U.S. Department of Health and Human Services
Office of Inspector General
Data Snapshot
September 2020, OEI-03-19-00200

Some Manufacturers Reported Inaccurate Drug Product Data to CMS

What OIG Did

The Office of Inspector General (OIG) conducted a review of the accuracy of average sales price (ASP) product data and average manufacturer price (AMP) product data for 1,345 National Drug Codes (NDCs) associated with drugs covered by Medicare Part B for 2018. (Drugs covered by Part B are generally those that are injected or infused in physicians' offices or hospital outpatient settings.) We identified these out of a total of 3,527 NDCs associated with Part B-covered drugs for which manufacturers submitted both ASP data and AMP data for that year. For Part B-covered drugs, the Centers for Medicare & Medicaid Services (CMS) uses manufacturer-reported ASP pricing and product data to determine reimbursement amounts. For Medicaid-covered drugs, CMS uses manufacturer-reported AMP pricing and product data to calculate the statutorily required Medicaid rebates that reduce the net cost of those drugs.

To assess the accuracy of ASP and AMP product data, we compared (1) the package size and package quantity that manufacturers reported as part of the ASP product data against the drugs' labels, drug package inserts, and drug manufacturers' websites (hereinafter referred to as "publicly available sources"); (2) the unit type and units per package size that manufacturers reported as part of the AMP product data against the information listed in publicly available sources; and (3) the package size that manufacturers reported as part of the ASP product data against the unit type reported with the AMP product data.

Key Takeaway

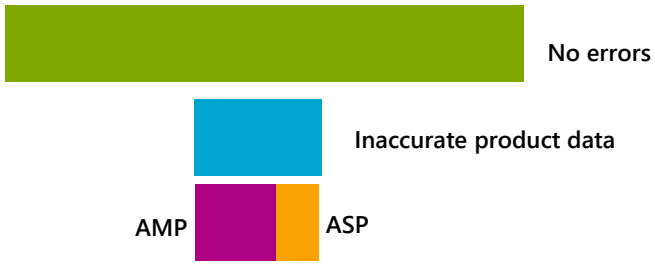
Some manufacturers reported inaccurate product data that could result in inaccurate Medicare reimbursement and Medicaid rebates amounts.

Results

Manufacturers reported inaccurate drug product data for 14 percent of NDCs associated with Part B-covered drugs

- Manufacturers' product data contained an error in at least 1 quarter of 2018 for 14 percent of the NDCs we reviewed (192 of 1,345).
- Across the four quarters of 2018, manufacturers inaccurately reported product data 581 times for these 192 NDCs.
- Most of these errors (151 of 192) were associated with only AMP product data, e.g., the unit type and/or units per package size reported with AMP data did not correspond to the package size and/or package quantity from publicly available sources.
- There were 41[1] NDCs with errors in the ASP product data reported by manufacturers.
- In 2018, manufacturers corrected product information in a subsequent quarter for only 35 NDCs or 18 percent of those associated with an error.

Exhibit 1: Manufacturers reported inaccurate product data found for 192 NDCs



Source: OIG analysis of ASP and AMP product data, 2019.

Twenty-four percent of all manufacturers reported inaccurate drug product data

- Twenty-four percent of all manufacturers—43 of 182—were associated with inaccurate drug product data.
- These errors could result in inaccurate payment amounts and fewer price substitutions in Medicare Part B, as well as inaccurate rebates in Medicaid.
- Eight manufacturers accounted for 60 percent of the reported errors.
- These eight manufacturers reported between 10 and 23 errors each.

Why this Matters

CMS uses ASP and AMP product data to determine overall reimbursement in both Medicare and Medicaid. Medicare Part B and Medicaid expenditures for prescription drugs total nearly $100 billion each year. In Medicare Part B, CMS uses ASP to directly calculate drug reimbursement amounts paid to providers. When these data are not accurate, Medicare and its beneficiaries may make inaccurate payments for drugs. In Medicaid, CMS uses AMP product data to determine the rebate amounts owed by manufacturer for covered drugs. The Medicaid rebate program is an important cost-containment tool that offsets State and Federal expenditures for most prescription drugs. If this product data is incorrect, Medicaid may collect inaccurate rebates from manufacturers and not reap the program's full benefits.

In addition, when Congress established ASP as the basis for Part B drug reimbursement, it provided a mechanism for monitoring market prices and limiting potentially excessive ASP-based payment amounts. This mechanism requires OIG to conduct a comparison of quarterly ASP and AMP product data—the results of this comparative analysis can trigger reductions in Part B reimbursement for certain drugs. If the ASP and AMP data—which include the prices and product data such as package size and package quantity—are incorrect, this can lead to inaccurate comparisons or the exclusion of certain drugs from the comparative analysis, which can, in turn, potentially lead to fewer price substitutions and higher costs. For 2018 data, OIG was not able to complete mandated analysis for price substitution for 44 Part B drug procedure codes[2] because of questionable product data reported for 1 or more of the NDCs associated with the procedure code.

What OIG Recommends

To ensure the accuracy of manufacturer-reported data, Part B reimbursement amounts, and Medicaid rebate amounts, CMS should:

Work with the manufacturers associated with errors to correct and resubmit accurate product data.

We will provide CMS the list of NDCs and manufacturers associated with inaccurate product data. After reviewing this information, CMS should work with these manufacturers to update and revise their product data—fixing actual errors and discrepancies—and take steps to ensure that future submissions are correct. Given the various ways that ASP and AMP product data potentially impact Medicare reimbursement and Medicaid rebate amounts, it is vitally important that manufacturers provide CMS with accurate ASP and AMP product data.

Agency Comments and OIG Response

CMS did not explicitly concur or nonconcur with OIG's recommendation for it to work with manufacturers associated with errors to correct and resubmit accurate product data. Although CMS did not explicitly concur with the recommendation, it outlined actions that it has taken and actions that it plans to take to achieve the recommendation's goal of ensuring that manufacturers submit accurate product data. CMS emphasized that the potential inconsistencies between the manufacturer-reported data and the publicly available sources that OIG used do not necessarily indicate that the ASP or AMP data, or the associated payment or rebate amounts, are incorrect. CMS said that for example, it has reviewed the OIG-identified inconsistencies associated with the ASP product data identified in this report and found that only 7 out of 41, or just 17 percent, of OIG-identified NDCs impacted pricing and that the overall impact on pricing appeared to be minimal. CMS reported that each of the errors has been addressed and updates are reflected in the July 2020 ASP drug pricing file. CMS also stated that it will review OIG-identified inconsistencies in AMP product data and address any errors that affect rebate amounts.

OIG appreciates the efforts that CMS has taken to work with manufacturers to ensure that pricing and rebate data are accurate. We agree with CMS that inaccurate ASP and AMP product data may not always result in incorrect Part B payment amounts or rebate amounts. However, the results of CMS's review indicate that in some instances these product data inaccuracies *did* result in incorrect payment amounts being established by CMS. OIG encourages CMS to continue its efforts to ensure that all manufacturer-reported product data are accurate. We ask that CMS specify in its Final Management Decision whether it concurs with our recommendation and how it plans to continue its efforts to address inconsistencies in the AMP data. For the full text of CMS's comments, see the Appendix.

Methodology

Data Collection. We obtained 3,527 NDCs associated with Part B-covered drugs for which 182 manufacturers submitted both ASP data and AMP data to CMS in at least 1 quarter of 2018. These data were obtained from CMS and had been used for OIG's mandated ASP and AMP price comparison. In addition to including prices, these data include product data such as the drug's package size, package quantity, unit type, the units per package size, and the manufacturer name. From publicly available sources—including the drugs' labels, drug package inserts, and drug manufacturers' websites—we obtained additional product information to evaluate the accuracy of product data that manufacturers reported to CMS.

Data Analysis. For this in-depth review, we targeted a more limited number of NDCs that may be associated with errors. First, we reviewed all 3,527 NDCs for which manufacturers submitted both ASP and AMP product data to CMS in at least 1 quarter in 2018. To identify ASP and AMP data that had potential errors, we used our previous experience with ASP and AMP data comparisons to develop four review criteria for identifying NDCs with potential errors.

We reviewed the following:

(1) all NDCs that were newly reported to CMS during 2018;

(2) all NDCs for which product data changed or was adjusted in at least 1 quarter of 2018;[3]

(3) outlier NDCs, i.e., those for which the ASP exceeded the AMP by 100 percent or more in at least one quarter, or NDCs for which the ASP was at least 90 percent lower than the AMP in at least one quarter;[4] and

(4) all NDCs associated with a potential price substitution in any quarter, i.e., NDCs associated with procedure codes for which the ASP exceeded the AMP by at least 5 percent and procedure codes that had complete AMP data.[5]

As a result of this analysis, we identified 1,345 NDCs to target for an in-depth review.

For each of these 1,345 NDCs, we compared the following:

(1) the package size and package quantity that manufacturers reported as part of the ASP product data against the package size and package quantity from publicly available sources;

(2) the unit type and units per package size that manufacturers reported as part of the AMP product data against the package size and package quantity from publicly available sources; and

(3) the package size that manufacturers reported as part of the ASP product data against the unit type that manufacturers reported as part of the AMP product data.

We determined the number of NDCs for which the package size and/or package quantity that manufacturers reported as part of the ASP product data did not match the package size and/or package quantity reported in publicly available sources, and we considered these to be errors. We determined the number of NDCs for which the units per package size and unit type that manufacturers reported as part of the AMP product data did not correspond to the package size and/or package quantity reported in publicly available sources, and we considered these to be errors. We then determined the number of NDCs for which the package size that manufacturers reported as part of the ASP data did not correspond to the unit type reported with the AMP data and required an adjustment to ensure an equivalent comparison.[6] For example, if the manufacturer of a drug reported an ASP package size of 1 vial and an AMP unit type of milliliter, the ASP package size would be adjusted to the number of milliliters in the vial. We did not determine the accuracy of the prices in the ASP or AMP data provided by manufacturers.

Finally, we grouped all NDCs associated with an error by the manufacturer name[7] to determine which manufacturers were associated with errors in their product data as well as the number of NDCs associated with each manufacturer. We then determined how many NDCs were associated with corrected product data over the course of 2018.

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.

Acknowledgments

Conswelia McCourt served as team leader for this study. Office of Evaluation and Inspections staff who provided support include Althea Hosein, Christine Moritz, and Michael Novello. This report was prepared under the direction of Linda Ragone, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Edward Burley, Deputy Regional Inspector General.

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Endnotes

[1]Two of these 41 NDCs had both ASP and AMP errors identified.

[2]A procedure code is a standardized billing code that is used primarily to identify products, supplies, and other services. A procedure code specifies the name and the amount of the drug and may represent one or more NDCs.

[3]During OIG's quarterly comparisons of ASP and AMP pricing data, OIG may adjust the reported ASP package size and/or reported package quantity to ensure equivalent comparisons, when applicable.

[4]This includes only outlier NDCs associated with HCPCS codes that had complete AMP data in a quarter.

[5]This includes only NDCs associated with HCPCS codes that had complete AMP data in a quarter.

[6]To ensure that the AMP would be comparable to the ASP, it was necessary to convert the AMP for each NDC so that it represented the total amount of the drug designated by the NDC.

[7]We conducted a manual review of the manufacturer names to determine the unique number of manufacturer names reported with the NDCs under review. In several cases in which the name was similar—but not an exact match—we also reviewed the first five digits of the NDC, i.e., the labeler code. In these specific cases, if the labeler codes matched, we considered these to be the same manufacturer for the purposes of this analysis.

Appendix: Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: September 2, 2020

TO: Suzanne Murrin
Deputy Inspector General for Evaluation and Inspections
Office of Inspector General

FROM: Seema Verma
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Data Snapshot: Some Manufacturers Report Inaccurate Drug Product Data to CMS (OEI-03-19-00200)

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 strives to maximize the affordability and availability of drugs for Medicare and Medicaid beneficiaries while protecting taxpayer dollars. CMS uses manufacturer reported average sales price (ASP) and average manufacturer price (AMP) product data to calculate Part B drug payment limits and Medicaid rebate amounts respectively. 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 and the states work with manufactures to mitigate and address concerns identified with the data. For example, CMS provides technical assistance when manufacturers inquire about how to properly report their data and when states inquire about potential discrepancies in the data.

CMS would like to emphasize that the potential inconsistencies between the publicly available sources utilized by the OIG and the manufacturer reported data do not necessarily indicate that the ASP or AMP data, or the associated payment or rebate amounts, are incorrect. For example, CMS has reviewed the inconsistencies identified by OIG associated with the ASP product data identified in this report and found that only seven out of 41, or just 17 percent, of the National Drug Codes (NDCs) identified by the OIG impacted pricing and that the overall impact on pricing appeared to be minimal. Based on the information in this report, 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.

OIG's recommendation to CMS and CMS's response are below.

OIG Recommendation
The OIG recommends that CMS work with the manufacturers associated with errors to correct and resubmit accurate product data.

CMS Response

As stated above, there are processes in place to promote the accuracy of manufacturer reported data. CMS has reviewed the inconsistencies identified by OIG associated with the ASP product data identified in this report and found that only seven out of 41, or just 17 percent, of the NDCs identified by the OIG impacted pricing and that the overall impact on pricing appeared to be minimal. Each of the errors has been addressed and updates are reflected in the July 2020 ASP drug pricing file.[1] Based on the information in this report, 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.

CMS will review the inconsistencies identified by OIG associated with the AMP product data and will address any actual errors or discrepancies that affect rebate amounts.

CMS thanks the OIG for their efforts on this issue and looks forward to working with OIG on other issues in the future.

[1] https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2020-asp-drug-pricing-files