Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE PART B DRUG PAYMENTS: IMPACT OF PRICE SUBSTITUTIONS BASED ON 2014 AVERAGE SALES PRICES

Suzanne Murrin
Deputy Inspector General

OEI-03-16-00540
August 2017

Report in Brief
August 2017
OEI-03-16-00540

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2014 Average Sales Prices

Why OIG Did This Review

When Congress established average sales price (ASP) as the basis for Medicare Part B drug reimbursement, it also provided a mechanism for monitoring market prices and limiting potentially excessive payment amounts. The Social Security 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) outlined that it would make this substitution only if the ASP for a drug exceeds the AMP by 5 percent in the 2 previous quarters or 3 of the previous 4 quarters.

Over the last decade, OIG has produced annual reports aggregating the results of our mandated quarterly ASP-to-AMP comparisons. This annual report quantifies the savings to Medicare and its beneficiaries that are a direct result of CMS's price-substitution policy based on 2014 average sales prices, and this report also offers ways for additional savings.

How OIG Did This Review

To determine the effects of the price-substitution policy, we determined 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. To account for a 3-quarter lag between the reporting of pricing data and applying price substitutions, we used drug utilization data for the fourth quarter of 2014 through the third quarter of 2015 to calculate the savings based on 2014 ASP data.

What OIG Found

- CMS lowered Part B reimbursement for 14 drugs on the basis of 2014 data.
- CMS's price-substitution policy saved Medicare and its beneficiaries $24 million over 1 year based on 2014 data.
- Medicare and its beneficiaries could have saved up to an additional $9 million over 1 year by expanding the price-substitution criteria to include drugs that exceeded the 5-percent threshold in a single quarter.

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

Source: OIG analysis of ASP and AMP data from 2014

What OIG Recommends

Because of the potential for savings to Medicare beneficiaries and the program, OIG recommends that CMS expand the price-substitution policy. CMS did not concur with the recommendation. However, 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. OIG recognizes that CMS, in setting policy for payment substitution, needs to achieve an important 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 is below the provider acquisition cost.

Full report can be found at http://oig.hhs.gov/oei/reports/oei-03-16-00540.asp

BACKGROUND

When Congress established average sales price (ASP) as the basis for Medicare Part B drug reimbursement, it also provided a mechanism for monitoring market prices and adjusting ASP-based payments in certain situations. Specifically, the Social Security Act (the Act) mandates that the Office of Inspector General (OIG) compare ASPs with average manufacturer prices (AMPs).[1] 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 (after being notified by OIG) to substitute the payment amount with the lesser of the widely available market price (if any) or 103 percent of the AMP.[2, 3]

Drug Pricing Terms

Manufacturer's Average Sales Price (ASP)

In general, the manufacturer's ASP for a unit of drug that is sold is defined as the manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter.

Average Manufacturer Price (AMP)

In general, AMP is defined as the average price paid to the manufacturer for the drug in the United States by (1) wholesalers for drugs distributed to retail community pharmacies and (2) retail community pharmacies that purchase drugs directly from the manufacturer.

National Drug Code (NDC)

An NDC is a code used to identify a drug based on its manufacturer, product, and package size.

Healthcare Common Procedure Coding System (HCPCS) Code

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

Payments for Prescription Drugs Under Medicare Part B

Medicare Part B covers a limited number of outpatient prescription drugs. These drugs are usually administered in a physician's office or other outpatient setting and include, for example, drugs used to treat cancer. To obtain reimbursement for Part B drugs, health care providers submit claims to Medicare contractors using Healthcare Common Procedure Coding System (HCPCS) codes. (Hereafter in this report, we refer to HCPCS codes as "drugs."[4])

CMS calculates the payment amount for these drugs using information provided by manufacturers. Certain manufacturers must provide CMS with the ASP and volume of sales for each of their national drug codes (NDCs) on a quarterly basis.[5, 6] CMS then calculates an ASP-based payment amount for the drug, which includes all of the NDCs associated with the drug.[7] 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.[8] However, under sequestration legislation, the payment amount for most drugs is reduced by 2 percent.[9]

Quarterly reimbursement amounts are not based on current quarter data because there is a 2-quarter lag between the sales period for which ASPs are reported and the effective date of the reimbursement amounts. For example, manufacturers' ASPs from the first quarter of 2014 were used to establish reimbursement amounts for the third quarter of 2014.

Manufacturer Reporting of AMPs

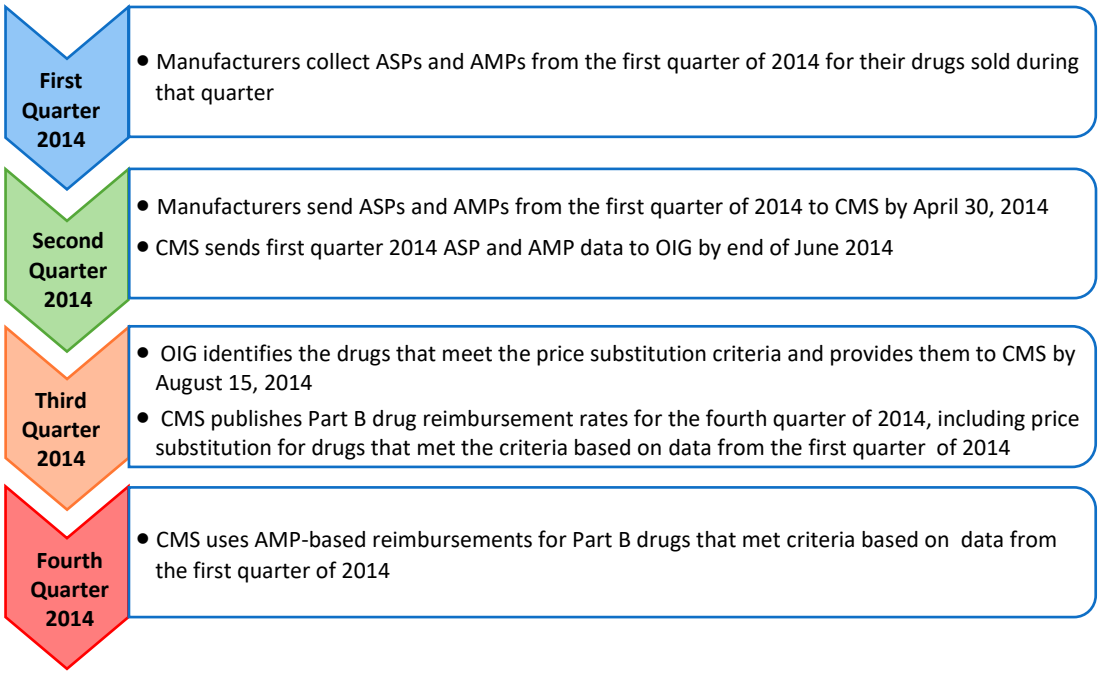
In addition to providing quarterly ASPs, certain manufacturers must provide CMS quarterly with the AMP for each of their NDCs.[10, 11] The AMP is generally calculated as a weighted average of prices for all of a manufacturer's package sizes of a drug and is reported for the lowest identifiable quantity of the drug, e.g., 1 milliliter, one tablet, one capsule.

AMP-Based Price Substitutions

Through regulation, CMS established the criteria under which it would implement a price substitution for a drug. CMS may substitute 103 percent of the AMP for the ASP-based reimbursement amount when OIG identifies a drug that exceeds the 5-percent threshold in the two previous quarters or three of the previous four quarters.[12] CMS implemented the AMP substitution policy in April 2013. Because CMS believes that comparisons based on partial AMP data may not adequately reflect market trends, the agency will consider lowering reimbursement amounts only when corresponding AMP data is available for each of the NDCs used to determine the published reimbursement amount for a drug.[13] To prevent the price-substitution policy from inadvertently raising Medicare reimbursement amounts, CMS does not substitute prices when the substituted amount is greater than the ASP-based payment amount calculated for the quarter in which the price substitution takes effect.[14] CMS also does not substitute prices when a drug is identified by the Food and Drug Administration (FDA) as being in short supply.[15] Price substitutions take effect in the quarter after OIG shares the results of its most recent pricing comparison and remain in effect for one quarter.[16]

Because of the 2-quarter lag between the ASP reporting period and the effective date of reimbursement amounts, and the additional quarter that is necessary for OIG to complete its pricing comparison, there is a 3-quarter lag between the ASP reporting period and the effective date of the price substitutions. As shown in Exhibit 2, price substitutions that took effect in the fourth quarter of 2014 were based on comparisons of ASPs and AMPs from the first quarter of 2014.

Exhibit 2: Timeline for AMP-Based Price Substitutions in 2014



OIG Monitoring of ASPs and AMPs

To comply with its statutory mandate, OIG has provided CMS with pricing comparisons since the January 2005 implementation of the ASP reimbursement methodology for Part B drugs. OIG issued six annual public reports for the years prior to CMS's April 2013 implementation of the AMP price-substitution policy. These reports estimated that Medicare and its beneficiaries would have saved $35 million if CMS implemented AMP price substitutions. OIG's 2013 annual report was the first to provide annual savings that were a direct result of CMS's price-substitution policy. CMS's price substitutions based on 2013 data saved Medicare and its beneficiaries an estimated $13 million.

RESULTS

CMS's price-substitution policy saved Medicare and its beneficiaries $24 million over 1 year

CMS initiated price substitutions for 14 drugs based on 2014 data. Price substitutions for these drugs saved Medicare and its beneficiaries $24 million over the 1-year period between the fourth quarter of 2014 and the third quarter of 2015. Exhibit 3 lists the 14 drugs, the quarter(s) during which the price substitution occurred, and the savings.

Exhibit 3: Drugs With Price Substitutions Based on 2014 Data

Drug	Description	Quarter(s) in Which Price Substitutions Occurred				Savings
		Fourth Quarter 2014	First Quarter 2015	Second Quarter 2015	Third Quarter 2015	
J0132	Acetylcysteine injection		✓			**$48**
J0717	Certolizumab pegol injection			✓	✓	**$7,548,763**
J1650	Enoxaparin sodium injection	✓				**$7,706**
J2400	Chloroprocaine HCl injection		✓			**$1,777**
J2675	Progesterone injection	✓	✓	✓	✓	**$233**
J2820	Sargramostim injection	✓				**$172,016**
J3070	Pentazocine injection	✓				**$950**
J3415	Pyridoxine HCl injection	✓	✓	✓	✓	**$36,307**
J7507	Tacrolimus immediate release oral		✓			**$2,702,226**
J7626	Budesonide noncompounded	✓	✓			**$13,296,014**
J9200	Floxuridine injection	✓	✓	✓	✓	**$19,920**
J9263	Oxaliplatin			✓		**$69,012**
J9280	Mitomycin injection	✓				**$63,706**
Q0167	Dronabinol oral				✓	**$3,457**
					Total	**$23,922,135**

Source: OIG analysis of ASP and AMP data from 2014

Expanding the price-substitution criteria could have generated up to $9 million in additional savings for Medicare and its beneficiaries

CMS has maintained a cautious approach to price substitutions. However, this cautious approach may restrict the Government's ability to limit potentially excessive payment amounts based on ASPs. If CMS had expanded its price-substitution criteria to include certain other Part B drugs in 2014, Medicare and its beneficiaries could have saved up to an additional $9 million over 1 year.

Millions could be saved by expanding the substitution criteria to include drugs that exceeded the 5-percent threshold in a single quarter. Nineteen drugs with complete AMP data exceeded this threshold in at least 1 quarter of 2014 but were not eligible for price substitution in that quarter because they did not meet CMS's duration criteria, i.e., they did not exceed the threshold in the 2 previous quarters or 3 of the previous 4 quarters.[17] If the 19 drugs had been eligible for price reductions on the basis of data from a single quarter only, Medicare and its beneficiaries could have saved up to an additional $9 million between the fourth quarter of 2014 and the third quarter of 2015.

Previously, CMS has expressed concern that price substitutions based on results from a single quarter may represent 1 aberrant quarter of pricing rather than a market trend.[18] However, price discrepancies for the majority of the 19 drugs do not appear to have resulted from isolated fluctuations. According to 2013 and 2014 data, 11 of these 19 drugs exceeded the 5-percent threshold more than once over the 2-year period.[19] Over the 2-year period, 6 of the 19 exceeded the threshold in 2 of the 8 quarters, and another 5 drugs exceeded the threshold three or four times in the 8 quarters.

If CMS would prefer to employ a more cautious approach than substitution based on a single quarter of data, it could expand its price-substitution criteria to include drugs that exceed the 5-percent threshold in 2 of the previous 6 quarters. Under this approach, 6 drugs would have been eligible for price substitutions, and Medicare and its beneficiaries could have saved an estimated $3 million on these 6 drugs.

CONCLUSION AND RECOMMENDATION

Under the current price-substitution policy, 14 drugs were subject to reimbursement reductions on the basis of data from 2014, saving Medicare and its beneficiaries $24 million between the fourth quarter of 2014 and the third quarter of 2015. The agency could achieve even greater savings for Medicare and its beneficiaries by expanding its criteria for AMP-based price substitutions.

OIG has previously recommended that CMS expand the price-substitution criteria. CMS indicated that it does not concur with expanding the price-substitution policy and continues to believe that more experience with this policy is needed before it can be expanded. CMS also 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 supports current safeguards to prevent substitutions for drugs that are identified by FDA 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 CMS with greater flexibility, any revisions that CMS makes to its' 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.

Therefore, we continue to recommend that CMS:

- **Expand the price-substitution policy**
  To more effectively limit excessive payment amounts based on ASPs and to generate greater savings for Medicare and its beneficiaries, CMS should consider broadening its price-substitution criteria to include at least some additional drugs. For example, a more expansive policy might include drugs with complete AMP data that exceed the 5-percent threshold in a single quarter. However, CMS also could consider a more modest expansion of the policy that better captures drugs that repeatedly exceed the threshold. It could expand the criteria to include drugs with complete AMP data that exceed the 5-percent threshold in 2 of 6 quarters.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS did not concur with our recommendation. However, 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 2 consecutive quarters or 3 of 4 quarters—identify situations in which AMP consistently exceeds ASP.

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 2014 data shows that if the policy had been expanded to include the 19 drugs that exceeded the 5-percent threshold in a single quarter, up to an additional $9 million could have been saved by beneficiaries and the program. The majority of the 19 drugs we identified for these potential savings exceeded the threshold multiple times over a 2-year period. Expanding the policy to capture drugs that exceed the threshold in a single quarter could increase the savings to beneficiaries and the program and still ensure access to drugs.

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.

For the full text of CMS's comments, see the Appendix B.

APPENDIX A: METHODOLOGY

Data Collection and Analysis

We obtained NDC-level ASP data and AMP data for Part B drugs from CMS for 2014. 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 2014 through the third quarter of 2015. In addition, we obtained the drugs that had price substitutions based on data from 2014.

For each quarter of 2014, we calculated volume-weighted AMPs 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 2 previous quarters or 3 of the previous 4 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 from the ASP-based reimbursement amount for the quarter in which the price substitution occurred[20] and multiplied the difference by the Part B utilization for each drug in the respective quarter that the price substitution occurred. We used this same method to calculate savings for potential price substitutions that could be made if CMS expanded the price-substitution policy.

Limitations

We did not verify the accuracy of manufacturer-reported ASP and AMP data, nor did we verify the underlying methodology used by manufacturers to calculate ASPs and AMPs. We also did not verify the accuracy of CMS's calculations of Part B drug reimbursement amounts.

Manufacturers are required to submit their quarterly ASP and AMP data to CMS within 30 days after the close of the quarter. We did not determine whether manufacturers provided any updated data to CMS at a later date.

Standards

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

APPENDIX B: AGENCY COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: JUL 28 2017

TO: Daniel R. Levinson
Inspector General

FROM: Seema Verma
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2014 Average Sales Prices (OEI-03-16-00540)

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 beneficiaries while protecting taxpayer dollars.

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 $24 million over a one-year period between the fourth quarter of 2014 and the third quarter of 2015 by reducing payment limits on 14 Healthcare Common Procedure Coding System billing codes.

OIG's recommendations and CMS' responses are below.

OIG Recommendation

The OIG recommends that CMS expand the price substitution policy to include additional drugs.

CMS Response

CMS non-concurs with OIG's recommendation. CMS appreciates the OIG's study and 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.

ENDNOTES

[1] Section 1847A(d)(2)(B) of the Act.
[2] Section 1847A(d)(3) of the Act.
[3] Pursuant to § 1847A(d)(3)(B)(ii) of the Act, the threshold percentage has been maintained at 5 percent.
[4] A HCPCS code for a drug defines the drug name and the amount of the drug represented by the HCPCS code but does not specify the manufacturer or package size.
[5] Section 1927(b)(3) of the Act.
[6] An NDC is a drug code that represents a specific manufacturer, product, and package size.
[7] Section 1847A(c) of the Act. Certain types of sales are exempted from ASP, and ASP is net of any price concessions (with limited exceptions).
[8] Section 1847A(b)(1) of the Act. Medicare beneficiaries are responsible for 20 percent of this amount in the form of coinsurance.
[9] 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, 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.
[10] Section 1927(b)(3) of the Act.
[11] Section 1927(k)(1) of the Act.
[12] 42 CFR § 414.904(d)(3).
[13] Ibid.
[14] Ibid.
[15] Ibid.
[16] Ibid.
[17] These 19 drugs were not identified by FDA 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.
[18] 76 Fed. Reg. 73026, 73288 (Nov. 28, 2011).
[19] This analysis is based on pricing comparison results for the 2-year period between the first quarter of 2013 and the last quarter of 2014.
[20] AMP-based price substitutions based on data from the first through fourth quarters of 2014 were applied in the fourth quarter of 2014 through the third quarter of 2015, respectively.

ACKNOWLEDGMENTS

Conswelia McCourt served as the team leader for this study. Office of Evaluation and Inspections staff who provided support include Joe Chiarenzelli, Althea Hosein, Meghan Kearns, and Christine Moritz.

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.