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DATA BRIEF

September 2026 | OEI-03-26-00080

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2024 Average Sales Prices

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Why OIG Did This Review

- Medicare Part B annually spends billions of dollars to cover a limited number of outpatient prescription drugs. To safeguard Medicare and its enrollees from excessive payment amounts, Congress established a mechanism for monitoring market prices whereby OIG identifies and refers to CMS Part B drugs with prices that exceed a specific threshold every quarter. CMS then applies its price-substitution policy to lower payment amounts for these drugs.
- This data brief is one in a series of annual reports that quantifies the savings to Medicare and its enrollees that result from CMS applying its price-substitution policy to drugs identified and referred by OIG.

What OIG Found

CMS's application of its price-substitution policy to drugs identified and referred by OIG has saved Medicare and its enrollees $78 million since 2013, including $1.6 million for 2024.

Since CMS instituted its price-substitution policy in 2013, CMS has implemented price substitutions for 101 drugs that OIG identified and referred to CMS. Price substitutions for 14 drugs based on 2024 data saved Medicare and its enrollees $1.6 million over 1 year.

Potential errors in the average manufacturer price (AMP) data submitted to CMS prevented OIG from determining whether 31 drugs qualified for a price substitution.

When OIG identifies potential errors during its quarterly analysis of the average sales price (ASP) and AMP data, it notifies CMS and requests that CMS review the accuracy of the manufacturers' data. If the drug data were correct, OIG could determine whether to recommend additional drugs for price substitutions, which would further reduce costs to Medicare and its enrollees.

What OIG Concludes

Since 2013, CMS has lowered prescription drug costs by $78 million by applying its price-substitution policy to 101 drugs identified and referred by OIG while maintaining access to lifesaving drugs for Medicare and its enrollees. We encourage CMS to continue to work with manufacturers to review and respond to potential errors in the drug data identified by OIG each quarter to bolster the effectiveness of the price-substitution policy. These potential errors could limit the effectiveness of the price-substitution policy by reducing the number of drugs eligible for a price substitution because of concerns about the accuracy of the underlying data. This data brief contains no recommendations.

Primer: Medicare Part B Coverage and Payment for Prescription Drugs

In 2024, Medicare Part B and its enrollees spent $61 billion on a limited number of covered 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. 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. Under the ASP pricing methodology, the Medicare reimbursement for most Part B drugs is equal to 106 percent of the volume-weighted ASP for the drug.

Price Substitutions. When Congress established ASPs as the basis for reimbursement for Medicare Part B drugs, it also provided a mechanism for monitoring market prices and limiting potentially excessive payment amounts. The Social Security Act (the Act) mandates that the Office of Inspector General (OIG) compare ASPs with average manufacturer prices (AMPs). If OIG finds that the ASP for a drug exceeds the AMP by 5 percent, the Act directs the Secretary of Health and Human Services to substitute the ASP-based payment amount with a lower calculated rate based on AMPs.[1]

Through regulation, CMS stated that it would make this substitution only if the ASP for a drug exceeds the AMP by 5 percent in the two previous consecutive quarters or three of the previous four quarters. CMS lowers reimbursement amounts only when ASP and AMP comparisons are based on the same set of drug products (i.e., based on complete AMP data).[2] To prevent CMS from inadvertently raising the Medicare reimbursement amount, a price substitution is not implemented if the substituted amount would exceed the ASP-based payment amount for the quarter in which the price substitution would take effect. In addition, price substitutions are not implemented for drugs that the Food and Drug Administration (FDA) identifies as being in short supply.

Related Work. In four quarterly memos based on data from 2024, OIG (1) identified and referred to CMS the Part B drugs eligible for price substitutions and (2) notified CMS of potential errors in CMS's ASP and AMP data.[3] This annual report summarizes the results of those four quarterly memos.

For each quarter, OIG notifies CMS about the potential errors that it identifies in the ASP and AMP data and asks CMS to review them and provide responses so that we can incorporate CMS's responses into our analysis of the next quarter's data. CMS, in turn, works to review and correct the potential errors, including coordinating with manufacturers when needed.

FINDINGS

CMS's application of its price-substitution policy to drugs identified and referred by OIG has saved Medicare and its enrollees $78 million since 2013, including $1.6 million for 2024.

Since 2013, CMS has implemented price substitutions for 101 drugs identified and referred by OIG. These price substitutions have saved Medicare and its enrollees $78 million. For 2024, CMS initiated price substitutions for 14 drugs identified and referred by OIG that saved Medicare and its enrollees $1.6 million over 1 year.[4] See the Appendix for a list of these drugs.

Potential errors in the AMP data submitted to CMS prevented OIG from evaluating the eligibility of 31 drugs for price substitution.

OIG identified 31 drug codes that had potential errors—in either the drug's unit type for the AMP or the drug's AMP amount—that could result in an incorrect price substitution. When OIG identifies potential errors during its quarterly analysis of the ASP and AMP data, it notifies CMS and requests that CMS review the accuracy of the manufacturers' data. In addition, OIG does not include these drugs with potential errors in its price substitutions.[5] OIG takes this approach to prevent price substitutions based on potentially incorrect data. If CMS lowered payment amounts on the basis of incorrect data, it might inappropriately lower the Medicare payment amount and limit enrollees' access to these drugs.

Seven of these 31 drugs with potential errors met the 5-percent threshold in at least 1 quarter. If CMS were to confirm the accuracy of the manufacturers' data, OIG would be able to recommend more drugs for price substitutions, which would further reduce costs to Medicare and its enrollees.

For the majority of these 31 drugs with potential errors in the manufacturer-reported AMP data, OIG identified the potential errors multiple times during its review of 2024 data. Specifically, for 17 of the 31 drugs, OIG reported the potential errors to CMS for at least 3 quarters of 2024. Furthermore, of these 17 drugs, 15 had potential errors in at least 5 of the previous 12 quarters.

CONCLUSION

Since 2013, CMS has lowered prescription drug costs by $78 million by applying its price-substitution policy to 101 drugs identified and referred by OIG while maintaining access to lifesaving drugs for Medicare and its enrollees.

Throughout 2025, CMS corrected potential errors identified by OIG each quarter, sometimes coordinating with manufacturers when needed. We encourage CMS to continue to work with manufacturers to review and respond to potential errors in the drug data identified by OIG each quarter to bolster the effectiveness of the price-substitution policy. If the ASP and/or AMP data OIG uses in its calculations of payment amounts are incorrect, this can lead to inaccurate comparisons or the exclusion of certain drugs from OIG's analysis, which can, in turn, potentially lead to fewer price substitutions and higher costs. These potential errors could limit the effectiveness of the price-substitution policy by reducing the number of drugs eligible for a price substitution because of concerns about the accuracy of the underlying data.

METHODOLOGY

Data Collection

We obtained national drug code (NDC)-level ASP data and AMP data for Part B drugs from CMS for 2024. We obtained data identifying the drugs that had price substitutions based on ASP data from 2024. We also obtained ASP-based reimbursement amounts and Part B drug utilization data for the quarters in which price substitutions occurred—i.e., the fourth quarter of 2024 through the third quarter of 2025. In addition, we compiled a list of drug codes that had potential errors in the AMP data for each quarter of 2024 and identified how many of these potential errors occurred multiple times from 2022 through 2024. We also identified which of these drug codes with potential errors met the threshold for a price substitution.

Data Analysis

For each quarter of 2024, we calculated the volume-weighted AMP for drugs consistent with CMS's methodology for calculating volume-weighted ASPs. We then compared the volume-weighted ASPs and AMPs and identified all drugs with ASPs that exceeded the AMP by at least 5 percent.

To calculate the savings associated with price substitutions, we first reduced AMP-based and ASP-based reimbursement amounts (103 percent of the volume-weighted AMP and 106 percent of the volume-weighted ASP, respectively) by the 2 percent required by sequestration. After making the appropriate reductions resulting from sequestration, we subtracted the AMP-based reimbursement amount from the ASP-based reimbursement amount for the quarter in which the price substitution occurred. We then multiplied this difference by each drug's Part B utilization for the quarter(s) in which the price substitution occurred.

We determined the number of drug codes that had a potential error in at least one quarter of their drug data for 2024.[6] For these drug codes, we determined how often the potential errors occurred and how many of these drug codes met the 5-percent threshold but were not recommended for price substitution because of these potential errors.

Limitations

We did not verify the accuracy of manufacturer-reported ASP and AMP data, nor did we verify the underlying methodology that manufacturers used to calculate ASPs and AMPs. We also did not verify the accuracy of CMS's calculations of reimbursement amounts for Part B drugs. Manufacturers are required to submit their quarterly ASP

and AMP data to CMS within 30 days of the close of the quarter. We did not determine whether manufacturers later provided any updated data to CMS.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued in 2020 by the Council of the Inspectors General on Integrity and Efficiency.

Appendix: Drug codes for which CMS implemented a price substitution

		Quarter(s) in Which Price Substitution Occurred			
Drug	**Description**	**Fourth Quarter 2024**	**First Quarter 2025**	**Second Quarter 2025**	**Third Quarter 2025**
J0878	Daptomycin injection				●
J1652	Fondaparinux Sodium				●
J2247	Micafungin injection (Par Pharma)		●	●	
J2360	Orphenadrine injection				●
J2469	Palonosetron HCl	●	●	●	●
J2501	Paricalcitol	●			
J9036	Belrapzo/Bendamustine injection				●
J9058	Apotex/Bendamustine injection	●			
J9059	Bendamustine injection (Baxter)	●			
J9071	Cyclophosphamide injection (Auromedics)		●	●	
J9206	Irinotecan injection		●		●
J9263	Oxaliplatin			●	
J9294	Pemetrexed injection (Hospira)	●	●		
Q5117	Kanjinti injection			●	

Source: OIG analysis of ASP and AMP data from 2024.

ENDNOTES

[1] Social Security Act, § 1847A(d).

[2] 42 CFR § 414.904(d)(3).

[3] OIG, *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the First Quarter of 2024* (OEI-03-24-00070), Aug. 13, 2024; *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Second Quarter of 2024* (OEI-03-25-00010), Nov. 18, 2024; *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Third Quarter of 2024* (OEI-03-25-00020), Feb. 19, 2025; *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Fourth Quarter of 2024* (OEI-03-25-00030), May 15, 2025.

[4] We could not calculate savings for two of these drugs because the drug codes changed and there were no ASP data for the quarter in which the substitution was implemented.

[5] In addition to the 31 drug codes with potential errors in AMP unit type or AMP amount, OIG identified 4 drug codes with potential errors in ASP data. For these four drugs, CMS provided an explanation that the error did not affect the calculation of payment amounts or that it corrected the error.

[6] Every quarter, OIG reviews selected NDCs to identify potential errors. During these reviews, OIG identifies NDCs for which (1) the package size and/or package quantity reported as part of the ASP product data did not match the package size and/or package quantity reported in publicly available sources; (2) 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; (3) the unit type reported was "milliliter" for a product that is in powder form, which does not comply with CMS reporting rules that manufacturers should report products in powder form as "each" or "grams"; and (4) the converted AMP (i.e., the AMP value for the entire package that OIG calculates by multiplying the AMP by the package size and package quantity) was an extremely large or small value relative to the ASP, which indicates that the AMP value may not have been reported correctly. For example, an NDC has the reported AMP unit type of milliliter, for a 10-milliliter vial sold in a carton of 10 vials. To calculate the converted AMP, we multiply the number of milliliters in the vial by the number of vials in the carton and multiply that number by the AMP value. In this example, if the result of this converted AMP calculation is a value that is 10 times as great as the ASP, OIG will identify this as a potential error in that the AMP value may have been reported incorrectly.

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TIPS.HHS.GOV

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Anyone who suspects fraud, waste, and abuse should report their concerns to the OIG Hotline. OIG addresses complaints about misconduct and mismanagement in HHS programs, fraudulent claims submitted to Federal health care programs such as Medicare, abuse or neglect in nursing homes, and many more. Learn more about complaints OIG investigates.

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Every complaint helps OIG carry out its mission of overseeing HHS programs and protecting the individuals they serve. By reporting your concerns to the OIG Hotline, you help us safeguard taxpayer dollars and ensure the success of our oversight efforts.

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