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Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2017 Average Sales Prices

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Report in Brief
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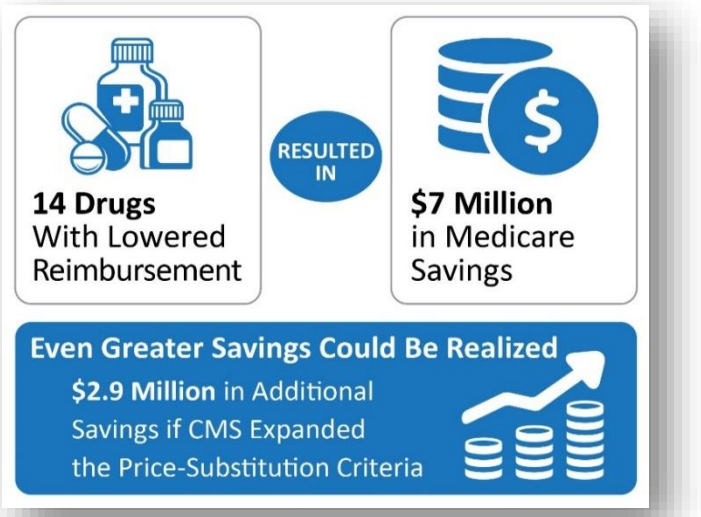
Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2017 Average Sales Prices

What OIG Found

- The Centers for Medicare & Medicaid Services (CMS) lowered Part B reimbursement for 14 drugs on the basis of 2017 data.
- CMS's price-substitution policy saved Medicare and its beneficiaries $7 million over 1 year.
- Medicare and its beneficiaries could have saved up to an additional $2.9 million over 1 year if CMS implemented a more expansive price-substitution policy that, for example, allowed substitution for drugs that exceeded the 5-percent threshold in a single quarter.

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



Source: OIG analysis of ASP and AMP data from 2017.

What OIG Recommends

Because of the potential for savings to Medicare beneficiaries and to the program, the Office of Inspector General (OIG) recommends that CMS expand the price-substitution policy. CMS did not concur with the recommendation, instead stating that as additional data become 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 provider acquisition costs.

Full report can be found at http://oig.hhs.gov/oei/reports/oei-03-19-00260.asp

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 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, 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 ASPs from 2017. This report also offers a recommendation for achieving additional savings.

How OIG Did This Review

To determine the effects of the price-substitution policy, 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. To account for a 3-quarter lag between the reporting of pricing data and the application of price substitutions, we used drug utilization data for the fourth quarter of 2017 through the third quarter of 2018 to calculate the savings based on 2017 ASP data.

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BACKGROUND

Objectives

1. To quantify the Medicare savings based on 2017 average sales prices that resulted from price substitutions for certain Part B-covered drugs.
2. To estimate the financial impact of expanding the Centers for Medicare & Medicaid Services' (CMS) criteria for price substitution.

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 that identifies a drug's 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.

When Congress established the 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]

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. (Hereinafter 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) quarterly.[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

[1] Section 1847A(d)(2)(B) of the Social Security Act (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 represents the drug name and a specific amount of the drug 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 identifies 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).

Part B drugs is equal to 106 percent of the volume weighted ASP for the drug.[8] However, under sequestration legislation, Medicare's portion of 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 2018 were used to establish reimbursement amounts for the third quarter of 2018.

Manufacturer Reporting of AMPs

In addition to providing quarterly ASPs, certain manufacturers must provide CMS with the AMP for each of their NDCs quarterly.[10] 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 2 previous quarters or 3 of the previous 4 quarters.[11] 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 are available for each of the NDCs used to determine the published reimbursement amount for a drug.[12] 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.[13] CMS also does not substitute prices when the Food and Drug Administration (FDA) has identified a drug as being in short supply.[14] Price substitutions take effect in the quarter after OIG shares the

[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, 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.

[10] Section 1927(b)(3) of the Act.

[11] 42 CFR § 414.904(d)(3).

[12] Ibid.

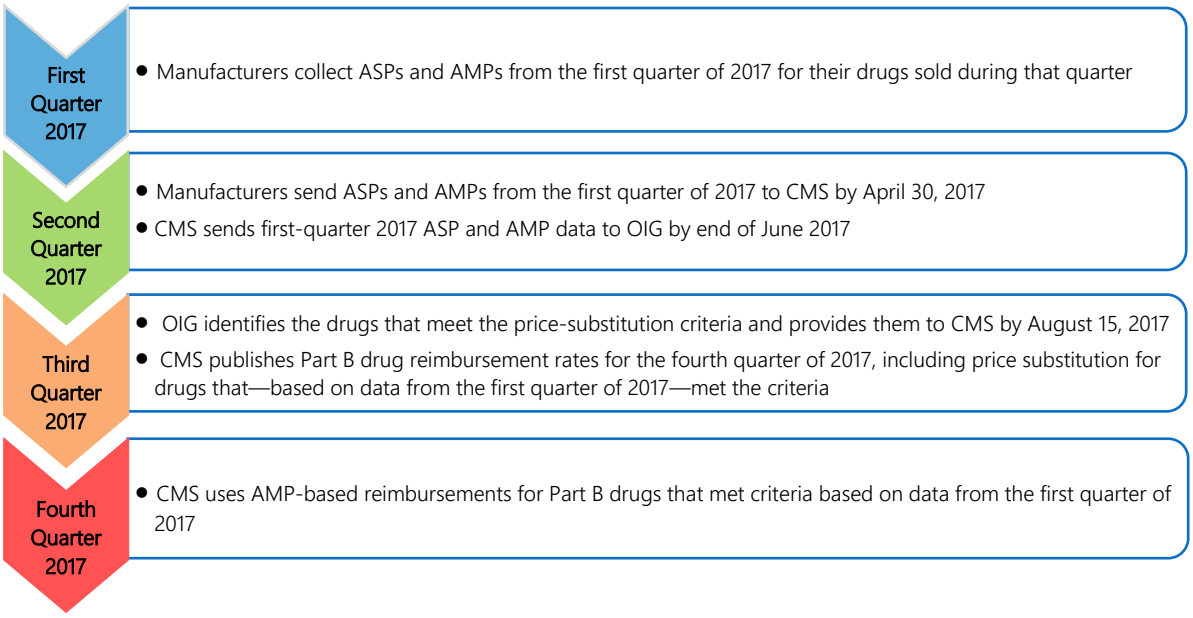
[13] Ibid.

[14] Ibid.

results of its most recent pricing comparison and remain in effect for one quarter.[15]

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 1, price substitutions that took effect in the fourth quarter of 2017 were based on comparisons of ASPs and AMPs from the first quarter of 2017.

Exhibit 1: Timeline for AMP-Based Price Substitutions in 2017



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 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 based on data from 2009 through 2012 if CMS implemented the AMP price substitutions. OIG's 2013 annual report was the first to calculate annual savings that were a direct result of CMS's price-substitution policy.

Methodology

To determine the effects of the price-substitution policy, 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. To account for a 3-quarter lag between the reporting of pricing data and the application of price substitutions, we used drug utilization data for the fourth quarter of 2017

[15] 42 CFR § 414.904(d)(3).

through the third quarter of 2018 to calculate the savings based on 2017 ASP data. Appendix A provides a more detailed methodology.

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

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.

FINDINGS

CMS's price-substitution policy saved Medicare and its beneficiaries $7 million over 1 year

CMS initiated price substitutions for 14 drugs based on 2017 data. Price substitutions for these drugs saved Medicare and its beneficiaries $7 million over the 1-year period between the fourth quarter of 2017 and the third quarter of 2018, as shown in Exhibit 2. Since CMS instituted its price-substitution policy in 2013, Medicare and its beneficiaries have saved $62.5 million, including the $7 million amount in 2017.

Exhibit 2: Price substitutions saved Medicare and its beneficiaries $7 million

		Quarter(s) in Which Price Substitutions Occurred				
Drug	**Description**	**Fourth Quarter 2017**	**First Quarter 2018**	**Second Quarter 2018**	**Third Quarter 2018**	**Savings**
J0592	Buprenorphine hydrochloride			✓		$195
J0670	Mepivacaine HCl injection	✓	✓	✓	✓	$1,315
J1580	Garamycin gentamicin injection				✓	$8,322
J1670	Tetanus immune globulin injection		✓			$15,740
J2400	Chloroprocaine HCl injection	✓	✓	✓	✓	$2,896
J2501	Paricalcitol	✓	✓	✓	✓	$1,107
J2720	Protamine sulfate injection	✓	✓	✓		$335
J3315	Triptorelin pamoate			✓	✓	$1,867,572
J3486	Ziprasidone mesylate				✓	$13
J7520	Sirolimus oral	✓	✓	✓	✓	$5,110,869
J9100	Cytarabine HCl injection				✓	$374
J9200	Floxuridine injection		✓	✓		$316
Q0166	Granisetron HCl oral		✓	✓	✓	$351
Q0167	Dronabinol oral	✓	✓		✓	$5,923
					Total	**$7,015,328**

Source: OIG analysis of ASP and AMP data from 2017

Expanding the price-substitution criteria could have generated up to $2.9 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 2017, Medicare and its beneficiaries could have saved up to an additional $2.9 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. Eighteen drugs with complete AMP data exceeded this threshold in at least 1 quarter of 2017 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. If the 18 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 $2.9 million between the fourth quarter of 2017 and the third quarter of 2018.[16] Since 2013, Medicare and its beneficiaries could have saved up to an additional $29.1 million (including the $2.9 million for 2017) if CMS had expanded its criteria to include drugs that exceeded the 5-percent threshold in a single quarter.

Previously, CMS has expressed concern that price substitutions based on results from a single quarter may represent an aberrant quarter of pricing rather than a market trend.[17] However, according to 2016 and 2017 data, 10 of these 18 drugs exceeded the 5-percent threshold more than once over the 2-year period.[18] These 10 drugs accounted for $2.4 million of the $2.9 million in additional savings. Over the 2-year period, 7 of the 10 exceeded the threshold in 2 of the 8 quarters, and the other 3 drugs exceeded the threshold three or more times in the 8 quarters.

[16] These 18 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. One of these drugs did not have any allowed Part B utilization during the reviewed period; therefore, the estimated savings for this drug were $0. We excluded one additional injectable drug from this analysis because the oral form of this drug was identified by FDA as being in short supply.

[17] 76 Fed. Reg. 73026, 73288 (Nov. 28, 2011).

[18] This analysis is based on pricing comparison results for the 2-year period between the first quarter of 2016 and the last quarter of 2017.

CONCLUSION AND RECOMMENDATION

Under the current price-substitution policy, 14 drugs were subject to reimbursement reductions on the basis of data from 2017, saving Medicare and its beneficiaries $7 million between the fourth quarter of 2017 and the third quarter of 2018. Since the inception of price substitution, Medicare and its beneficiaries have saved $62.5 million. Price substitution continues to be an important mechanism for CMS to employ in ensuring reasonable payments for Medicare Part B drugs.

CMS 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. Since 2013, Medicare and its beneficiaries could have saved up to an additional $29.1 million if CMS had expanded its criteria. CMS stated that it 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 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 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 recommend that CMS expand its price-substitution criteria to include at least some additional drugs. 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.

AGENCY COMMENTS AND OIG RESPONSE

CMS did not concur with our recommendation, instead stating 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 drugs that consistently exceed the threshold.

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 2017 data shows that if the policy had been expanded to include the 18 drugs that exceeded the 5-percent threshold in a single quarter, beneficiaries and the program could have saved up to an additional $2.9 million. The majority of the 18 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 Appendix B.

APPENDIX A: Detailed Methodology

We obtained NDC-level ASP data and AMP data for Part B drugs from CMS for 2017. 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 2017 through the third quarter of 2018. In addition, we obtained the drugs that had price substitutions based on data from 2017.

For each quarter of 2017, 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 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.[19] We then subtracted the AMP-based reimbursement amount 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.

[19] One of these drugs associated with a potential price substitution did not have a payment amount based on ASP during the quarter the substitution would have taken place. However, we used the same method to calculate potential savings, i.e., we calculated the difference between the proposed substituted amount and the actual payment amount and multiplied that difference by the Part B utilization.

[20] AMP-based price substitutions based on data from the first through fourth quarters of 2017 were applied in the fourth quarter of 2017 through the third quarter of 2018, respectively.

APPENDIX B: Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUL 17 2019

TO: Joanne Chiedi
Acting Inspector General
Office of Inspector General

FROM: Seema Verma
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2017 Average Sales Prices (OEI-03-19-00260)

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. The Administration has developed a plan, called *American Patients First*, for lowering drug costs and reducing out of pocket expenses. This comprehensive blueprint addresses many of the challenges and opportunities impacting American patients and consumers, and HHS has begun taking many of the actions outlined in the plan.

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 $7 million over a one-year period between the fourth quarter of 2017 and the third quarter of 2018 by reducing payment limits for 14 Healthcare Common Procedure Coding System billing codes.

Based on the 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.

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 real changes to the price of a drug, and thereby minimizes the potential risk of impacting beneficiary access to medically necessary drugs. 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.

ACKNOWLEDGMENTS

Conswelia McCourt served as the 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.

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