# 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 2012

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**March 2014**
**OEI-03-13-00570**

# EXECUTIVE SUMMARY: COMPARING AVERAGE SALES PRICES AND AVERAGE MANUFACTURER PRICES FOR MEDICARE PART B DRUGS: AN OVERVIEW OF 2012
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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 29 quarterly pricing comparisons since the ASP reimbursement methodology for Part B drugs was implemented in January 2005. CMS began substituting payment amounts in April 2013 in accordance with its published price substitution policy, which currently applies to only certain codes with complete AMP data.

## HOW WE DID THIS STUDY
We identified (1) drug codes that would have been eligible for price substitution on the basis of data from one or more quarters of 2012, (2) the codes for which CMS actually substituted prices, and (3) the codes that would not have been eligible for price substitution because they did not meet one or more of CMS's substitution criteria. We also estimated savings for each of the drug codes that exceeded the 5-percent threshold in a given quarter of 2012.

## WHAT WE FOUND
Under CMS's price substitution policy, 14 drug codes would have been subject to reimbursement reductions on the basis of data from 2012, saving Medicare and its beneficiaries an estimated $1.8 million between the fourth quarter of 2012 and the third quarter of 2013. However, because CMS did not begin substituting prices until the second quarter of 2013, only eight drug codes were actually subject to reductions, generating an estimated $819,000 in savings. If CMS had expanded its price substitution criteria, the agency could have generated a quarter of a million dollars in additional savings.

## WHAT WE RECOMMEND
CMS has already generated savings by implementing its current price substitution criteria and could achieve even greater savings by expanding those criteria. Therefore, we recommend that CMS (1) expand the price substitution policy to include drug codes with complete AMP data in a single quarter and (2) expand the price substitution policy to include drug codes with partial AMP data. CMS did not concur with either of our recommendations.

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## OBJECTIVES

1. To estimate the financial impact of substituting Medicare Part B reimbursement amounts for drugs in 2012 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

The Social Security Act (the Act) mandates that the Office of Inspector General (OIG) compare average sales prices (ASPs) with average manufacturer prices (AMPs).[1] The Act states that if OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (currently 5 percent), the Secretary of Health and Human Services (the Secretary) may disregard the ASP for the drug when setting reimbursement amounts.[2, 3] The Act further states:

> … the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment … the lesser of (i) the widely available market price … (if any); or (ii) 103 percent of the average manufacturer price….[4]

### Coverage of Prescription Drugs Under Medicare Part B

Medicare Part B covers a limited number of outpatient prescription drugs, including injectable drugs administered by a physician; oral anticancer drugs and immunosuppressive drugs; drugs used in conjunction with durable medical equipment; and some vaccines.

### Payments for Prescription Drugs Under Medicare Part B

To obtain reimbursement for covered outpatient prescription drugs, health care providers submit claims to Medicare contractors using Healthcare Common Procedure Coding System (HCPCS) codes. In the case of prescription drugs, each HCPCS code defines the drug name and the amount of the drug represented by the HCPCS code but does not specify the manufacturer or package size.

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

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

[3] Section 1847A(d)(3)(B)(ii) of the Act authorizes the Secretary to adjust the applicable threshold percentage in 2006 and subsequent years; however, the threshold percentage has been maintained at 5 percent.

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

Medicare and its beneficiaries spent $13.6 billion for Part B drugs in 2012.[5] Although Medicare paid for more than 700 outpatient prescription drug HCPCS codes that year, spending for Part B drugs was concentrated on a relatively small subset of those codes. In 2012, 72 HCPCS codes accounted for 90 percent of the expenditures for Part B drugs; only 16 of these codes represented the majority of Part B drug expenditures.

## Reimbursement Methodology 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.[6] Manufacturers that participate in the Medicaid drug rebate program must provide CMS with the ASP and volume of sales for each of their national drug codes (NDCs) on a quarterly basis; submissions are due 30 days after the close of each quarter.[7] An NDC is an 11-digit identifier that represents a specific manufacturer, product, and package size.

Because Medicare Part B reimbursement for outpatient drugs is based on HCPCS codes rather than NDCs and more than one NDC may meet the definition of a particular HCPCS code, CMS has developed a file that matches, or "crosswalks," manufacturers' NDCs to HCPCS codes. CMS uses information in this crosswalk file to calculate volume-weighted ASPs for covered HCPCS codes.[8]

[5] Medicare expenditures for Part B drugs in 2012 were calculated using CMS's Part B Analytics Reporting System (PBAR).

[6] Section 1847A(c) of the Act. The ASP is net of any price concessions, with limited exceptions.

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

[8] The equation that CMS uses to calculate volume-weighted ASPs is described in section 1847A(b)(6) of the Act and is provided in Appendix A.

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.[9, 10] However, 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 2012 were used to establish reimbursement amounts for the third quarter of 2012.

### Manufacturer Reporting of AMPs

In addition to providing quarterly ASPs, manufacturers that participate in the Medicaid drug rebate program must provide CMS with the AMP for each of their NDCs on a quarterly basis; quarterly AMP submissions are due 30 days after the end of each quarter.[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). 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.[12, 13]

### OIG's Monitoring of ASPs and AMPs

To comply with its statutory mandate, OIG has completed 29 quarterly pricing comparisons since the ASP reimbursement methodology for Part B drugs was implemented in January 2005.[14] In addition, OIG has

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[9] Section 1847A(b)(1) of the Act. Medicare beneficiaries are responsible for 20 percent of this amount in the form of coinsurance.

[10] 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.

[11] Section 1927(b)(3) of the Act and 42 CFR §§ 447.510(a) and (d).

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

[13] Pursuant to § 1927(k)(10) of the Act, "retail community pharmacy" means an independent, chain, supermarket, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include pharmacies that dispense prescription medications to patients primarily through the mail; pharmacies in nursing homes, long-term-care facilities, or hospitals; clinics; charitable or not-for-profit pharmacies; government pharmacies; or pharmacy benefit managers.

[14] This report total includes pricing comparisons for five quarters that were not made available to the public. OIG issued the results for these quarters directly to CMS to facilitate price substitutions.

completed five annual overviews of ASPs and AMPs for the years 2007 through 2011. OIG has consistently recommended that CMS lower reimbursement for drugs that exceed the 5-percent threshold as directed by the Act.

## AMP-Based Price Substitutions

In November 2012, CMS published a final rule that, among other things, specifies the criteria for AMP-based price substitutions.[15, 16] Pursuant to this final rule, CMS substitutes 103 percent of the AMP for the ASP-based reimbursement amount when OIG identifies a HCPCS code that exceeds the 5-percent threshold in two consecutive quarters or three of four quarters.[17] 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).[18] 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.[19] 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.[20] 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.[21]

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[15] 77 Fed. Reg. 68892, 69368 (Nov. 16, 2012).

[16] This is the third time that CMS has pursued rulemaking on AMP-based price substitutions. In July 2010, CMS published a proposed rule that specified the circumstances under which AMP-based price substitutions would occur, effective January 2011(75 Fed. Reg. 40040, 40259 (July 13, 2010)); however, the agency opted not to finalize this proposed rule partly on the basis of impending changes to the definition of AMP (75 Fed. Reg. 73170, 73471 (Nov. 29, 2010)). In November 2011, CMS published a final rule that again specified circumstances under which price substitutions would occur (76 Fed. Reg. 73026, 73473 (Nov. 28, 2011)), but the agency did not implement that policy in light of access concerns related to drug shortages.

[17] 77 Fed. Reg. 68892, 69368 (Nov. 16, 2012). CMS has expressed concern that price substitutions based on results from a single quarter will not accurately account for temporary fluctuations in market prices and believes that focusing on drugs that consistently exceed the threshold over multiple quarters is more appropriate. See, e.g., 76 Fed. Reg. 73026, 73288, 73291 (Nov. 28, 2011).

[18] 76 Fed. Reg. 73026, 73289 (Nov. 28, 2011).

[19] 77 Fed. Reg. 68892, 69368 (Nov. 16, 2012). See also 75 Fed. Reg. 40040, 40158 (July 13, 2010). For example, if the AMP-based substitution amount were $5 and the ASP-based reimbursement amount were $4 for the quarter in which the substitution would take place, CMS would not make the price substitution.

[20] 77 Fed. Reg. 68892, 69368 (Nov. 16, 2012).

[21] See, e.g., 76 Fed. Reg. 73026, 73473 (Nov. 28, 2011).

CMS began applying its price substitution policy to reimbursement amounts published for the second quarter of 2013. Because of the two-quarter lag between the period for which ASPs are reported 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. Therefore, price substitutions that were published by CMS for the second quarter of 2013 were based on comparison of ASPs and AMPs from the third quarter of 2012.

## METHODOLOGY

We obtained files from CMS containing NDC-level ASP data from the first through fourth quarters of 2012, which were used to establish Part B drug reimbursement amounts for the third quarter of 2012 through the second quarter of 2013, respectively. These files also include information that crosswalks NDCs to their corresponding HCPCS codes. We also obtained ASP-based reimbursement amounts for the quarters in which price substitutions would have occurred/did occur (i.e., the fourth quarter of 2012 through the third quarter of 2013),[22] as well as AMP data and wholesale acquisition cost (WAC) data from CMS for the first through fourth quarters of 2012.[23]

### Calculating Volume-Weighted AMPs for 2012

As part of our analysis for each quarter of 2012, we calculated a volume-weighted AMP for each HCPCS code, consistent with CMS's methodology for calculating volume-weighted ASPs. To ensure that the broadest range of drug codes is subject to OIG's pricing comparisons, we examined HCPCS codes with complete AMP data (i.e., HCPCS codes with AMP data for every NDC that CMS used in its calculation of volume-weighted ASPs), as well as HCPCS codes with partial AMP data (i.e., HCPCS codes with AMP data for only some of the NDCs that CMS used in its calculation of volume-weighted ASPs).

For all HCPCS codes with partial AMPs, we accounted for missing data by substituting each missing AMP value with the manufacturer-reported

[22] Of these four quarters, CMS made actual AMP-based price substitutions only in the second and third quarters of 2013.

[23] ASP, WAC, and crosswalk data from the first through fourth quarters of 2012 were current as of June 2012, September 2012, December 2012, and March 2013, respectively. AMP data from the first through fourth quarters of 2012 were current as of May 2012, August 2012, January 2013, and March 2013, respectively.

WAC for the NDC.[24] This approach enabled us to calculate volume-weighted AMPs for these HCPCS codes using the full set of NDCs. Because WACs do not represent actual transaction prices and do not include "prompt pay" discounts or other discounts, rebates, or price reductions, they are typically higher than AMPs and therefore function as conservative proxies for missing AMP values.[25, 26] Appendix B describes in more detail the methods used to calculate volume-weighted AMPs for all HCPCS codes.

### Comparing Volume-Weighted ASPs and AMPs for 2012

For each quarter of 2012, we compared the volume-weighted ASPs and AMPs and identified all HCPCS codes with ASPs that exceeded the AMPs by at least 5 percent.

In addition, we identified codes with complete AMP data that exceeded the threshold in two consecutive quarters or three of four quarters,[27] codes that were identified by FDA as being in short supply,[28] and codes with AMP-based substitution amounts that were greater than the ASP-based payment amounts for the quarter in which the price substitution would have occurred.[29]

We merged the results of the four quarterly pricing comparisons and identified (1) the HCPCS codes that would have been eligible for price substitution on the basis of data from one or more quarters of 2012, (2) the codes for which CMS actually substituted prices, and (3) the codes that would not have been eligible for price substitution because they did not meet one or more of CMS's criteria.

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[24] Pursuant to section 1847A(c)(6)(B) of the Act, the WAC is defined as the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States as reported in wholesale price guides or other publications of pricing data for drugs or biologicals.

[25] First Databank, Inc., *Drug Pricing Policy*, accessed at http://www.fdbhealth.com/policies/drug-pricing-policy on October 23, 2013.

[26] WACs were greater than AMPs for over 90 percent of NDCs included in CMS's quarterly ASP files for 2012; median percentage differences in each quarter ranged from 42 to 51 percent.

[27] To accurately identify codes that exceeded the 5-percent threshold in two consecutive or three of four quarters, our pricing comparisons from the first three quarters of 2012 also examined quarterly results from 2011.

[28] To identify drugs that FDA determined to be in short supply, we consulted FDA's *Current Drug Shortages Index*, available online at http://www.fda.gov/drugs/drugsafety/drugshortages. Accessed on September 24, 2012; November 6, 2012; February 4, 2013; and April 4, 2013.

[29] As mentioned previously, AMP-based price substitutions based on pricing data from the first through fourth quarters of 2012 would have applied in the fourth quarter of 2012 through the third quarter of 2013, respectively.

We also estimated savings for each of the HCPCS codes that exceeded the 5-percent threshold in a given quarter of 2012.[30] To do this, we calculated 103 percent of the volume-weighted AMP and subtracted this amount from the reimbursement amount for the HCPCS code during the quarter in which the price substitution would have occurred/did occur.[31] For example, for each code that exceeded the threshold in the first quarter of 2012, we subtracted 103 percent of that quarter's volume-weighted AMP from the published reimbursement amount for the fourth quarter of 2012. Then, to estimate the financial effect of lowering reimbursement for the applicable quarter, we multiplied the difference by one-fourth of the number of services that were allowed by Medicare for each HCPCS code in 2012, as reported in the PBAR.

### 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 crosswalk files or examine NDCs that CMS opted to exclude from its calculation 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.

### 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.

[30] Our published quarterly pricing comparisons for the first and second quarters of 2012 contained savings estimates that may differ from the savings estimates presented in this annual overview because of updated data and changes to the way OIG compares prices for HCPCS codes with partial AMPs. Results from our quarterly pricing comparisons for the third and fourth quarters of 2012 did not contain savings estimates and were not made available to the public.

[31] Savings estimates for price substitutions that occurred in the second and third quarters of 2013 were calculated without regard to the reductions imposed by sequestration.

## FINDINGS

### CMS's price substitution policy would have saved Medicare and its beneficiaries almost $2 million over 1 year

Of the 472 HCPCS codes examined during 2012, 14 met all of CMS's price substitution criteria during at least one quarter. 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 would have occurred/did occur.[32] If CMS had substituted the ASP-based reimbursement amounts with 103 percent of the AMPs for all 14 HCPCS codes during the applicable quarters, Medicare and its beneficiaries would have saved an estimated $1.8 million between the fourth quarter of 2012 and the third quarter of 2013.[33]

Because CMS did not begin lowering reimbursement amounts for eligible drugs until the second quarter of 2013, only 8 of the 14 eligible HCPCS codes were subject to actual price substitutions. According to OIG estimates, price substitutions in the second and third quarters of 2013 for these eight HCPCS codes saved Medicare and its beneficiaries approximately $819,000, which represents 46 percent of the total estimated savings for the year.

Table 1 lists the 14 HCPCS codes, including the quarter(s) during which the price substitution would have occurred/did occur.

[32] Seven additional HCPCS codes exceeded the 5-percent threshold in two consecutive quarters or three of four quarters but were identified as being 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 price substitutions would have occurred.

[33] As mentioned previously, AMP-based price substitutions calculated using pricing data from the first through fourth quarters of 2012 would have been applied in the fourth quarter of 2012 through the third quarter of 2013, respectively.

**Table 1: HCPCS Codes That Met CMS's Price Substitution Criteria**

| HCPCS Code | Description | HCPCS Code Dosage | Quarter(s) in Which Price Substitutions Would Have Occurred/Did Occur | | | |
|---|---|---|---|---|---|---|
| | | | Fourth Quarter 2012 | First Quarter 2013 | Second Quarter 2013 | Third Quarter 2013 |
| J0456 | Azithromycin injection | 500 mg | | | X* | X* |
| J0500 | Dicyclomine injection | 20 mg | X | | X* | |
| J0595 | Butorphanol tartrate injection | 1 mg | | | X* | |
| J0610 | Calcium gluconate injection | 10 mL | X | X | | |
| J1205 | Chlorothiazide sodium injection | 500 mg | X | | | |
| J1570 | Ganciclovir sodium injection | 500 mg | | | X* | |
| J1756 | Iron sucrose injection | 1 mg | X | X | | |
| J1955 | Levocarnitine injection | 1 gm | X | | | |
| J2501 | Paricalcitol injection | 1 mcg | X | X | | |
| J2675 | Progesterone injection | 50 mg | X | | X* | |
| J2780 | Ranitidine HCl injection | 25 mg | X | | | |
| J9065 | Cladribine injection | 1 mg | X | X | X* | |
| J9211 | Idarubicin HCl injection | 5 mg | X | X | X* | X* |
| J9214 | Interferon alfa-2b injection | 1 million units | X | X | X* | X* |

Note: Because CMS began making price substitutions in the second quarter of 2013, codes marked with an asterisk (*) had actual price substitutions in the specified quarters.

Source: OIG analysis of ASP and AMP data from 2011 and 2012.

## Expanding the price substitution criteria would have generated a quarter of a million dollars in additional savings for Medicare and its beneficiaries

CMS has maintained a cautious approach to price substitutions to ensure that reimbursement is reduced only in appropriate cases. However, this cautious approach reduces the effectiveness of statutorily mandated ASP monitoring by limiting the number of Part B drugs eligible for price substitution. If CMS had expanded its price substitution criteria to include certain other Part B drugs in 2012, Medicare and its beneficiaries would have saved an additional $253,000 over 1 year.[34]

### *An additional $225,000 would have been saved by expanding the criteria to include HCPCS codes with complete AMP data in a single quarter*

Nineteen HCPCS codes with complete AMP data exceeded the 5-percent threshold in at least one quarter of 2012 but were not eligible for price

[34] All savings estimates in this finding have been rounded to the nearest thousand.

substitution in that quarter because they did not meet CMS's duration criteria (i.e., did not exceed the threshold in two consecutive quarters or three of four quarters).[35] Of these 19 HCPCS codes, 7 exceeded the threshold during multiple quarters of 2012, indicating that the price discrepancies were not merely the results of temporary price fluctuations. In fact, two of the codes were actually subject to price substitutions in subsequent quarters. If the 19 drug codes had been eligible for price reduction on the basis of data from a single quarter only, Medicare and its beneficiaries would have saved an additional $225,000 between the fourth quarter of 2012 and the third quarter of 2013. A list of the 19 HCPCS codes is presented in Appendix C.

### *An additional $29,000 would have been saved by expanding the criteria to include HCPCS codes with partial AMP data*

When we used WACs as proxies for missing AMPs, five HCPCS codes exceeded the threshold in at least one quarter of 2012.[36, 37] Given that WACs were higher than AMPs for the vast majority of drug products covered under Part B in 2012, these results suggest that the ASPs for these five HCPCS codes may be excessive and that price substitutions may be warranted in these cases. We estimate that if reimbursement amounts for the five HCPCS codes had been based on 103 percent of the AMPs during the applicable quarters, Medicare expenditures would have been reduced by $29,000 between the fourth quarter of 2012 and the third quarter of 2013. A list of the five HCPCS codes is presented in Appendix D.

[35] 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 quarter(s) during which the substitution(s) would have occurred.

[36] These five 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 quarter(s) during which the substitution(s) would have occurred.

[37] An additional six HCPCS codes with partial AMP data exceeded the 5-percent threshold in at least one quarter of 2012 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 RECOMMENDATIONS

When Congress established ASP as the basis for Medicare Part B drug reimbursement, it also provided a mechanism for monitoring market prices and limiting potentially excessive ASP-based payment amounts. Specifically, the ASP statute mandates that OIG monitor ASPs by comparing them with AMPs and widely available market prices and directs CMS to lower reimbursement for certain drugs on the basis of OIG's findings. Since the ASP payment methodology took effect in January 2005, OIG has fulfilled its responsibility to monitor ASP-based payment amounts by completing 29 quarterly comparisons of ASPs and AMPs and consistently recommending that CMS lower reimbursement for drugs that exceed the 5-percent threshold. CMS began making price substitutions in April 2013.

Currently, CMS's price substitution policy is relatively narrow in scope; it is limited to only certain codes with complete AMP data. Under this policy, 14 drug codes would have been subject to reimbursement reductions on the basis of data from 2012, saving Medicare and its beneficiaries an estimated $1.8 million between the fourth quarter of 2012 and the third quarter of 2013. However, because CMS did not begin substituting prices until the second quarter of 2013, only eight drug codes were actually subject to reductions, generating an estimated $819,000 in savings.

Although the dollars associated with short-term payment adjustments may be modest relative to total expenditures for Part B drugs, savings achieved through price substitution in the long term could reduce waste and conserve taxpayer funds at a time when increased focus has been placed on rising health care costs and fiscal responsibility. We estimate that CMS has already generated over $800,000 in savings by implementing its current price substitution criteria and that the agency could achieve even greater savings for Medicare and its beneficiaries by expanding those criteria. Therefore, we recommend that CMS:

### Expand the price substitution policy to include HCPCS codes with complete AMP data that exceed the threshold in a single quarter

CMS has expressed concern that price substitutions based on results from a single quarter would not account for temporary fluctuations in market prices; therefore, the agency lowers reimbursement amounts for only those codes with complete AMP data that exceed the 5-percent threshold in two consecutive quarters or three of four quarters. However, this cautious approach reduced the effectiveness of ASP monitoring in 2012.

Even temporary fluctuations in ASPs and AMPs may represent legitimate pricing discrepancies that lead Medicare and its beneficiaries to overpay for certain drugs, if only for a single quarter. Because price substitutions will remain in effect for only one quarter and will be resolved when any temporary fluctuations are corrected, we recommend that CMS include in its price substitution policy all HCPCS codes with complete AMP data that exceed the 5-percent threshold, regardless of the duration of the price discrepancies.

### Expand the price substitution policy to include HCPCS codes with partial AMP data

Because we used WACs as proxies for missing AMPs rather than removing the NDCs from our calculations, the pricing comparisons for HCPCS codes with partial AMP data in 2012 are based on the same set of NDCs. This new methodological approach should help alleviate CMS's concerns that comparisons for codes with partial AMP data may lead to incomplete and inaccurate volume-weighted prices because different sets of NDCs' sales are used in the calculations. Because the risk of substituting ASP-based reimbursement with an artificially low volume-weighted AMP is likely diminished when WACs are used in place of missing AMP values, we recommend that CMS include HCPCS codes with partial AMP data in its price substitution policy.

Furthermore, by excluding from its policy all codes with partial AMP data, CMS may inadvertently provide drug manufacturers with a disincentive to submit timely AMPs. CMS could avoid this potential disincentive by expanding the price substitution policy to include HCPCS codes with partial AMPs.

## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS did not concur with our recommendation to expand the price substitution policy to include HCPCS codes with complete AMP data that exceed the threshold in a single quarter. CMS stated that it appreciates the potential for additional cost savings but is concerned that results from a single quarter may suggest aberrance rather than a market trend and that implementing a more aggressive version of the price substitution policy may affect access to the affected drugs by inadvertently lowering payment amounts below providers' acquisition costs. CMS additionally noted that implementing this recommendation would require the agency to undertake notice-and-comment rulemaking.

CMS also did not concur with our recommendation to consider expanding the price substitution policy to include certain HCPCS codes with partial AMP data. CMS remains concerned that partial AMP data comparisons may not adequately account for market-related drug price changes and may lead to the substitution of inaccurate prices. According to CMS, these substitutions may impact physician and beneficiary access to drugs, even when using conservative approaches, such as substituting missing AMPs with WACs.

OIG agrees that access to prescription drugs is a significant concern that should always be considered when contemplating pricing policies. 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.

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

# APPENDIX A

## CMS's Equation for Calculating Volume-Weighted Average Sales Prices

A volume-weighted ASP is calculated for the dosage amount associated with the HCPCS code. In the following equation, the "Number of Billing Units" represents the number of HCPCS code doses that are contained in an NDC. CMS uses billing units when calculating a volume-weighted ASP because the amount of the drug represented by an NDC may differ from the amount of the drug specified by the HCPCS code.

$$\textit{Volume-Weighted ASP for Dosage Amount of HCPCS Code} = \frac{\textit{Sum of (ASP for NDC} \times \textit{Number of NDCs Sold)}}{\textit{Sum of (Number of NDCs Sold} \times \textit{Number of Billing Units in NDC)}}$$

## APPENDIX B

### Detailed Methodology for Calculating Volume-Weighted Average Manufacturer Prices for 2012

To ensure that the broadest range of drugs would be subject to OIG's pricing comparisons, we examined HCPCS codes with AMP data for every NDC that was used to calculate Medicare reimbursement (i.e., HCPCS codes with complete AMP data), as well as HCPCS codes with AMP data for only some of the NDCs that were used to calculate Medicare reimbursement (i.e., HCPCS codes with partial AMP data).

#### *Accounting for Missing AMPs*

For HCPCS codes with partial AMPs, we accounted for missing data by substituting each missing AMP value with the manufacturer-reported WAC for the NDC, as provided in CMS's quarterly ASP files. If neither the WAC nor the AMP was available for a given NDC, we excluded the corresponding HCPCS code from the analysis.

WACs function as conservative proxies for missing AMP values because WACs are typically higher than AMPs. Unlike AMPs, WACs do not represent actual transaction prices and do not include "prompt pay" discounts or other discounts, rebates, or price reductions. As a result, WACs usually exceed AMPs by a significant margin for both Medicare and Medicaid drugs. According to our analysis, WACs exceeded AMPs for over 90 percent of drug products included in CMS's quarterly ASP files; median percentage differences in each quarter ranged from 42 to 51 percent. A 2005 OIG report found a similar trend among drugs reimbursed by Medicaid; AMP equaled WAC minus 25 percent at the median for all drugs and WAC minus 40 percent at the median for generic drugs.[38]

There are also indications that WACs exceed drug acquisition costs. According to estimates in a 2011 OIG report, invoice prices for single-source drugs averaged 99.46 percent of WACs, while invoice prices for multisource drugs averaged 66.68 percent of the WACs.[39]

[38] OIG, *Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices*, OEI-05-05-00240, June 2005.

[39] OIG, *Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices*, A-06-11-00002, October 2011. Invoice prices are the prices for drugs as listed on invoices provided by sampled pharmacies. OIG did not attempt to identify any discounts, rebates, or other price incentives not reflected in the invoice prices.

### *Calculating Converted AMPs*

Because an AMP is reported for the lowest identifiable quantity of the drug contained in the NDC (e.g., 1 milligram, 1 milliliter, one tablet, one capsule) and the ASP is reported for the entire amount of the drug contained in the NDC (e.g., 50 milliliters, 100 tablets), it was necessary to convert each AMP so that it represents the total amount of the drug contained in the NDC. To do this, we multiplied the AMP for each NDC in each quarter by the total amount of the drug contained in the NDC, as identified by sources such as CMS's crosswalk file, manufacturer Web sites, and drug labels. For some NDCs, we could not identify the amount of the drug reflected by the ASP or AMP and therefore could not calculate a converted AMP. The extent to which NDCs with problematic AMP conversions affected our analysis differed depending on whether the associated HCPCS code had complete AMP data or partial AMP data.

*HCPCS Codes With Complete AMP Data*. If a HCPCS code with complete AMP data had one or more NDCs with a problematic AMP conversion, we automatically excluded that HCPCS code from our pricing comparison for the quarter.

*HCPCS Codes With Partial AMP Data*. If a HCPCS code with partial AMP data had one or more NDCs with a problematic AMP conversion, we did not automatically exclude that HCPCS code from our pricing comparison. Rather, we replaced the converted AMP with the WAC for the NDC. However, if the WAC was not available or if all of the NDCs associated with the HCPCS code had problematic AMP conversions, we dropped the HCPCS code from that quarter's analysis.

### *Calculating Volume-Weighted AMPs*

We calculated a volume-weighted AMP for each HCPCS code consistent with the methodology for calculating volume-weighted ASP. Because we used WACs as proxies for missing AMPs rather than removing the NDCs from our calculations, comparisons between ASPs and AMPs are based on the same set of NDCs for all HCPCS codes, including those with only partial AMP data.

# APPENDIX C

## Nineteen Drug Codes That Would Have Been Eligible for Price Reduction If Criteria Had Been Expanded To Include All Codes With Complete Average Manufacturer Price Data

| Drug Code | Description | Drug Code Dosage | Quarter(s) in Which Price Substitutions Would Have Occurred | | | |
|---|---|---|---|---|---|---|
| | | | Fourth Quarter 2012 | First Quarter 2013 | Second Quarter 2013 | Third Quarter 2013 |
| J0456* | Azithromycin injection | 500 mg | | X | | |
| J0636 | Calcitriol injection | 0.1 mcg | X | | | |
| J0770 | Colistimethate sodium injection | 150 mg | | X | | |
| J1110 | Dihydroergotamine mesylate injection | 1 mg | | | | X |
| J1165 | Phenytoin sodium injection | 50 mg | | | | X |
| J1270 | Doxercalciferol injection | 1 mcg | X | | | X |
| J1570* | Ganciclovir sodium injection | 500 mg | | X | | |
| J1742* | Ibutilide fumarate injection | 1 mg | | | | X |
| J1953* | Levetiracetam injection | 10 mg | | | X | |
| J2360 | Orphenadrine injection | 60 mg | | X | | X |
| J2720 | Protamine sulfate injection | 10 mg | | X | | |
| J2800 | Methocarbamol injection | 10 mL | | X | | |
| J3303 | Triamcinolone hexacetonide injection | 5 mg | | | X | |
| J3415 | Pyridoxine HCl injection | 100 mg | | | X | |
| J7500 | Azathioprine, oral | 50 mg | X | | | |
| J9060 | Cisplatin injection | 10 mg | | X | | |
| J9185 | Fludarabine phosphate injection | 50 mg | | | | X |
| J9208 | Ifosfamide injection | 1 g | X | | | |
| Q0164 | Prochlorperazine maleate, oral | 5 mg | | | | X |

Note: All of the above codes were ineligible for price substitutions in the given quarters only because they did not meet CMS's duration criteria (i.e., did not exceed the threshold in two consecutive quarters or three of four quarters). Each code marked with an asterisk (*) either had actual price substitutions in another quarter or would have had price substitutions in another quarter if the drug had not been in short supply or did not have an AMP-based substitution amount that was greater than the ASP-based reimbursement amount.

Source: OIG analysis of ASP and AMP data from 2012.

# APPENDIX D

## Five Drug Codes That Would Have Been Eligible for Price Reduction If Criteria Had Been Expanded To Include Codes With Partial Average Manufacturer Price Data

| Drug Code | Description | Drug Code Dosage | Quarter(s) in Which Price Substitutions Would Have Occurred | | | |
|---|---|---|---|---|---|---|
| | | | Fourth Quarter 2012 | First Quarter 2013 | Second Quarter 2013 | Third Quarter 2013 |
| J1650* | Enoxaparin sodium injection | 10 mg | X | | | |
| J2515 | Pentobarbital sodium injection | 50 mg | | X | | |
| J2540 | Penicillin g potassium injection | 600,000 units | | X | | |
| Q0163* | Diphenhydramine HCl injection | 50 mg | | X | | |
| Q0164 | Prochlorperazine maleate, oral | 5 mg | | X | | |

* These drug codes also exceeded the 5-percent threshold on the basis of partial AMP data in other quarters of 2012 but during those quarters were identified as being in short supply or had AMP-based substitution amounts that were greater than the ASP-based reimbursement amounts.

Source: OIG analysis of ASP and AMP data from 2012.

# APPENDIX E

## Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

*Administrator*
Washington, DC 20201

**DATE:** JAN - 8 2014

**TO:** Daniel R. Levinson
Inspector General

**FROM:** Marilyn Tavenner /S/
Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: Comparing of Average Sales Prices and Average Manufacturer Prices for Medicare Part B Drugs: An Overview of 2012 (OEI-03-13-00570)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the above subject 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. OIG's objectives for the 2012 overview were to—(1) Estimate the financial impact of substituting Medicare Part B reimbursement amounts for drugs in 2012 that met criteria established by CMS; and (2) Estimate the financial impact of expanding CMS's criteria for price substitution.

The 2012 overview found that the AMP-based price substitution policy that was finalized during rulemaking (77 FR 68892, 69140 (Nov. 16, 2012)) resulted in an estimated $819,000 in cost savings during the first two quarters after its implementation. Eight price substitutions were made during these two quarters. However, OIG's review was conducted over a four quarter period, which began two quarters before the price substitution policy was implemented, and the overview identified a total of 14 Healthcare Common Procedure Coding System (HCPCS) codes that met the finalized price substitution criteria during the entire review period. Had all 14 substitutions been made during the fourth quarter review period, the estimated savings would have increased to $1.8 million. OIG also estimated that expanding the price substitution policy by including HCPCS codes that exceeded the threshold for a single quarter and by including HCPCS codes with partial AMP data could have resulted in an additional quarter of a million dollars in savings.

In this overview, OIG substituted missing AMP data with manufacturer-reported wholesale acquisition cost (WAC). The OIG stated that this approach resulted in a conservative value for missing AMPs. Overall, this report identifies modest savings for the Medicare program that was achieved by the implementation of a price substitution policy. As with most previous AMP price substitution reports, the drugs that exceeded the five percent substitution threshold were typically associated with low Medicare utilization. OIG recommendations and CMS responses to those recommendations are discussed below.

## Agency Comments (continued)



**OIG Recommendation**

The OIG recommends that CMS expand the price substitution policy to include HCPCS codes with complete AMP data that exceed the threshold in a single quarter.

**CMS Response**

The CMS does not concur with this recommendation. The price substitution policy applies only to those HCPCS codes with complete AMP data where AMP exceeds ASP by more than five percent in two consecutive quarters or three of four quarters. OIG is recommending that CMS expand the price substitution policy to HCPCS codes that have complete AMP data and that exceed the ASP by more than five percent in a single quarter. The price substitution policy includes safeguards finalized through rulemaking, as cited earlier, including the requirement that the applicable threshold must be exceeded in two consecutive or three of four quarters as well as not be a drug that has been determined to be in short supply the Food and Drug Administration. The purpose of the two consecutive and three of four quarter criteria is to ensure that we are identifying situations where ASP is not typical of the drug's market price. Using a single quarter of pricing may suggest one aberrant pricing quarter rather than a market trend. As discussed in the rule cited earlier and previous rules, we have maintained a cautious approach regarding the implementation of this policy and public comments have supported such an approach, including the use of safeguards to prevent the inadvertent application of this policy to drugs that may be in shortage. While CMS appreciates the potential for additional cost savings associated with this recommendation, we remain concerned that implementing a more aggressive version of the price substitution policy at a time when the definition of AMP has recently undergone change may affect access to the affected drugs by inadvertently lowering the payment amount to a level that is below providers' acquisition cost. In addition, making this change would also require CMS to undertake notice and comment rulemaking.

**OIG Recommendation**

The OIG recommends that CMS expand the price substitution policy to include HCPCS codes with partial AMP data.

**CMS Response**

The CMS does not concur with this recommendation. Our price substitution policy is limited to only those situations where ASP and AMP comparisons are based on the same set of national drug codes (NDCs) for a billing code and AMP data is available for each NDC; our policy that we finalized through rulemaking does not utilize proxy data. CMS continues to believe that a distinction between "complete" and "partial" data is necessary because we remain concerned that partial AMP data comparisons may not adequately account for market-related drug price changes and may lead to the substitution of inaccurate volume-weighted prices. Substitutions, even when using conservative approaches such as substitution of missing AMP data with WAC values, may impact physician and beneficiary access to drugs.

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

## ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office.

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

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