMS uses manufacturer-reported ASPs—which are based on manufacturers' actual quarterly drug sales—to calculate provider payment amounts for these drugs. When drug manufacturers' data are not accurate, Medicare and its enrollees—who are generally responsible for the 20-percent coinsurance amount—may pay too much for these drugs. To protect the Medicare program and its enrollees, it is vital that CMS conduct robust oversight to ensure the accuracy of ASP data. The Consolidated Appropriations Act, 2021, directed OIG to review manufacturer-reported ASP data.[1] We conducted this evaluation to provide insight into CMS's oversight of ASP data, including assessing the accuacy of ASP data before using them to calculate Medicare Part B payment amounts.

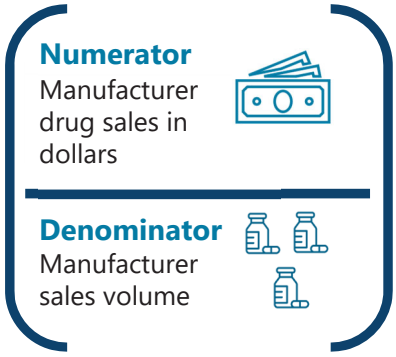
Medicare Part B Coverage and Payment for Prescription Drugs

Medicare Part B covers a limited number of outpatient prescription drugs and biologicals (hereafter referred to as drugs). These drugs are usually administered in a physician's office or other outpatient setting and include, for example, drugs used to treat cancer, autoimmune diseases, and macular degeneration.[2] To obtain payment for these drugs, healthcare providers submit claims to Medicare contractors using Healthcare Common Procedure Coding System (HCPCS) codes (hereafter referred to as drug codes).

Medicare pays healthcare providers for most Part B drug codes on the basis of ASPs. Under the ASP payment methodology, the Medicare payment for a Part B drug code is 106 percent of the volume-weighted ASP for the Part B drug code. In general, an ASP is calculated by dividing (1) the total dollar amount of a manufacturer's quarterly drug sales to all purchasers in the United States by (2) the total number of units sold by the manufacturer (hereafter referred to as "sales volume") in the same quarter.[3]

CMS Collection and Oversight of Manufacturer-Reported ASP Data. To collect the data needed to calculate the ASP-based Medicare payment amount for each Part B drug code, CMS requires certain manufacturers to submit quarterly ASPs and the sales volume for each of their national drug codes (NDCs).[4, 5] Manufacturers calculate a quarterly ASP for each NDC by dividing total sales by the sales volume, as shown in Exhibit 1. Manufacturers must also report to CMS certain product information for each NDC, including product strength as well as information that CMS uses to determine the package size and package quantity—each of which affects

Exhibit 1: Manufacturers' ASP calculations for NDCs



Source: Section 1847A(c) of the Social Security Act

the calculation of the Medicare payment amount.[6] When CMS is unable—because of missing or invalid data—to use ASP data from manufacturers to calculate a Medicare payment amount for a drug code, it uses the wholesale acquisition cost (WAC) for the affected code.[7]

To facilitate manufacturers' submissions of complete and accurate ASP data for each NDC, CMS implemented an online ASP data collection system—the Medicare Part B Drug ASP Application (hereafter referred to as the ASP system)—in April 2019. After a manufacturer submits its ASP data, the manufacturer must certify the data's accuracy and completeness.[8] After manufacturers submit and certify data, CMS performs numerous quality checks every quarter, the results of which may determine whether an NDC's ASP and sales volume amounts will be included in CMS's calculation of the payment amount. To facilitate this process, CMS developed formal written procedures (hereafter referred to as "internal controls"), that outline the steps it takes to (1) collect and review manufacturer-reported ASP data and (2) calculate Medicare payment amounts.

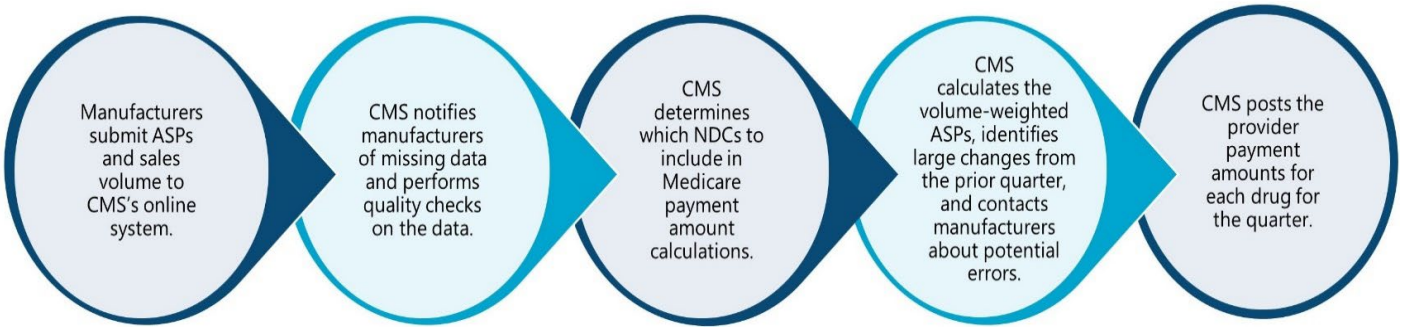
In conducting its oversight, CMS determines whether manufacturers submitted complete data. After this review, CMS assigns a status indicator value for each NDC. This status indicator value denotes whether CMS considers the ASP data for that NDC to be usable for the calculation of the ASP-based payment amount. As a result of this review, CMS may seek clarification or corrections from manufacturers that submit incomplete or inaccurate data. CMS also identifies data that display certain characteristics which may indicate inaccurate data. These characteristics include (1) an ASP that is higher than the reported WAC and (2) duplicate submissions for a single NDC.

CMS's Calculation of Medicare Part B Payment Amounts. CMS must calculate ASP-based payment amounts in a timely manner every quarter. CMS determines quarterly payment amounts for Part B-covered drug codes rather than individual NDCs. Because a drug code may correspond to multiple NDCs, CMS creates a file that links each NDC to its associated drug code (hereafter referred to as the "background file"). The background file includes the manufacturer-reported ASP and sales volume for each NDC. This file also includes product information—i.e., package size, package quantity, billing units, and billing units per package—that CMS derives from manufacturer-reported data and publicly available information from drug resources such as *Redbook*. In addition to the background file, CMS creates a separate file—the code pricing file—that contains the Medicare payment amount for each drug code. This file also identifies the basis for the payment amount for each drug code (e.g., ASP, WAC, or average manufacturer price (AMP)).

CMS may not include every NDC associated with a drug code in its calculation of payment amounts, as shown in Exhibit 2. CMS includes only NDCs assigned a status indicator value of "D" in its calculation of payment amounts for drug codes. A status indicator value of "D" indicates valid data. "Valid data" means that the manufacturer reported both the ASP value and sales volume values as greater than zero. According to CMS, in some cases, a manufacturer's ASP data may appropriately include ASP and sales volume values equal to or less than zero. A manufacturer may include adjustments in the current quarter's data that are based on changes to sale prices and sales volumes that occurred in previous quarters. These adjustments can cause the current quarter's ASP to reflect a value equal to or less than zero. Regardless of whether CMS deems these values to be appropriate, it does not include these values of zero or less-than-zero in its calculation of Part B payment amounts. For the purposes of this report, we will refer to ASPs that are equal to or less than zero as invalid data.

To calculate a single volume-weighted ASP for each drug code, CMS uses the ASP data from associated NDCs that have been deemed to have valid data (i.e., a status indicator value of "D"). CMS calculates the volume-weighted ASP by weighting the ASPs for all the NDCs associated with a drug code by the proportion of each NDC's sales volume. CMS then calculates 106 percent of the volume-weighted ASP for each drug code to determine the Medicare payment amount. Finally, CMS posts a file—known as the payment file—that contains these payment amounts on its website.[9] Medicare pays providers the same amount for the drug code regardless of which product (and associated NDC) they give to the enrollee.

Exhibit 2: The process for calculating Medicare payment amounts



Source: OIG review of CMS's *ASP Pricing Process Standard Operating Procedures*

Related Work

OIG is also conducting a companion study that provides insight into ASPs for high-expenditure Part B drugs compared to benchmark prices and factors that manufacturers consider when determining which sales, discounts, and fees to include in their ASP calculations.[10]

In a data snapshot released in 2020, OIG examined the accuracy of manufacturer-reported pricing data and identified specific errors in ASP and average

manufacturer price (AMP) data.[11] This work identified instances in which manufacturers made changes to reported product information that did not seem to be supported by changes in the drugs' publicly available packaging information. These changes raised questions about the accuracy of the data being reported by manufacturers.

In 2010 and 2014 reports, OIG identified vulnerabilities in CMS's oversight procedures. Specifically, OIG identified manual data entry systems (e.g., systems whereby data entry was done by either typing or using the "copy and paste" function), limited tracking processes, and incomplete manufacturer reporting as shortcomings with CMS's oversight.[12, 13] We also found that manufacturers did not submit all required ASP data within the specified timeframes. CMS established its online data collection system for ASPs, in part, to implement OIG's recommendations from both reports that it establish an automated system to collect ASP data. To implement the remaining recommendations from OIG's 2014 report, CMS ensured the accuracy of product information for NDCs listed in its files and continued to assist OIG in identifying and penalizing manufacturers that do not meet ASP reporting requirements. Although CMS did not concur with the recommendation to seek legislative change to require all manufacturers of Part B-covered drugs to submit ASPs, recent legislation now requires that manufacturers report ASP data.[14]

For over 15 years, OIG has conducted a comparison of drug codes' ASPs with AMPs. These comparisons identify drug codes associated with potentially excessive ASP-based payment amounts and recommend payment amount reductions. OIG provides the results of its analysis to CMS; CMS, in turn, determines whether to implement the recommended payment reductions. It is CMS that decides whether to use the lower AMP-based payment amount (103 percent of AMP) rather than the higher ASP-based payment amount (106 percent of ASP). ASP data—including package size, package quantity, and the status indicator—play a vital role in the effort to reduce Medicare expenditures. CMS's implementation of OIG's recommended payment amount reductions has saved Medicare and its enrollees $73.1 million since 2013.[15]

RESULTS

Gaps continue to exist in CMS's oversight of ASP data accuracy

CMS's internal controls do not include specific procedures to review the manual processes used by staff to analyze ASP data. CMS uses manual processes to select NDCs that populate certain data fields in its drug files including the ASP, sales volume, and status indicator values. CMS has not implemented a quality assurance process to review manual processes used by staff to analyze data in the background, code pricing, and payment files. However, CMS stated that it is developing an automated process to reduce its reliance on manual processes.

CMS makes limited use of its online ASP system for oversight

CMS has not leveraged its online ASP data collection system in ways that would assist with oversight. CMS produces a small number of reports from this system to track manufacturer data submissions. Specifically, each quarter CMS generates a report that identifies manufacturers that submitted their ASP data after the deadline. CMS generates two additional reports that contain (1) a single manufacturer's entire submission for the quarter and (2) all manufacturer submissions for a quarter. However, these reports enable CMS to review only data completeness in a single quarter rather than identify trends of problematic data and associated manufacturers over time. CMS stated that it can request custom reports from the ASP system, but it does not regularly generate reports that could help it conduct more targeted oversight.

Although CMS does not make extensive use of the ASP system's reporting function, it has incorporated several edits into the system to evaluate ASP data as manufacturers submit them. For example, CMS has an edit that generates a warning message to a manufacturer that enters an ASP or sales volume value equal to or less than zero. The system does not prohibit manufacturers from entering these values, but rather provides a warning, because values equal to or less than zero may be correct in certain circumstances. For example, we found that 634 NDCs associated with 61 manufacturers had negative ASP data. Some of these may have valid reasons for having negative ASP data—e.g., sales adjustments from previous quarters. However, CMS does not require the manufacturers to explain why negative values may be appropriate. Instead, manufacturers may contact CMS by email to explain these zero and negative values or provide this information as part of the reasonable assumption details they enter into the ASP system. Because these explanations occur over email or in a field in the ASP system not specific to negative values, CMS does not have a single location for manufacturer explanations of potentially problematic data.

Gaps in CMS's oversight of ASP data have resulted in it implementing incorrect Part B payment amounts

CMS did not accurately implement all price reductions, which are an important tool to lower prescription drug costs. Gaps in CMS's oversight processes prevented the program and its enrollees from realizing millions in savings.

CMS did not correctly implement reductions in Part B payment amounts for multiple drug codes; this resulted in a loss of $2.8 million in savings to Medicare and its enrollees.[16, 17] CMS reported that the errors in the Part B payment amounts occurred because its staff manually entered data from the wrong spreadsheet column when it created the payment file.

It was OIG analysis, in February 2022, that alerted CMS that it may have incorrectly implemented price reductions for seven drug codes in the third quarter of 2020. OIG recommended that CMS reduce the price for these seven codes. In response, CMS decided to use the lower AMP-based payment amount rather than the higher ASP-based payment amount. However, CMS then confirmed that it set incorrect—and higher—Medicare payment amounts for these seven drug codes.

- OIG determined that CMS set the Medicare payment amounts for two drugs at 106 percent of the ASP rather than at 103 percent of the AMP—the lower amount for which CMS substitutes ASP in response to OIG's quarterly recommendations.
- Also, OIG determined that CMS implemented incorrect—and smaller—payment amount reductions for five additional drugs. For these five drug codes, CMS erroneously set the payment amounts at 100 percent of ASP rather than the correct amount—103 percent of AMP.

In March 2022, CMS eventually corrected the second-quarter 2021 payment amounts for the seven drugs.[18] The payment amount reductions that CMS made based on this inaccurate 2020 ASP data caused it to achieve less than $10,000 in actual savings—and not the millions that it should have saved. This is the lowest savings amount CMS achieved since it implemented payment amount reductions in 2013. This recent occurrence is not the only instance of OIG identifying errors in CMS-established drug payment amounts. OIG identified 41 NDCs from calendar year 2018 with errors in the ASP data.[19] These errors included problems with the package quantity, a value CMS enters based on manufacturer-reported data. For 7 of the 41 errors, CMS confirmed that these errors impacted the accuracy of its calculation of drug code payment amounts. CMS stated that it subsequently corrected these payment amounts. In 2017, OIG notified CMS of an error CMS made in the payment amount for one drug code. For this code, CMS set the payment amount at 106 percent of ASP rather than the amount at which it should have been set—103 percent of AMP.[20]

In addition to finding errors in CMS-established drug payment amounts, OIG has identified potential errors in CMS's background and code pricing files, for over 10 years, and notified CMS of these potential errors. For some of these errors, CMS

has corrected the data values stored in these files. For others, CMS stated that when it has faced time and resource constraints, certain data fields receive less emphasis in its quality control checks because they do not directly impact the calculation of the payment amount.

Because of invalid or missing ASP data, CMS could not calculate an ASP-based payment amount for 8 percent of drug codes at least once between 2016 and 2020

For 8 percent (59 of 780) of drug codes in our review, CMS could not calculate an ASP-based payment amount in at least 1 quarter of our 5-year timeframe because there were no valid ASP data for any of NDCs associated with these drug codes. Specifically, CMS was unable to calculate an ASP-based payment amount for these drugs due to several reasons. These reasons included that (1) the manufacturer reported negative sales or ASP value; or (2) the manufacturer had no sales to report for that quarter.

CMS uses the ASP payment methodology as a cost-containment measure. However, if the ASP data are not available, CMS must use an alternative payment methodology (WAC for these drugs) to determine the Part B payment amount. Because WAC amounts represent manufacturers' published catalog price for sales of a drug to wholesalers and do not include manufacturer discounts, they are often higher than the ASP. CMS set a WAC-based payment amount in at least 1 quarter for all 59 drug codes for which it did not set an ASP-based payment amount.

Nearly one quarter of drug codes were missing some ASP data in at least one quarter between 2016 and 2020

Twenty-four percent of drug codes (190 of 780) were associated with at least 1 NDC that CMS classified as having ASP data missing. In total, there were 614 NDCs with missing data associated with these drug codes. Over half of these NDCs had data missing in three or more quarters over the 5 years reviewed. Overall, over one-fifth of the 614 NDCs had 4 or more quarters of missing data. CMS reports that there may be valid reasons for some NDCs with missing ASP data—e.g., the manufacturer did not produce the drug that quarter, or there may be problems with the manufacturer's supply or distribution. However, CMS's missing status indicator does not distinguish the reasons for missing ASP data.

Missing data frequently did not prevent CMS from implementing an ASP-based payment amount. For 178 of these 190 drug codes, CMS implemented an ASP-based payment amount that excluded the NDCs with missing ASP data.[21] In total, 582 NDCs with missing data were associated with these 178 drug codes. A total of 33 manufacturers produced NDCs that were missing data in 4 or more quarters.

Missing data can affect expenditures for both the program and its enrollees. For drug codes with missing ASP data, CMS is not able to calculate a comprehensive drug payment amount, which is a cause for concern. As a result, CMS may set a payment amount that is not reflective of the market and may result in CMS and enrollees paying more for a Part B drug. Moreover, the frequency with which some manufacturers repeatedly do not provide required ASP data is cause for even greater concern.

CMS reported challenges that hinder its ability to conduct oversight of ASP data

CMS reported challenges to ensuring the accuracy of ASP data. CMS reported that manufacturers' failure to meet data reporting deadlines was a challenge—in fact, the most significant challenge it faces. CMS also reported the lack of authority to compel manufacturers to respond to questions about inaccurate data as a challenge, but noted that it was not as significant a challenge as late data submissions. Both late and inaccurate data may hinder CMS's ability to ensure complete and accurate quarterly calculations of Part B payment amounts.

Late ASP data submissions from manufacturers substantially hindered CMS's ability to ensure the receipt of timely and accurate ASP data

When manufacturers submit their ASP data late, CMS must devote its staff resources and limited time to request and obtain the required data from manufacturers. This reduces the already limited time that CMS has to calculate and publish Part B payment amounts for the quarter. Further, CMS reported that very few staff members are primarily responsible for completing this intensive process. In 2022, CMS hired two additional staff to review ASP data and calculate ASP-based payment amounts.

CMS must complete its data collection, analysis, and quality control process to calculate Part B payment amounts in less than 2 months. To illustrate, ASP data for the first quarter of calendar year 2022 were due to CMS by April 30, 2022, i.e., 30 days from the end of the previous quarter. CMS then had approximately 5 weeks to (1) calculate the ASP-based Medicare payment amounts; (2) develop its payment files; and (3) complete its entire review and analysis process in time to publish the Part B payment amounts in early June. Once CMS publishes its payment files on its website, CMS affords manufacturers and the public an opportunity to identify and correct potential errors. CMS also aimed to provide 2 weeks for the Medicare Administrative Contractors to test the files in advance of the effective date of July 1, 2022.

CONCLUSION AND RECOMMENDATION

To protect the Medicare program and its enrollees, it is vital that CMS conduct robust oversight to ensure the accuracy of ASP data. CMS has opportunities to improve its oversight of manufacturer-reported ASP data and reduce the likelihood of paying inappropriately for prescription drugs. Our findings indicate that while CMS has some oversight procedures in place (e.g., system edits in the ASP data collection system and CMS's internal reviews of manufacturer data), it allowed inaccurate data to impact Medicare Part B payment amounts.

Gaps in CMS's own internal control processes resulted in the implementation of incorrect Part B drug payment amounts by CMS. The challenges that CMS faces—including late submissions from manufacturers and the inability to compel manufacturers to submit accurate data—hinder CMS's ability to include all ASPs for NDCs that are associated with a drug code in its payment amount calculations. This lack of ASP inclusivity can impact the payment amount implemented for drug codes because it may result in inaccurate Medicare Part B payment amounts.

Taken together, the vulnerabilities in CMS's processes, coupled with the errors OIG has identified, highlight the need for CMS to strengthen its oversight of ASP data. For over 5 years, OIG has identified potential errors in CMS's pricing files and notified CMS of these potential errors. For some of these errors, CMS has corrected the data values stored in these files. For other errors, CMS reported that time and resource constraints may limit its quality control checks of certain data fields. Although CMS has corrected some of these errors, its oversight processes do not seem to enable CMS to identify data errors independently.

Given the cost and importance of these life-saving drugs, it is vital that CMS conduct robust oversight to ensure that Medicare makes appropriate payments for Part B-covered drugs. The recommendation that follows aims to promote accurate Medicare Part B drug payment amounts and aid CMS in its efforts at improving ASP data accuracy.

We recommend that CMS:

Build a strategy to strengthen its internal controls for ensuring the accuracy of Part B drug payments

CMS could implement additions to its oversight procedures to reduce the likelihood of errors in collecting ASP data and calculating Medicare payment amounts. These additions could include:

- new or more enhanced quality checks of manual data processes;

- new reports generated from the ASP system that CMS could use to enhance its oversight of manufacturer reporting of ASP data manufacturers that may be submitting inaccurate ASPs (e.g., the ASP reported exceeds the WAC reported by the manufacturer in the ASP system); and
- processes for correcting potential errors in its data files.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with our recommendation. In its comments, CMS noted that there can be valid reasons for using a WAC-based payment amount and valid reasons for which manufacturers may have missing ASP data. OIG agrees and has included this context in our report.

CMS stated that it believes ASP reporting is consistent with statutory requirements and results in the determination of accurate payment limits, but that it shares OIG's concerns about the potential impact that missing or inaccurate ASP data could have on Medicare Part B payment amounts.

In response to our recommendation, CMS reported that it will identify ways to strengthen its internal controls and is working on enhancements to (1) the current ASP system and (2) its internal processes. CMS also stated that it will consider OIG's suggestions as it continues to make enhancements in the area of ASP data.

For the full text of CMS's comments, please see the Agency Comments appendix at the end of the issue brief.

METHODOLOGY

Data Sources

To identify CMS's oversight activities for manufacturer-reported ASP data, we received documentation from CMS that outlined its oversight procedures, including its internal controls, for ASP data submissions. We also received from CMS documentation that described its methods for determining which NDCs to include in the calculation of the Medicare payment amount.

In addition, we interviewed CMS to collect information related to its policies and procedures to ensure the accuracy of ASP data. We asked CMS to describe its:

- oversight procedures to identify and correct inaccurate ASP data;
- challenges in conducting effective oversight and whether any additional tools, resources, or authorities would bolster its oversight procedures; and
- process for assigning status indicator values to NDCs.

We obtained CMS's background files and the code pricing files for 2016 through 2020. CMS creates these files each quarter. The background file contains manufacturer-reported ASP data for each NDC, including ASP and sales volume. The background file also includes information entered by CMS, including the status indicator, package size, and package quantity. The code pricing file contains the Medicare payment amount for the drug code and the payment methodology used to calculate the payment amount for the drug code.

We used CMS's database of drug manufacturers that have entered into a Medicaid National Drug Rebate Agreement —found online at Medicaid.gov—to identify the drug manufacturer associated with each NDC. This file contains the labeler code, i.e., the first five digits of an NDC, for each manufacturer that is required to report ASP data. We used this file to ensure that the manufacturer was required to report ASP data in a specific quarter.

We obtained from the Food and Drug Administration's (FDA's) website the NDC SPL Data Elements File (FDA's NDC file). FDA's data include the date on which a manufacturer started marketing a product and, where applicable, the expiration date of the last lot distributed. We used this file to ensure that the drugs under review were on the market at the time at which data submitted by manufacturers were missing or negative.

Data Analysis

Review of CMS's Oversight Procedures and Challenges. We reviewed the documentation CMS submitted and its responses to our interview questions to identify its oversight methods, including its internal controls. We identified potential vulnerabilities that may inhibit its ability to ensure the accuracy of ASP-based payment amounts. We further identified some of the effects of potential vulnerabilities. We reviewed the challenges CMS faces in conducting effective oversight. We reviewed the tools, resources, and authorities that CMS currently uses to collect and analyze data as well as any new tools, resources, or authorities that CMS stated would bolster its oversight processes.

Review of ASP Data. We used the code pricing file to first identify all drug codes that had an ASP-based payment amount for at least one of the quarters under review. We determined the number of these drug codes for which CMS did not calculate an ASP-based payment amount in at least one quarter because none of the ASP submissions were deemed valid by CMS. To do this, for each quarter, we identified drug codes for which all associated NDCs were assigned a status indicator value other than "D." For the drug codes for which CMS did calculate an ASP-based payment amount in at least one quarter during our timeframe, we determined the frequency of the alternative payment methodologies implemented by CMS when it did not calculate an ASP-based payment amount. We did not include in this count drugs for which the only WAC-based payment amounts occurred in the first two quarters the drug was reported during the timeframe under review. This was because a manufacturer may not have complete sales data for new drugs and, therefore, may not be able to report ASPs. We also did not include in this count the drug codes for which the manufacturers of the associated NDCs were not required to report ASP data. To identify these drugs, we determined whether the associated NDCs were produced by manufacturers with a Medicaid drug rebate agreement. To do this, we compared the NDCs in the ASP files to the NDCs in CMS's drug manufacturer database. If none of the NDCs were associated with manufacturers that had an active Medicaid drug rebate agreement in effect, we concluded that the manufacturer was not required to report ASP data to CMS during the periods under review.[22]

We used status indicator values to identify the number of drug codes and NDCs associated with missing ASP and sales volume values. In each quarter under review, we counted the number of drug codes for which at least one NDC associated with that code was missing ASP data (i.e., the status indicator value was "M"). We also identified the frequency of missing submissions as well as the number of manufacturers associated with the missing data submissions. For these NDCs, we reviewed a combination of the background file, FDA's NDC file, and CMS's drug manufacturer database to determine whether (1) the manufacturer associated with the NDC was required to report ASP data to CMS and (2) the drug was on the market.

Limitations

We did not verify the accuracy of the manufacturer-reported data submitted to CMS by manufacturers.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

APPENDIX

Appendix A: Agency Comments

Following this page are the official comments from CMS.

DATE: December 9, 2022

TO: Ann Maxwell
Deputy Inspector General for Evaluation and Inspections
Office of Inspector General

FROM: Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Issue Brief: CMS Should Bolster Its Oversight of Manufacturer-Submitted ASP Data to Ensure Accurate Part B Drug Payments (OEI-03-21-00390)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report.

CMS serves the public as a trusted partner and steward, dedicated to advancing health equity, expanding coverage, and improving health outcomes. As such, CMS strives to maximize the affordability and availability of drugs for individuals with Medicare while protecting taxpayer dollars. CMS uses manufacturer reported average sales price (ASP) product data to calculate Part B drug payment limits. Manufacturer reported data is vetted by CMS to verify that the reported values are consistent with the reported quantity of the drug. For example, files are reviewed to identify outliers and potential discrepancies are addressed on a case by case basis. Additionally, CMS works with manufacturers to mitigate and address concerns identified with the data. This includes providing technical assistance when manufacturers inquire about how to properly report their data.

OIG has provided CMS with a list of the 59 drug codes for which CMS did not calculate an ASP-based payment amount in at least one quarter of the five-year audit timeframe. CMS has completed an initial review of the codes and found legitimate reasons for the decision to not calculate an ASP-based payment amount (for example, the code was not active during the entire period of the study, there were zero or negative sales data reported, etc.). Based on the initial review, CMS continues to believe that ASP reporting is consistent with statutory requirements and results in the determination of accurate payment limits under section 1847A of the Social Security Act.

In addition, CMS would like to clarify that the OIG's report references invalid ASP data and defines "invalid ASP data" for purposes of the report as ASP data equal to or less than zero. Zero and negative sales data may be valid; however, we do not include them in volume weighted

calculations because there is no impact of including zeros in volume weight calculations and including that data can also cause "divide by zero" errors. When manufacturers have negative or zero sales, they should report that data, as it is valid ASP data. Also, CMS does not include negative sales, because it may lead to skewed results.

OIG also noted that they identified drugs associated with missing data values. CMS would like to clarify that there could be several legitimate reasons for missing data for certain drugs on the file such as skin substitutes, generics, repackagers, transferred and deactivated National Drug Codes (NDCs). CMS notes that missing data values may or may not be reflective of non-compliance with ASP reporting. For example, not all drug manufacturers will have sales in every quarter. Many skin substitute products have low sales volume with multiple patch sizes and not all the patch sizes are sold every quarter. Similarly, for repackagers there are multiple bottles with low volumes and all sizes may not sell every single quarter.

We appreciate the OIG's work on this area and look forward to working collaboratively on this and other issues in the future.

The OIG's recommendations and CMS' responses are below.

OIG Recommendation

The OIG recommends that CMS build a strategy to strengthen its internal controls for ensuring the accuracy of Part B drug payments.

CMS Response

CMS concurs with this recommendation and is committed to ensuring the accuracy of Medicare Part B drug payments. While we believe that ASP reporting is consistent with statutory requirements and results in the determination of accurate payment limits under section 1847A of the Social Security Act, we understand and share OIG's concerns about the potential impact that missing or inaccurate ASP data could have on Medicare Part B payment amounts. As such, we are proactively looking for ways to strengthen our internal controls and are actively working on enhancements to the current ASP system and internal processes. We will take OIG's suggestions into considerations as we continue to make enhancements in this area.

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

Conswelia McCourt served as the team leader for this study. Others in the Office of Evaluation and Inspections who conducted the study include Emily A. Dieckman, Amy Sernyak, and Karolina Hill. Office of Evaluation and Inspections headquarters staff who provided support include Michael Novello and Melissa Baker.

This report was prepared under the direction of Linda Ragone, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Edward K. Burley, Deputy Regional Inspector General.

Contact

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ABOUT THE OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the healthcare industry concerning the anti-kickback statute and other OIG enforcement authorities.

ENDNOTES

[1] Division CC, Title IV, Section 401(d), of the Consolidated Appropriations Act, 2021, P.L. No. 116-260 (Dec. 27, 2020).

[2] 42 CFR § 414.900(b) and CMS, *Medicare Benefit Policy Manual*, Pub. No. 100-02, ch. 15 § 50.

[3] Section 1847A(c) of the Social Security Act (the Act).

[4] Pursuant to section 1927(b)(3) of the Act, manufacturers that have a rebate agreement to participate in the Medicaid Drug Rebate Program are required to report ASP data. Pursuant to section 1874A(f)(2) of the Act, beginning on January 1, 2022, manufacturers without a drug rebate agreement are also required to report ASP data. Division CC, Title IV, Section 401, of the Consolidated Appropriations Act, 2021, P.L. No. 116-260 (Dec. 27, 2020).

[5] An NDC is a code used to identify a drug based on its manufacturer, product, and package size. Multiple NDCs may be associated with a single drug code.

[6] In addition to the information it receives from manufacturers, CMS stated that it verifies manufacturer-reported data against sources such as *Redbook* and *DailyMed* to determine package size and quantity.

[7] Section 1847A(c)(6)(B) of the Act defines WAC as the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, not including certain price reductions or rebates, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data.

[8] The manufacturer must certify all revised and resubmitted data as accurate and complete.

[9] CMS, *Medicare Part B Drug Average Sales Price*, https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice, accessed October 11, 2022.

[10] OIG, Workplan Summary: *Accuracy of Manufacturer-Reported Average Sales Pricing*, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000616.asp, accessed October 11, 2022.

[11] OIG, *Some Manufacturers Reported Inaccurate Drug Product Data to CMS*, OEI-03-19-00200, September 2020.

[12] OIG, *Average Sales Prices: Manufacturer Reporting and CMS Oversight*, OEI-03-08-00480, February 2010.

[13] OIG, *Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs*, OEI-12-13-00040, July 2014.

[14] Pursuant to section 1874A(f)(2) of the Act, beginning on January 1, 2022, manufacturers without a drug rebate agreement are required to report ASP data like manufacturers with such an agreement. Division CC, Title IV, Section 401, of the Consolidated Appropriations Act, 2021, P.L. No. 116-260 (Dec. 27, 2020).

[15] OIG, *Medicare Part B Drug Payments: Impact of Price Reductions Based on 2020 Average Sales Prices*, OEI-03-22-00170, September 2022.

[16] OIG, *Medicare Part B Drug Payments: Impact of Price Reductions Based on 2020 Average Sales Prices*, OEI-03-22-00170, September 2022.

[17] To calculate savings, we used Part B utilization data obtained in January 2022. CMS implemented the correction to the second-quarter 2021 payment amounts in March 2022. Therefore, any claims for the drugs associated with incorrect payment amounts billed after CMS implemented the corrected payment amounts would not be included in our calculation of savings. CMS reported that it calculated lost savings that were 2 percent or approximately $53,500 less than OIG's calculation of lost savings.

[18] Although CMS corrected these payment amounts for these drugs in its payment files, it stated that it will not take action to retroactively reduce the payment amounts for these drugs on second-quarter 2021 claims paid prior to the payment correction implemented in March 2022.

[19] OIG, *Some Manufacturers Reported Inaccurate Drug Product Data to CMS*, OEI-03-19-00200, September 2020.

[20] OIG, *Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2015 Average Sales Prices*, OEI-03-17-00360, September 2017.

[21] For 10 of the remaining 12 drug codes, CMS based the Medicare payment amount on WAC for the quarters in which associated NDCs were missing data. For the other two drug codes, CMS did not publish a Medicare payment amount for the quarters in which associated NDCs were missing data.

[22] Pursuant to section 1874A(f)(2) of the Act, beginning on January 1, 2022, manufacturers without a drug rebate agreement are required to report ASP data like manufacturers with such an agreement. Division CC, Title IV, Section 401, of the Consolidated Appropriations Act, 2021, P.L. No. 116-260 (Dec. 27, 2020).