Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

COMPARING AVERAGE SALES PRICES AND AVERAGE MANUFACTURER PRICES FOR MEDICARE PART B DRUGS: AN OVERVIEW OF 2013

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EXECUTIVE SUMMARY: COMPARING AVERAGE SALES PRICES AND AVERAGE MANUFACTURER PRICES FOR MEDICARE PART B DRUGS: AN OVERVIEW OF 2013
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WHY WE DID THIS STUDY
When Congress established average sales prices (ASPs) as the primary basis for Medicare Part B drug reimbursement, it also mandated that the Office of Inspector General (OIG) compare ASPs with average manufacturer prices (AMPs) and directed the Centers for Medicare & Medicaid Services (CMS) to substitute payment amounts for drugs with ASPs that exceed AMPs by a threshold of 5 percent. To comply with its statutory mandate, OIG has completed over 30 quarterly pricing comparisons. In April 2013, CMS began substituting payment amounts in accordance with its published price substitution policy, which currently applies to only certain drug codes with complete AMP data that exceed the 5-percent threshold in two consecutive quarters or three of the previous four quarters.

HOW WE DID THIS STUDY
We identified drug codes that had price substitutions on the basis of data from 2013, as well as codes that exceeded the 5-percent threshold but were not eligible for price substitution under CMS's current criteria. We also estimated the financial impact of reducing reimbursement for each of the drug codes that exceeded the 5-percent threshold.

WHAT WE FOUND
Under CMS's price substitution policy, 15 drug codes were subject to reimbursement reductions on the basis of data from 2013, saving Medicare and its beneficiaries an estimated $13 million from the fourth quarter of 2013 through the third quarter of 2014. We estimate that if CMS had expanded its price substitution criteria to include drug codes with complete AMP data in a single quarter or certain codes with partial AMP data, the agency could have generated almost $6 million in additional savings.

WHAT WE RECOMMEND
CMS has maintained a cautious approach to price substitutions and has expressed concern that expanding the criteria for price substitution may impede physician and beneficiary access to drugs. OIG agrees that CMS should always be mindful of access to prescription drugs; however, we continue 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 with ASPs that exceed the AMPs by the threshold percentage. Therefore, we recommend that CMS consider pursuing rulemaking to expand the price substitution policy to include at least some additional drug codes. CMS responded that more experience with the policy is needed before it is expanded.

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OBJECTIVES

1. To estimate the financial impact of substituting Medicare Part B reimbursement amounts for drugs in 2013 that met criteria established by the Centers for Medicare & Medicaid Services (CMS).
2. To estimate the financial impact of expanding CMS's criteria for price substitution.

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 limiting potentially excessive payment amounts based on ASPs. 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—OIG must notify the Secretary of Health and Human Services. The Act directs the Secretary to then 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. To obtain reimbursement for Part B drugs, health care providers submit claims to Medicare contractors using Healthcare Common Procedure Coding System (HCPCS) codes.[4] In 2013, Medicare and its beneficiaries spent over $13 billion for Part B drugs.

Medicare Part B pays for most covered drugs using a reimbursement methodology based on ASPs. As defined by law, an ASP is 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.[5] Certain manufacturers must

[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 a specific amount of the drug but does not specify the manufacturer or package size.

[5] 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).

provide CMS with the ASP and volume of sales for each of their national drug codes (NDCs) on a quarterly basis.[6, 7]

HCPCS codes represent one or more NDCs. 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 HCPCS code.[8, 9] There is a two-quarter lag between the sales period for which ASPs are reported and the effective date of the reimbursement amounts. For example, ASPs from the first quarter of 2013 were used to establish reimbursement amounts for the third quarter of 2013.

Manufacturer Reporting of AMPs

In addition to providing quarterly ASPs, certain manufacturers must provide CMS with the AMP for each of their NDCs on a quarterly basis.[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). By law, 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.[11]

OIG's Monitoring of ASPs and AMPs

To comply with its statutory mandate, OIG has completed over 30 quarterly pricing comparisons since the ASP reimbursement methodology for Part B drugs was implemented in January 2005. In addition, OIG has completed six annual overviews of ASPs and AMPs for the years 2007 through 2012.

AMP-Based Price Substitutions

Since April 2013, CMS has substituted 103 percent of the AMP for the ASP-based reimbursement amount when OIG identifies a HCPCS code

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

[7] An NDC is an 11-digit identifier that represents a specific manufacturer, product, and package size.

[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 effective payment rate for most Part B drugs is 104.3 percent of the volume-weighted ASP.

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

[11] Section 1927(k)(1) of the Act, as amended by § 2503 of the Patient Protection and Affordable Care Act, P.L. 111-148.

that exceeds the 5-percent threshold in two consecutive quarters or three of the previous four quarters.[12] Because CMS believes that comparisons based on partial AMP data may not adequately reflect market trends, the agency lowers reimbursement amounts only when ASP and AMP comparisons are based on the same set of NDCs (i.e., are based on complete AMP data).[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 the drug and dosage form described by the HCPCS code are 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 two-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 three-quarter lag between the ASP reporting period and the effective date of the price substitutions. For example, price substitutions that took effect in the fourth quarter of 2013 were based on comparisons of ASPs and AMPs from the first quarter of 2013.

METHODOLOGY

Data Collection and Analysis

We obtained NDC-level ASP data, AMP data, and wholesale acquisition cost (WAC) data from CMS for the first through fourth quarters of 2013. We also obtained ASP-based reimbursement amounts for the quarters in which price substitutions occurred (i.e., the fourth quarter of 2013 through the third quarter of 2014).

For HCPCS codes in each quarter of 2013, we calculated volume-weighted AMPs consistent with CMS's methodology for calculating volume-weighted ASPs. For HCPCS codes with partial AMP data (i.e., HCPCS codes that had AMP data for only some of the NDCs that CMS used to calculate volume-weighted ASPs), we accounted for

[12] 42 C.F.R. § 414.904(d)(3).
[13] Ibid. See also 76 Fed. Reg. 73026, 73289 (Nov. 28, 2011).
[14] Ibid. See also 75 Fed. Reg. 40040, 40158 (July 13, 2010).
[15] Ibid.
[16] Ibid.

missing data by substituting each missing AMP value with the manufacturer-reported WAC.[17, 18]

For each quarter of 2013, we compared the volume-weighted ASPs and AMPs and identified all HCPCS codes with ASPs that exceeded the AMPs by at least 5 percent. We identified HCPCS codes that had price substitutions on the basis of data from 2013, as well as HCPCS codes that exceeded the 5-percent threshold but were not eligible for price substitution under CMS's current criteria. To identify trends over time for HCPCS codes in the latter group, we reviewed pricing comparison results for the 2-year period from the first quarter of 2012 through the last quarter of 2013.

To estimate the savings associated with reducing reimbursement for each HCPCS code that exceeded the 5-percent threshold, we subtracted 103 percent of the volume-weighted AMP from the ASP-based reimbursement amount for the quarter in which the price substitution would have occurred/did occur.[19] We then multiplied the difference by one-fourth of the number of services that were allowed by Medicare for each HCPCS code in 2013.

Limitations

We did not verify the accuracy of manufacturer-reported ASP, AMP, and WAC 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. Our analyses were performed on ASP and AMP data compiled by CMS soon after that deadline. We did not determine whether manufacturers provided any updated data to CMS at a later date.

Under sequestration, the effective payment rate for most Part B drugs is 104.3 percent of the volume-weighted ASP. However, savings estimates in this report were calculated without regard to sequestration and therefore may be slightly overstated.

Savings estimates for the fourth quarter of 2013 through the third quarter of 2014 were based on drug utilization from 2013. These estimates assume that the number of services that were allowed by Medicare

[17] WAC is defined in § 1847A(c)(6)(B) of the Act.

[18] WACs are typically higher than AMPs and therefore function as conservative proxies for missing AMP values.

[19] AMP-based price substitutions based on data from the first through fourth quarters of 2013 were applied in the fourth quarter of 2013 through the third quarter of 2014, respectively.

remained consistent from one quarter to the next and that there were no significant changes in utilization between 2013 and 2014.

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.

FINDINGS

CMS's price substitution policy saved Medicare and its beneficiaries an estimated $13 million over 1 year

Under CMS's price substitution policy, 15 HCPCS codes were subject to price reductions on the basis of data from 2013. These codes exceeded the 5-percent threshold in two consecutive quarters or three of four quarters using complete AMP data, were not identified by FDA as being in short supply, and had AMP-based substitution amounts that were less than the ASP-based reimbursement amounts for the quarter(s) in which a substitution occurred.[20] We estimate that price substitutions for these HCPCS codes saved Medicare and its beneficiaries approximately $13 million over the 1 year period from the fourth quarter of 2013 through the third quarter of 2014. Table 1 lists the 15 HCPCS codes, including the quarter(s) during which the price substitution occurred.

Table 1: HCPCS Codes That Had Price Substitutions on the Basis of Data from 2013

HCPCS Code	Description	HCPCS Code Dosage	Quarter(s) in Which Price Substitutions Occurred			
			Fourth Quarter 2013	First Quarter 2014	Second Quarter 2014	Third Quarter 2014
J0500	Dicyclomine injection	20 mg		X		
J1110	Dihydroergotamine mesylate injection	1 mg	X	X	X	X
J1270	Doxercalciferol injection	1 mcg	X			
J1953	Levetiracetam injection	10 mg	X			
J1955	Levocarnitine injection	1 g			X	
J2360	Orphenadrine injection	60 mg	X		X	
J2675	Progesterone injection	50 mg			X	X
J3070	Pentazocine injection	30 mg				X
J3410	Hydroxyzine HCl injection	25 mg		X	X	
J3415	Pyridoxine HCl injection	100 mg				X
J7626	Budesonide noncompounded, unit dose form	0.5 mg			X	X
J9040	Bleomycin sulfate injection	15 units		X		
J9190	Fluorouracil injection	500 mg			X	X
J9211	Idarubicin HCl injection	5 mg			X	
J9360	Vinblastine sulfate injection	1 mg		X	X	X

Source: OIG analysis of ASP and AMP data from 2013.

[20] Three additional HCPCS codes met CMS's duration criteria but were in short supply and/or had AMP-based substitution amounts that were greater than the ASP-based reimbursement amounts for the quarters in which the substitutions would have occurred.

Expanding the price substitution criteria could have generated almost $6 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 curb potentially excessive payment amounts based on ASPs. We estimate that if CMS had expanded its price substitution criteria to include certain other Part B drugs, Medicare and its beneficiaries could have saved an additional $5.9 million over 1 year.

An additional $3.6 million could have been saved over 1 year by expanding the criteria to include HCPCS codes with complete AMP data in a single quarter

Twenty HCPCS codes with complete AMP data exceeded the 5-percent threshold in at least one quarter of 2013 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 two consecutive quarters or three of four quarters).[21] We estimate that if these 20 drug codes had been eligible for price reductions on the basis of data from a single quarter only, Medicare and its beneficiaries could have saved an additional $3.6 million from the fourth quarter of 2013 through the third quarter of 2014.

CMS has expressed concern that price substitutions based on results from a single quarter would not account for temporary fluctuations in market prices.[22] However, price discrepancies for the majority of the 20 HCPCS codes do not appear to have resulted from only isolated fluctuations. Almost all of the codes also exceeded the 5-percent threshold at some point before and/or after the quarter in question,[23] with more than half of the codes (11 of 20) exceeding the 5-percent threshold at least once in the previous 5 quarters. For example, one HCPCS code was not eligible for price substitution in the first quarter of 2013 because it did not meet CMS's duration criteria, even though this code met all of CMS's price substitution criteria in the first and third quarters of the previous year.[24] Another HCPCS code exceeded the threshold in the third quarter of 2012

[21] These 20 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.

[22] 76 Fed. Reg. 73026, 73288 (Nov. 28, 2011).

[23] This analysis is based on pricing comparison results for the 2-year period from the first quarter of 2012 through the last quarter of 2013.

[24] The ASP for this HCPCS code exceeded the AMP by at least 5 percent in the second quarter of 2013 as well, which triggered a price substitution because the code then exceeded the threshold for two consecutive quarters.

and again in the second and fourth quarters of 2013 but never had a price substitution because it never met CMS's specific duration criteria. If CMS had expanded its price substitution criteria to include codes that exceed the threshold in 2 of 6 quarters, all 11 codes that also exceeded the threshold in a prior quarter could have been eligible for price substitutions, saving Medicare and its beneficiaries approximately $600,000.

An additional $2.3 million could have been saved over 1 year by expanding the criteria to include HCPCS codes with partial AMP data in a single quarter

When we used WACs as proxies for missing AMPs, two HCPCS codes exceeded the threshold in at least one quarter of 2013.[25, 26] Given that WACs were higher than AMPs for the vast majority of drug products covered under Part B in 2013, these results suggest that the ASPs for these two HCPCS codes may be excessive and that price substitutions may be warranted in these cases. We estimate that if reimbursement amounts for the two HCPCS codes had been based on 103 percent of the AMPs during the applicable quarters, Medicare expenditures could have been reduced by $2.3 million from the fourth quarter of 2013 through the third quarter of 2014.

[25] These two HCPCS codes did not meet CMS's duration criteria. However, one of the codes exceeded the threshold during one quarter of 2012 using complete AMP data (and met all of CMS's price substitution criteria during that quarter). The two codes met CMS's other price substitution criteria (i.e., they were not identified by FDA as being in short supply, and they 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).

[26] An additional three HCPCS codes with partial AMP data exceeded the 5-percent threshold in at least one quarter of 2013 but were identified as being in short supply and/or having AMP-based substitution amounts that were greater than the ASP-based reimbursement amounts for the quarters in which the price substitutions would have occurred.

CONCLUSION AND RECOMMENDATION

Currently, CMS's price substitution policy is relatively narrow in scope; it is limited to only certain HCPCS codes with complete AMP data. Under this policy, 15 drug codes were subject to reimbursement reductions on the basis of data from 2013, saving Medicare and its beneficiaries an estimated $13 million from the fourth quarter of 2013 through the third quarter of 2014. The agency could achieve even greater savings for Medicare and its beneficiaries by expanding its criteria for AMP-based price substitutions.

In response to previous OIG recommendations, CMS expressed concern that expanding price substitution criteria may impede physician and beneficiary access to drugs. OIG agrees that CMS should always be mindful of access to prescription drugs, and we support current safeguards to prevent price substitutions for drugs that are in short supply. However, we continue 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 with ASPs that exceed the AMPs by the threshold percentage. Therefore, we recommend that CMS:

Consider pursuing rulemaking to expand the price substitution policy

To more effectively limit potentially excessive payment amounts based on ASPs and generate greater savings for Medicare and its beneficiaries, CMS should consider broadening its price substitution criteria to include at least some additional HCPCS codes. A more expansive policy might include HCPCS codes with complete AMP data that exceed the threshold in a single quarter, or those with partial AMP data that exceed the threshold when WACs are used as proxies for missing AMPs. Alternatively, CMS could consider a more modest expansion of the policy that better captures HCPCS codes that repeatedly exceed the 5-percent threshold. For example, CMS could expand the criteria to include codes with complete AMP data that exceed the 5-percent threshold in two of six quarters. To provide CMS with greater flexibility, any future regulations could provide the agency discretion to forgo a price substitution when there are indications that the substitution amount is below the provider acquisition cost.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In response to our recommendation, CMS stated that more experience with the price substitution policy is needed before it can be expanded. CMS appreciates OIG's findings and welcomes information from future pricing comparisons so that specific proposals may be considered on the basis of additional experience.

To help ensure that CMS has sufficient information for its deliberations regarding the price substitution policy, OIG will continue to provide CMS with the results from our quarterly pricing comparisons, along with annual assessments of the impact of the price substitution policy. Because CMS did not specifically state whether it concurs with our recommendation, we ask that CMS more clearly indicate in its final management decision whether it concurs with our recommendation and what steps, if any, it will take to implement it.

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

APPENDIX

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

JAN 16 2015

To: Daniel R. Levinson
Inspector General

From: Marilyn Tavenner /S/
Administrator
Centers for Medicare & Medicaid Services

Subject: OIG Draft Report: *Comparing Average Sales Prices and Average Manufacturer Prices for Medicare Part B Drugs: An Overview of 2013,* OEI-03-14-00520

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of the Inspector General's (OIG) draft report. This report is part of a series of average sales price (ASP) and average manufacturer price (AMP) comparisons required under section 1847A(d) of the Social Security Act. CMS is committed to being a good steward of taxpayer dollars by continuously striving to maximize the affordability and availability of drugs for Medicare patients. CMS is saving taxpayer money through this goal. According to the OIG's study, CMS's price substitution policy saved Medicare and its beneficiaries an estimated $13 million over a one-year period between the fourth quarter of 2013 and the third quarter of 2014 by reducing payment limits on 15 Healthcare Common Procedure Coding System (HCPCS) billing codes.

OIG Recommendation
The OIG recommends that CMS consider pursuing rulemaking to expand the price substitution policy to include at least some additional HCPCS codes.

CMS Response
CMS believes that more experience is needed with this policy before it is expanded, particularly in light of the recent statutory change to the definition of AMP, which may affect the AMP of certain drugs, including those used mainly in the physician's office. CMS appreciates the OIG's findings and welcomes information from continuing the studies that are required by the statute so that specific proposals based on more thorough experience may be considered. By continuing to take a cautious approach, as discussed in rulemaking and acknowledged in the OIG's report, CMS minimizes the risk of impacting physician and beneficiary access to drugs.

CMS thanks the OIG for their efforts on this issue and looks forward to working with the OIG on this and other issues in the future.

ACKNOWLEDGMENTS

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Lauren McNulty served as the team leader for this study. Central office staff who provided support include Meghan Kearns and Christine Moritz.

Office of Inspector General

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