HHS Office of Inspector General

REPORT HIGHLIGHTS

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Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2022 Average Sales Prices

Why OIG Did This Review

- Medicare Part B annually spends billions 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, and CMS implemented a price-substitution policy that results in lower costs for important, lifesaving drugs covered by Medicare Part B.
- This issue brief is one in a series of annual reports—produced since CMS implemented the price-substitution policy in 2013—that quantifies the savings to Medicare and its enrollees that result from CMS's price-substitution policy.

What OIG Found

CMS's price-substitution policy has saved Medicare and its enrollees $74.3 million since 2013, including nearly a million dollars for 2022. Since CMS instituted its price-substitution policy in 2013, CMS has implemented price substitutions for 83 drugs. Price substitutions for 26 drugs based on 2022 data saved Medicare and its enrollees $966,307 over 1 year.

CMS could have achieved even greater savings by expanding its criteria for price substitutions. If CMS expanded its price-substitution criteria to include more drugs, Medicare and its enrollees could have saved up to an additional $8.5 million for 2022.

Potential errors in the average manufacturer price (AMP) data submitted to CMS prevented OIG from determining whether 30 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 reduce costs to Medicare and its enrollees.

What OIG Concludes

CMS's price-substitution policy has lowered prescription drug costs by almost $75 million while maintaining access to lifesaving drugs for Medicare and its enrollees. We continue to support our open recommendation that CMS expand its price-substitution criteria to include additional drugs to more effectively limit excessive payment amounts and to generate greater savings for Medicare and its enrollees. We also 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.

Primer: Medicare Part B Coverage and Payment for Prescription Drugs

Medicare Part B and its enrollees spend over $40 billion annually 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.

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). 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 2022, OIG identified drug codes eligible for price substitutions and potential errors in CMS's ASP and AMP data.[1] This annual report summarizes the results of those four quarterly memos.

In addition, this annual report builds on two prior OIG evaluations related to the accuracy of pricing data:

- In a 2020 evaluation, OIG identified errors in the ASP and AMP data for 14 percent of reviewed drug codes, with most of these errors occurring in only the AMP data.[2] Subsequently, CMS implemented OIG's recommendation to work with the manufacturers associated with these errors to correct and resubmit ASP and AMP data, submitting accurate ASP and AMP data.
- In a 2022 evaluation, OIG identified gaps in CMS's oversight of ASP data that may limit its ability to ensure the accuracy of ASP data and result in inaccurate Part B drug payment amounts.[3] OIG recommended that CMS build a strategy to strengthen its internal controls for ensuring the accuracy of Part B drug payments. CMS implemented this recommendation by enhancing its ASP reporting system and updating its website to include improved (1) outreach and education materials; (2) guidance for drug manufacturers; (3) methods for communicating with manufacturers; and (4) audit capabilities and system edits.

For each quarter, OIG notifies CMS about the potential errors that it identifies in the ASP and AMP data and requests that CMS work with manufacturers, as necessary, to address potential errors.

RESULTS

Total Medicare Savings 2013-2022

Price substitutions resulted in **$74.3** million in savings—including **nearly a million dollars** for 2022.

CMS's price-substitution policy saved Medicare and its enrollees $74.3 million since 2013, including nearly a million dollars for 2022.

Since CMS instituted its price-substitution policy in 2013, CMS has implemented price substitutions for 83 drugs based on analysis performed by OIG. These price substitutions have saved Medicare and its enrollees **$74.3 million**.

CMS initiated price substitutions for 26 drugs based on 2022 data. Price substitutions for these drugs saved Medicare and its enrollees **$966,307** over 1 year.[4] See the Appendix for a list of these drugs.

Unrealized Medicare Savings for 2022

More price reductions could have resulted in **$8.5 million** in additional savings.

CMS could have achieved even greater savings by expanding its criteria for AMP-based price substitutions.

If CMS had expanded its price-substitution criteria to include drugs that exceeded the 5-percent threshold in a single quarter, Medicare and its enrollees could have saved up to an additional **$8.5 million** for 2022 for another 26 drugs.

These 26 drugs exceeded the 5-percent threshold in at least one quarter, but they were not eligible for price substitution because they did not meet CMS's requirement that prices exceed the threshold in the 2 previous consecutive quarters or 3 of the previous four quarters.[5] See the Appendix for a list of these drugs. Medicare and its enrollees could have saved up to an additional $57 million since 2013 if CMS had expanded its criteria for price substitutions.

Potential Errors in Drug Pricing Data for 2022

Potential errors reduced the number of drugs OIG evaluated to determine whether they were eligible for price substitutions.

Potential errors in the AMP data submitted to CMS prevented OIG from evaluating the eligibility of 30 drugs for price substitution.

OIG identified 30 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.[6] 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.

Eleven of these 30 drugs with potential errors exceeded the 5-percent threshold in at least 1 quarter. If CMS had implemented substitutions based on the manufacturer-reported data originally submitted to CMS, and subsequently provided to OIG, Medicare and its enrollees could have saved an additional **$20 million** over 1 year based on 2022 data.[7] If CMS were to confirm the accuracy of the manufacturers' data, OIG would be able to recommend more drugs for price substitutions, which would reduce costs to Medicare and its enrollees.

For the majority of these 30 drugs with potential errors in the manufacturer-reported AMP data, OIG identified the potential errors multiple times during its review of 2022 data. Specifically, for 19 of the 30 drugs, OIG reported the potential errors to CMS for at least 3 quarters of 2022. Furthermore, of these 19 drugs, 14 had different types of potential errors that persisted in at least 5 of the last 12 quarters.

CONCLUSION

Since the inception of CMS's price-substitution policy, Medicare and its enrollees have saved $74.3 million. CMS could have achieved even greater savings for Medicare and its enrollees by expanding its criteria for AMP-based price substitutions. Specifically, Medicare and its enrollees could have saved up to an additional $57 million since 2013 if CMS had expanded its criteria for price substitutions.

OIG has previously recommended that CMS expand the price-substitution criteria. However, CMS has not concurred with expanding the price-substitution policy and has expressed concern that expanding price-substitution criteria may impede physician and enrollee access to needed prescriptions. OIG agrees that access to prescription drugs should always be considered in contemplating pricing policies, and OIG supports current safeguards to prevent substitutions for drugs that FDA has identified as being in short supply. However, OIG continues to believe that CMS can achieve a better balance between safeguarding access to drugs and ensuring that Medicare and its enrollees do not overpay for drugs. To provide greater flexibility and achieve this continued balance, any future expansion of the price-substitution policy could contain a provision that would prevent a price substitution when there are indications that the substitution amount would be below provider acquisition costs.

To more effectively limit excessive payment amounts based on ASPs and to generate greater savings for Medicare and its enrollees, we continue to believe, CMS should expand its price-substitution criteria to include some additional drugs. For example, a more expansive policy might include all drugs (with complete AMP data) that exceed the 5-percent threshold in a single quarter. However, CMS also could consider other approaches to expanding the price-substitution policy that are designed to capture more drugs that repeatedly exceed the threshold.

We also 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. CMS could focus its efforts on manufacturers that frequently submit potentially incorrect AMP data. 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.

Drug codes for which CMS implemented a price substitution or which would be eligible for a price substitution under an expanded price-substitution policy

		Quarter(s) in Which Price Substitution Occurred or Would Have Occurred Under an Expanded Policy			
Drug	**Description**	**Fourth Quarter 2022**	**First Quarter 2023**	**Second Quarter 2023**	**Third Quarter 2023**
J0133	Acyclovir injection			●	●
J0134	Acetaminophen injection			●	
J0224	Lumasiran injection			●	
J0285	Amphotericin B injection			●	
J0360	Hydralazine Hcl injection		●	●	
J0642	Khapzory injection	●			
J0702	Betamethasone acetate & sodium phosphate injection		●	●	
J0720	Chloramphenicol sodium injection	●			
J0743	Cilastatin sodium injection		●	●	●
J1240	Dimenhydrinate injection				●
J1572	Flebogamma injection			●	
J1602	Golimumab			●	
J1611	Glucagon Hcl injection			●	●
J1631	Haloperidol decanoate injection	●			
J1652	Fondaparinux sodium				●
J1740	Ibandronate sodium injection	●			
J1756	Iron sucrose injection	●		●	●
J2185	Meropenem			●	●

● Substitution occurred.

● Expanded substitution policy would have resulted in a substitution in this quarter.

Drug	Description	Quarter(s) in Which Price Substitution Occurred or Would Have Occurred Under an Expanded Policy: Fourth Quarter 2022	First Quarter 2023	Second Quarter 2023	Third Quarter 2023
J2280	Moxifloxacin injection		●		
J2281*	Moxifloxacin injection			●	●
J2354	Octreotide injection		●	●	
J2501	Paricalcitol	●	●	●	●
J2704	Propofol injection			●	●
J2720	Protamine sulfate injection		●	●	●
J2800	Methocarbamol injection	●		●	
J3105	Terbutaline sulfate injection			●	
J3145	Testosterone undecanoate		●		●
J3260	Tobramycin sulfate injection		●	●	
J3411	Thiamine Hcl		●	●	●
J7042	5-percent Dextrose Normal Saline	●	●		
J7197*	Antithrombin III injection			●	●
J7608	Acetylcysteine non-compound		●	●	
J9000	Doxorubicin Hcl injection	●			
J9033	Treanda injection			●	●
J9046	Bortezomib injection				●
J9304	Pemetrexed injection			●	
J9360	Vinblastine sulfate injection	●	●	●	●
Q0167	Dronabinol Oral				●
Q9965	Low osmolar iodine			●	

● Substitution occurred.

● Expanded substitution policy would have resulted in a substitution in this quarter.

*There was no Part B utilization for these drugs in the quarters for which the substitutions were or would have been implemented.

Source: OIG analysis of ASP and AMP data from 2022.

METHODOLOGY

Data Collection. We obtained national drug code (NDC)-level ASP data and AMP data for Part B drugs from CMS for 2022. We obtained data identifying the drugs that had price substitutions based on ASP data from 2022. 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 2022 through the third quarter of 2023. In addition, we compiled a list of drug codes that had potential errors in the AMP data for each quarter of 2022 and identified how many of these potential errors occurred multiple times from 2020 through 2022. We also identified which of these drug codes with potential errors met the threshold for a price substitution.

Data Analysis. For each quarter of 2022, 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 AMP by at least 5 percent. We also identified drugs that exceeded the 5-percent threshold but did not meet CMS's duration criteria for price substitution—i.e., they did not exceed the threshold in the two previous consecutive quarters or three of the previous four quarters.

To calculate the savings associated with price substitutions, potential price substitutions that could be made by expanding the policy, or drugs with potential errors, 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 or could have occurred.

We determined the number of drug codes that had a potential error in at least one quarter of their drug data for 2022.[8] For these drug codes, we determined how often the potential errors occurred and how many of these drug codes exceeded the 5-percent threshold but were not recommended for price substitution because of these potential errors. We then calculated the potential savings that could have occurred if CMS implemented price substitutions for these drug codes that had potential errors and also met the 5-percent threshold in at least one quarter using the method described above.

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 by the Council of the Inspectors General on Integrity and Efficiency.

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ENDNOTES

[1] OIG, *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the First Quarter of 2022* (OEI-03-22-00210) August 12, 2022*; Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Second Quarter of 2022* (OEI-03-23-00070) November 15, 2022; *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Third Quarter of 2022* (OEI-03-23-00080) February 14, 2023; *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Fourth Quarter of 2022* (OEI-03-23-00090) May 11, 2023.

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

[3] OIG, *CMS Should Bolster Its Oversight of Manufacturer-Submitted Average Sales Price Data To Ensure Accurate Part B Drug Payments* (OEI-03-21-00390) December 22, 2022.

[4] Two drugs met the criteria but did not have any utilization, which resulted in no associated savings for the quarter in which the substitution was implemented.

[5] Besides not having prices exceed the threshold in the 2 previous consecutive quarters or 3 of the previous 4 quarters, these 26 drugs met all the other requirements under 42 CFR § 414.904(d)(3). These 26 drugs had complete AMP data and were not identified by FDA as being in short supply. They also did not have AMP-based substitution amounts that were greater than the ASP-based reimbursement amounts for the quarters in which substitutions would have occurred. Two drugs met the criteria but did not have any associated savings for the quarter in which the substitution would have been implemented.

[6] In addition to the 30 drug codes with potential errors in AMP unit type or AMP amount, OIG identified 11 drug codes with potential errors in ASP data. CMS provided an explanation that the error did not affect the calculation of payment amounts or that it corrected the error.

[7] There were no savings associated with three of these drugs. One of these drugs did not have any utilization for the quarter in which the substitution would have occurred. Another of these drugs was in shortage; for the third drug, there were no savings because the substituted amount would have exceeded the ASP-based payment for the quarter in which the substitution would have occurred.

[8] Every quarter, OIG reviews selected NDCs to identify potential errors. During these reviews, OIG identified 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.