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Issue Brief
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Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2021 Average Sales Prices

Key Takeaways

Total Medicare Savings, 2013-2021

Since 2013, Medicare and its enrollees have saved **$73.4 million** as a result of CMS's price-substitution policy for Part B-covered drugs.

Medicare Savings for 2021

CMS lowered Medicare payment amounts for **13 drugs**, resulting in **$273 thousand** in savings.

Unrealized Medicare Savings for 2021

Medicare and its enrollees could realize an additional **$889 thousand** in Medicare savings if CMS expanded the price-substitution criteria.

Why This Matters

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, and the Centers for Medicare & Medicaid Services (CMS) implemented a price-substitution policy that results in lower costs for important, lifesaving drugs covered by Medicare Part B.

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 outpatient settings. The Social Security Act (the Act) mandates that our office compare ASPs with average manufacturer prices (AMPs).[1] If the Office of Inspector General (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.[2] 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.[3]

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 beneficiaries that result from CMS's price-substitution policy.

What OIG Did

This issue brief quantifies the savings to Medicare and its enrollees that are a direct result of CMS's price-substitution policy based on ASPs from 2021. We calculated the difference between ASP-based payment and AMP-based payment for each drug with a price substitution. To calculate the savings based on 2021 ASP data, we then multiplied the difference by the Medicare utilization for each of these drugs for the time period when the price substitutions occurred—the fourth quarter of 2021 through the third quarter of 2022. We also determined the potential savings that could result from an expansion of the price-substitution criteria.

Results

CMS's price-substitution policy saved Medicare and its enrollees $73.4 million over the past 10 years.

- Since CMS instituted its price-substitution policy in 2013, CMS has implemented price substitutions for 68 drugs based on analysis performed by OIG. These price substitutions have saved Medicare and its enrollees **$73.4 million**.

CMS lowered Medicare payment amounts for 13 drugs on the basis of 2021 data.

- CMS initiated price substitutions for 13 drugs based on 2021 data. Price substitutions for these drugs saved Medicare and its enrollees **$273 thousand** over 1 year. See the Appendix for a list of these drugs.

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 **$889 thousand** in 2021 for another 19 drugs.[4]
- These 19 drugs exceeded the 5-percent threshold in at least one quarter, but they were not eligible for price substitutions 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.[5] See the Appendix for a list of these drugs.
- Medicare and its enrollees could have saved up to an additional $48 million since 2013 if CMS had expanded its criteria for price substitutions.

Conclusion

Since the inception of CMS's price-substitution policy, Medicare and its enrollees have saved $73.4 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 $48 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.[6] OIG agrees that access to prescription drugs should always be considered in contemplating pricing policies, and OIG supports current safeguards to prevent price 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 enrollees 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 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.

Methodology

Data Collection. We obtained national drug code (NDC)-level ASP data and AMP data for Part B drugs from CMS for 2021. In addition, we identified the drugs that had price substitutions based on ASP data from 2021. 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 2021 through the third quarter of 2022.

Data Analysis. For each quarter of 2021, 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. We also identified drugs that exceeded the 5-percent threshold but did not meet CMS's duration criteria for price substitutions—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 gained 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 amount required by sequestration. The payment reduction required by sequestration was suspended from May 1, 2020, through March 31, 2022. Therefore, we did not reduce the reimbursement amounts from the fourth quarter 2021 and first quarter of 2022.[7] However, legislation reinstated a sequestration reduction of 1 percent for the second quarter of 2022 and 2 percent for the third quarter of 2022. Therefore, we reduced

AMP-based and ASP-based reimbursement amounts by 1 percent for the second quarter of 2022 and by 2 percent for the third quarter of 2022.

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) for which the price substitution occurred or could have 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 later provided any updated data to CMS.

Appendix

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 a Price Substitution Occurred or Would Have Occurred Under an Expanded Policy			
Drug	**Description**	**Fourth Quarter 2021**	**First Quarter 2022**	**Second Quarter 2022**	**Third Quarter 2022**
J0641	Levoleucovorin injection			●	
J0642	Khapzory injection		●	○	○
J0720	Chloramphenicol sodium injection	○	○	○	○
J0895	Deferoxamine mesylate injection	○	○		
J1570	Ganciclovir sodium injection	●			
J1580	Garamycin gentamicin injection	○	○	○	
J1631	Haloperidol decanoate injection		○	○	
J1740	Ibandronate sodium injection			●	
J1756	Iron sucrose injection			●	○
J1953	Levetiracetam injection			●	
J2280	Moxifloxacin injection	●	○		
J2501	Paricalcitol	○	○	○	○
J2545	Pentamidine non-compounded unit			●	
J3411	Thiamine hcl			●	
J3475	Magnesium sulfate injection			●	
J7042	Dextrose/Normal Saline			●	○

○ Substitution occurred.

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

Drug	Description	Quarter(s) in Which a Price Substitution Occurred or Would Have Occurred Under an Expanded Policy: Fourth Quarter 2021	First Quarter 2022	Second Quarter 2022	Third Quarter 2022
J7626	Budesonide non-compounded unit			●	
J7631	Cromolyn sodium non-compounded unit		●		
J8530	Cyclophosphamide oral	●	●	●	
J9000	Doxorubicin hcl injection			●	●
J9021	Aspara Rylaze injection[1]				●
J9190	Fluorouracil injection		●		
J9245	Melphalan hcl injection	●			
J9280	Mitomycin injection			●	
J9360	Vinblastine sulfate injection	●	●	●	●
Q0139	Ferumoxtol			●	
Q0167	Dronabinol Oral			●	

● Substitution occurred.

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

[1] This drug code did not have any allowed Part B utilization during the review period; therefore, the savings that would have resulted from a price substitution would have been $0.

Source: OIG analysis of ASP and AMP data from 2021.

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] Section 1847A(d)(2) of Social Security Act (the Act).

[2] Section 1847A(d)(3) of the Act.

[3] 42 CFR § 414.904(d)(3).

[4] One drug code (J9021, Aspara Rylaze injection), met the criteria for the expanded price-substitution policy; however, this drug code did not have any allowed Part B utilization for the quarter for which the substitution would have occurred. Therefore, there the estimated savings for this drug were $0.

[5] These 19 drugs had complete AMP data and were not identified by the Food and Drug Administration 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. Further, these 19 drug codes met all of CMS's other requirements for a price substitution under 42 CFR § 414.904(d)(3).

[6] OIG, *Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2016 Average Sales Prices*, OEI-03-18-00120, August 2018; and OIG, *Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2017 Average Sales Prices*, OEI-03-19-00260, August 2019.

[7] Part B claims dated on or after April 1, 2013, incur a reduction in payment in accordance with the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012 (see CMS Medicare FFS Provider e-News, Mandatory Payment Reductions in the Medicare Fee-for-Service (FFS) Program –"Sequestration," March 8, 2013). Under this mandatory payment reduction, Medicare's portion of the payment rate for most Part B drugs is reduced by 2 percent. This reduction does not apply to the coinsurance portion of the Medicare allowed amount for Part B drugs. However, the sequestration payment reduction was suspended from May 1, 2020, through March 31, 2022; the sequestration reduction was then set to 1 percent from April 1, 2022, through June 30, 2022. The sequestration of payment reductions ended as of July 1, 2022, when cuts of 2 percent were reimposed. (See the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. No. 116-136) as amended by the Consolidated Appropriations Act, 2021 (P.L. 116-260); the Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes (P.L. No. 117-7); and the Protecting Medicare and American Farmers from Sequester Cuts Act (P.L. 117-71).)