



Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2018 Average Sales Prices

What OIG Did

When Congress established average sales prices (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. Generally, Part B-covered drugs are those that are injected or infused in physicians' offices or hospital outpatient settings. 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 a certain percentage (currently 5 percent), the Act directs the Secretary of Health and Human Services to substitute the ASP-based payment amount with a lower calculated rate. Through regulation, the Centers for Medicare & Medicaid Services (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.

This data snapshot quantifies the savings to Medicare and its beneficiaries that are a direct result of CMS's price-substitution policy based on ASPs from 2018. To determine these savings, we calculated the difference between ASP-based payment and AMP-based payment for each drug with a price substitution. We then applied this difference to the Medicare utilization for each of these drugs when the substitution occurred—the fourth quarter of 2018 through the third quarter of 2019—to calculate the savings based on 2018 ASP data.

Key Takeaway

Medicare and its beneficiaries saved \$4.4 million over 1 year based on CMS's price-substitution policy that limits excessive payments for drugs in Medicare Part B.

Results

CMS's price-substitution policy saved Medicare and its beneficiaries \$4.4 million over 1 year

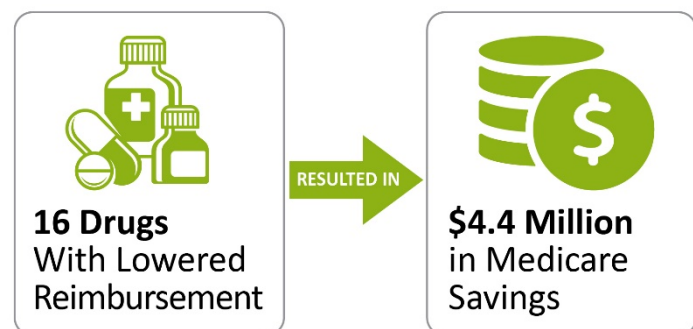
- CMS initiated price substitutions for **16 drugs** based on 2018 data.
- Price substitutions for these drugs saved Medicare and its beneficiaries **\$4.4 million** over 1 year, as shown in Exhibit 1.
- Since CMS instituted its price-substitution policy in 2013, Medicare and its beneficiaries have saved \$67 million, including the \$4.4 million amount in 2018.

Expanding the price-substitution policy could have generated additional savings for Medicare and its beneficiaries

If CMS expanded its price-substitution criteria to include drugs that exceeded the 5-percent threshold in a single quarter, Medicare and its beneficiaries could have saved up to an additional **\$1.7 million** over 1 year for another **17 drugs**.

These **17 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 two previous consecutive quarters or three of the previous four quarters.¹

Exhibit 1: Results of the Medicare Part B Price-Substitution Policy



Even Greater Savings Could Be Realized

\$1.7 Million in Additional Savings if CMS Expanded the Price-Substitution Criteria



Source: OIG analysis of ASP and AMP data from 2018.

Why This Matters

Medicare Part B annually spends billions to cover a limited number of outpatient prescription drugs. To safeguard Medicare and its beneficiaries 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.

Since CMS implemented the policy in 2013, OIG has produced annual reports quantifying the valuable savings to Medicare and its beneficiaries that are a direct result of CMS's price-substitution policy. These reports document millions in actual annual savings and continue to demonstrate that price substitution is an important and effective mechanism for ensuring reasonable payments for drugs in Medicare Part B.

What OIG Concludes

Since the inception of CMS's price-substitution policy, Medicare and its beneficiaries have saved \$66.9 million. However, CMS could have achieved even greater savings for Medicare and its beneficiaries by expanding its criteria for AMP-based price substitutions. Specifically, Medicare and its beneficiaries could have saved up to an additional \$30.8 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 did not concur with expanding the price-substitution policy and expressed concern that expanding price-substitution criteria may impede physician and beneficiary access to drugs. OIG agrees that access to prescription drugs should always be considered when contemplating pricing policies, and OIG supports current safeguards to prevent substitutions for drugs that the Food and Drug Administration 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 beneficiaries do not overpay for drugs. To provide greater flexibility and achieve this continued balance, any future expansion of the payment-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 beneficiaries, we continue to believe that 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.

Agency Comments and OIG Response

CMS responded that it continues to not concur with our recommendation. CMS stated that as additional data becomes available and as it continues to gain experience with the price-substitution policy, it will consider further changes as necessary. CMS believes the current policy safeguards—which identify drugs that exceed the 5-percent threshold for two consecutive quarters or three of four quarters—identify drugs that consistently exceed the threshold. CMS's full comments are included in the Appendix.

OIG continues to believe that expanding the policy can achieve a balance between safeguarding access to drugs and ensuring that Medicare and its beneficiaries do not overpay for drugs. Our examination of 2018 data shows that if the policy had been expanded to include the 17 drugs that exceeded the 5-percent threshold in a single quarter, beneficiaries and the program could have saved up to an additional \$1.7 million. To help ensure that CMS has sufficient information for its consideration regarding the price-substitution policy, OIG will continue to provide CMS with the results from our quarterly pricing comparisons, along with annual reports on the impact of the price-substitution policy.

Data: Results of the Medicare Part B Price-Substitution Policy

Exhibit 2: Price substitutions saved Medicare and its beneficiaries \$4.4 million

Drug	Description	Quarter(s) in Which Price Substitution Occurred				Savings
		Fourth Quarter 2018	First Quarter 2019	Second Quarter 2019	Third Quarter 2019	
J0287	Amphotericin b lipid complex	✓				\$4,730
J0289	Amphotericin b liposome injection				✓	\$38,927
J0670	Mepivacaine HCl injection	✓	✓	✓	✓	\$2,588
J0878	Daptomycin injection	✓				\$1,009,005
J1335	Ertapenem injection				✓	\$6,303
J1570	Ganciclovir sodium injection	✓		✓	✓	\$25,951
J1580	Garamycin gentamicin injection	✓				\$3,914
J1670	Tetanus immune globulin injection	✓				\$35,057
J1740	Ibandronate sodium injection			✓		\$13,070
J1955	Levocarnitine injection	✓				\$1,367
J2501	Paricalcitol	✓	✓	✓	✓	\$355
J2720	Protamine sulfate injection	✓	✓	✓		\$400
J3486	Ziprasidone mesylate	✓	✓	✓	✓	\$30
J7520	Sirolimus oral	✓	✓	✓	✓	\$3,304,957
J9100	Cytarabine HCl injection	✓	✓	✓	✓	\$3,037
Q0167	Dronabinol oral				✓	\$241
					Total	\$4,449,932

Source: OIG analysis of ASP and AMP data from 2018.

Methodology

Data Collection. We obtained National Drug Code-level ASP data and AMP data for Part B drugs from CMS for 2018. We also obtained ASP-based reimbursement amounts and Part B drug utilization for the quarters in which price substitutions occurred—i.e., the fourth quarter of 2018 through the third quarter of 2019. In addition, we obtained the drugs that had price substitutions based on data from 2018.

Data Analysis. For each quarter of 2018, 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 AMPs 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 or potential price substitutions that could be made by expanding the policy, 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 reduction required by sequestration legislation. We then subtracted the AMP-based reimbursement amount from the ASP-based reimbursement amount for the quarter in which the price substitution occurred and multiplied the difference by the Part B utilization for each drug in the respective quarter that the price substitution occurred.

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 provided any updated data to CMS at a later date.

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.

Endnote

¹ These 17 drugs had complete AMP data, were not identified by the Food and Drug Administration as being in short supply, and did not have AMP-based substitution amounts that were greater than the ASP-based reimbursement amounts in the quarters during which the substitutions would have occurred.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: July 23, 2020

TO: Christi Grimm
Principal Deputy Inspector General
Office of Inspector General

FROM: Seema Verma
Administrator
Centers for Medicare & Medicaid Services

A handwritten signature in blue ink that reads "Seema Verma".

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2018 Average Sales Prices (OEI-03-20-00130)

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

The President and the Department of Health and Human Services (HHS) are committed to putting American patients first by addressing the rising cost of prescription drugs for the American consumer and have taken a number of actions to do so. For example, between 2017 and 2020 the average Part D basic premiums decreased by 13.5 percent. Additionally, CMS has announced the Part D Senior Savings Model, a voluntary model that enables participating Part D enhanced plans to lower Medicare beneficiaries' out-of-pocket costs for insulin to a maximum \$35 copay per thirty-day supply throughout the benefit year.

CMS strives to maximize the affordability and availability of drugs for Medicare beneficiaries while protecting taxpayer dollars, and the current average manufacturer price substitution policy is consistent with this goal. As the OIG notes in its report, CMS' price substitution policy saved Medicare and its beneficiaries an estimated \$4.4 million over a one-year period between the fourth quarter of 2018 and the third quarter of 2019 by reducing payment limits for 16 Healthcare Common Procedure Coding System billing codes. The OIG also identified an additional potential savings of \$1.7 million over one year if the price substitution policy was expanded.

The additional potential savings of \$1.7 million identified by the OIG represents less than one one-hundredth of a percent of total spending for Part B drugs based on 2018 spending.¹ Based on these audit findings, the OIG continues to recommend that CMS expand the price substitution policy to include additional drugs. While CMS appreciates the OIG's review in this area, CMS continues to non-concur with OIG's recommendation.

¹ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB>

CMS looks forward to evaluating additional data related to the potential expansion of the price substitution policy and taking it into consideration when developing plans for future rulemaking in this area. As additional data becomes available and CMS continues to gain experience with this policy, CMS will consider further changes as necessary.

CMS notes the current price substitution policy includes several safeguards finalized through rulemaking, including the requirement that the applicable threshold must be exceeded in two consecutive or three of four quarters. This safeguard is intended to identify situations where average manufacturer price consistently exceeds average sales price, rather than using a single quarter of pricing, which may suggest one aberrant pricing quarter rather than a market trend. This approach ensures changes to payment are based on more sustained changes to the price of a drug, and thereby minimizes the potential risk of impacting beneficiary access to medically necessary drugs, which is particularly important as we work to ensure that beneficiaries do not experience disruptions in care or prescription drug access during the public health emergency posed by COVID-19. While CMS appreciates that OIG has continued to evaluate drugs that may be subject to average manufacturer price based price substitution, CMS maintains that more systematic data analysis is needed in order to evaluate trends and then further consider the recommendation and any potential impacts to beneficiary access.