

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**COMPARISON OF AVERAGE  
SALES PRICES AND AVERAGE  
MANUFACTURER PRICES:  
AN OVERVIEW OF 2011**



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## **EXECUTIVE SUMMARY: COMPARISON OF AVERAGE SALES PRICES AND AVERAGE MANUFACTURER PRICES: AN OVERVIEW OF 2011**

### **OEI-03-12-00670**

#### **WHY WE DID THIS STUDY**

When Congress established average sales prices (ASP) 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 (AMP) and directed the Centers for Medicare & Medicaid Services (CMS) to lower reimbursement for drugs with ASPs that exceed AMPs by a threshold of 5 percent. This is OIG's 29<sup>th</sup> report comparing ASPs to AMPs since the ASP reimbursement methodology was implemented in January 2005. CMS has yet to make any changes to Part B drug reimbursement as a result of OIG's studies. However, the agency published a final rule in November 2012 that specifies the circumstances under which AMP-based price substitutions will occur beginning in 2013.

#### **HOW WE DID THIS STUDY**

We identified drug codes that exceeded the 5-percent threshold in one or more quarters of 2011 and estimated the financial impact of lowering reimbursement amounts for those drugs. We also identified drug codes that were removed from our pricing comparison in one or more quarters of 2011 because they did not have AMP data.

#### **WHAT WE FOUND**

In 2011, 58 drug codes exceeded the 5-percent threshold in 1 or more quarters when complete AMP data were used. If reimbursement amounts for these 58 codes had been lowered to 103 percent of the AMPs during the applicable quarter(s), Medicare expenditures would have been reduced by an estimated \$14.4 million over 1 year. Under CMS's proposed price substitution policy, reimbursement amounts for over 40 percent of these codes would have been reduced, saving an estimated \$7 million over 1 year. An additional 24 drug codes met the 5-percent threshold when partial AMP data were used. Furthermore, at least 9 percent of drug codes were excluded from OIG's pricing comparisons in each quarter of 2011 because none of the associated drug products had AMP data.

#### **WHAT WE RECOMMEND**

To ensure the appropriateness of Medicare Part B payments, we recommend that CMS (1) finalize the price substitution policy in the proposed rule and lower Medicare reimbursement amounts for drugs that exceed the 5-percent threshold, (2) consider expanding the price substitution policy to include all Healthcare Common Procedure Coding System (HCPCS) codes with complete AMP data, (3) consider expanding the price substitution policy to include certain HCPCS codes with partial AMP data, and (4) consider seeking a legislative change to require manufacturers of Part B-covered drugs to submit both ASPs and AMPs. CMS concurred with our first recommendation and did not concur with the remaining three.

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## OBJECTIVES

1. To identify drugs with average sales prices (ASP) that exceeded average manufacturer prices (AMP) by at least 5 percent in any quarter of 2011.
2. To examine the impact of missing and unavailable AMP data on the Office of Inspector General's (OIG) pricing comparisons in 2011.

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## BACKGROUND

The Social Security Act (the Act) mandates that OIG compare ASPs with AMPs.<sup>1</sup> The Act states that if OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (5 percent through 2012), the Secretary of Health and Human Services (the Secretary) may disregard the ASP for the drug when setting reimbursement amounts.<sup>2, 3</sup> 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....<sup>4</sup>

### **Coverage of Prescription Drugs Under Medicare Part B**

Medicare Part B covers only a limited number of outpatient prescription drugs. Covered drugs include injectable drugs administered by a physician; certain self-administered drugs, such as 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**

The Centers for Medicare & Medicaid Services (CMS) contracts with private companies to process and pay Medicare Part B claims, including those for prescription drugs. To obtain reimbursement for covered outpatient prescription drugs, health care providers submit claims to Medicare contractors using Healthcare Common Procedure Coding System (HCPCS) codes.<sup>5</sup> In the case of prescription drugs, each HCPCS

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<sup>1</sup> Section 1847A(d)(2)(B) of the Act.

<sup>2</sup> Section 1847A(d)(3)(A) of the Act.

<sup>3</sup> 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.

<sup>4</sup> Section 1847A(d)(3)(C) of the Act.

<sup>5</sup> CMS established the HCPCS to provide a standardized coding system for describing the specific items and services provided in the delivery of health care.

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.

Medicare and its beneficiaries spent over \$12 billion for Part B drugs in 2011.<sup>6</sup> Although Medicare paid for more than 500 outpatient prescription drug HCPCS codes that year, most of the spending for Part B drugs was concentrated on a relatively small subset of those codes. In 2011, 62 HCPCS codes accounted for 90 percent of the expenditures for Part B drugs, with only 13 of these codes representing the majority of total 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.<sup>7</sup> As defined by law, an ASP is a 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.<sup>8</sup> The ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program.<sup>9</sup> Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in Medicaid's drug rebate program.<sup>10, 11</sup>

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 (NDC) on a quarterly basis, with submissions due 30 days after the close of each quarter.<sup>12</sup> 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

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<sup>6</sup> Medicare expenditures for Part B drugs in 2011 were calculated using CMS's Part B Analytics and Reports (PBAR). The PBAR data for 2011 were 98-percent complete when the data were downloaded in May 2012.

<sup>7</sup> Several Part B drugs, including certain vaccines and blood products, are not paid for under the ASP methodology.

<sup>8</sup> Section 1847A(c) of the Act, as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173.

<sup>9</sup> Section 1847A(c)(3) of the Act.

<sup>10</sup> Section 1847A(c)(2) of the Act.

<sup>11</sup> Pursuant to § 1927(c)(1)(C)(i) of the Act, "best price" is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, with certain exceptions.

<sup>12</sup> Section 1927(b)(3) of the Act.

“crosswalks” manufacturers’ NDCs to HCPCS codes. CMS uses information in this crosswalk file to calculate volume-weighted ASPs for covered HCPCS codes.<sup>13</sup>

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.<sup>14, 15</sup> 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 2011 were used to establish reimbursement amounts for the third quarter of 2011, and ASPs from the fourth quarter of 2011 were used to establish reimbursement amounts for the second quarter of 2012.

### **The Medicaid Drug Rebate Program and AMPs**

In general, for Federal payment to be available for covered outpatient drugs provided under Medicaid, the Act mandates that drug manufacturers enter into rebate agreements with the Secretary and pay quarterly rebates to State Medicaid agencies.<sup>16</sup> Under these rebate agreements and pursuant to the Act, manufacturers must provide CMS with the AMPs for each of their NDCs.<sup>17</sup> As further explained in regulation, manufacturers are required to submit AMPs within 30 days after the end of each quarter.<sup>18</sup>

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

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<sup>13</sup> To calculate a volume-weighted ASP, CMS uses an equation that involves the following variables: the ASP for the 11-digit NDC as reported by the manufacturer, the volume of sales for the NDC as reported by the manufacturer, and the number of billing units in the NDC as determined by CMS. The amount of the drug represented by an NDC may differ from the amount of the drug specified by the HCPCS code that providers use to bill Medicare. Therefore, the number of billing units in an NDC describes the number of HCPCS code units in that NDC. CMS calculates the number of billing units in each NDC when developing its crosswalk files.

<sup>14</sup> The equation that CMS currently uses to calculate volume-weighted ASPs is described in section 1847A(b)(6) of the Act. It is also provided in Appendix A.

<sup>15</sup> Section 1847A(b)(1) of the Act. Medicare beneficiaries are responsible for 20 percent of this amount in the form of coinsurance.

<sup>16</sup> Sections 1927(a)(1) and (b)(1) of the Act.

<sup>17</sup> Section 1927(b)(3) of the Act.

<sup>18</sup> 42 CFR § 447.510.

retail community pharmacies and (2) retail community pharmacies that purchase drugs directly from the manufacturer.<sup>19, 20</sup>

### **Penalties for Failure To Report Timely Drug Pricing Data**

Pursuant to the Act, manufacturers that fail to provide ASP and AMP data on a timely basis may be subject to civil monetary penalties and/or termination from the drug rebate program.<sup>21, 22</sup> Accordingly, CMS has terminated rebate agreements with a number of manufacturers for failure to report AMPs and, for the purposes of evaluating potential civil monetary penalties, has referred to OIG manufacturers that failed to submit timely ASPs and AMPs. In accordance with an enforcement initiative announced in September 2010, OIG has imposed civil monetary penalties on certain manufacturers that failed to report timely ASPs and/or AMPs.<sup>23</sup>

### **OIG's Monitoring of ASPs and AMPs**

To comply with its statutory mandate, OIG has issued 24 quarterly pricing comparisons since the ASP reimbursement methodology for Part B drugs was implemented in January 2005.<sup>24</sup> In addition, OIG has completed four annual overviews of ASPs and AMPs, which examined data across all four quarters of 2007, 2008, 2009, and 2010.

OIG has consistently recommended that CMS develop a price substitution policy and subsequently lower reimbursement for drugs that exceed the 5-percent threshold as directed by the Act. Although CMS has yet to make any changes to Part B drug reimbursement as a result of OIG's studies, the agency published a final rule in November 2012 that, among other things,

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<sup>19</sup> Section 1927(k)(1) of the Act, as amended by § 2503 of the Patient Protection and Affordable Care Act, P.L. 111-148.

<sup>20</sup> 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 a pharmacy that dispenses prescription medications to patients primarily through the mail; nursing home, long-term-care, or hospital pharmacies; clinics; charitable or not-for-profit pharmacies; government pharmacies; or pharmacy benefit managers.

<sup>21</sup> Sections 1927(b)(3)(C)(i) and (4)(B)(i) of the Act.

<sup>22</sup> The Secretary delegated to OIG the responsibility to impose civil monetary penalties for violations of § 1927(b)(3)(C) of the Act in 59 Fed. Reg. 52967 (Oct. 20, 1994).

<sup>23</sup> OIG, *Special Advisory Bulletin: Average Manufacturer Price and Average Sales Price Reporting Requirements*, September 2010. Available online at <http://www.oig.hhs.gov>.

<sup>24</sup> This report total does not include our pricing comparison for the third quarter of 2011, which was not made available to the public. Rather, OIG issued the results for that quarter directly to CMS to facilitate price substitutions that CMS intended to make beginning April 2012. However, CMS ultimately did not make those price substitutions in light of access concerns related to drug shortages.

specifies the circumstances under which AMP-based price substitutions will occur beginning in 2013.<sup>25, 26</sup>

### **CMS's Proposed Price Substitution Policy**

According to its November 2012 final rule, CMS will substitute 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.<sup>27</sup> Because CMS believes that comparisons based on partial AMP data may not adequately reflect market trends, the agency will lower reimbursement amounts only when ASP and AMP comparisons are based on the same set of NDCs (i.e., are based on complete AMP data).<sup>28</sup> HCPCS codes that meet the 5-percent threshold on the basis of partial AMP data will not be eligible for price substitution.

CMS plans to apply its price substitution policy on a quarterly basis beginning in 2013.<sup>29</sup> Price substitutions will take effect in the quarter after OIG shares the results of its most recent pricing comparison and will remain in effect for one quarter.<sup>30</sup> To prevent CMS's policy from inadvertently raising the Medicare reimbursement amount, a price substitution will not occur when the substituted amount is greater than the ASP-based payment amount calculated for the quarter in which the price substitution would take effect.<sup>31</sup> Price substitutions will also not occur

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<sup>25</sup> 77 Fed. Reg. 68892, 69368 (November 16, 2012).

<sup>26</sup> 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; 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)). Although the final rule took effect in January 2012, CMS did not implement that policy in light of access concerns related to drug shortages.

<sup>27</sup> 77 Fed. Reg. 68892, 69368 (November 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).

<sup>28</sup> 76 Fed. Reg. 73026, 73289 (Nov. 28, 2011)

<sup>29</sup> 77 Fed. Reg. 68892, 69368 (November 16, 2012).

<sup>30</sup> See, e.g., 76 Fed. Reg. 73026, 73473 (Nov. 28, 2011). After that one quarter, the reimbursement amount will be either 106 percent of the volume-weighted ASP for the current quarter or, if the HCPCS code continues to meet CMS's price substitution criteria, 103 percent of the volume-weighted AMP for the current quarter.

<sup>31</sup> 77 Fed. Reg. 68892, 69368 (November 16, 2012). 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.

when the drug and dosage form described by the HCPCS code is a critical or medically necessary drug identified by the Food and Drug Administration (FDA) as being in short supply.<sup>32</sup>

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## METHODOLOGY

We obtained files from CMS containing NDC-level ASP data from the first through fourth quarters of 2011, which were used to establish Part B drug reimbursement amounts for the third quarter of 2011 through the second quarter of 2012, respectively. These files also include information that crosswalks NDCs to their corresponding HCPCS codes. We also obtained AMP data from CMS for the first through fourth quarters of 2011.<sup>33</sup>

### **Calculating Volume-Weighted ASPs and AMPs for 2011**

As mentioned previously, Medicare does not base reimbursement for covered drugs on NDCs; instead, it uses HCPCS codes. Therefore, CMS uses quarterly ASP information submitted by manufacturers for each NDC to calculate a volume-weighted ASP for each covered HCPCS code. When calculating these volume-weighted ASPs, CMS includes only NDCs with ASP submissions that are deemed valid.

As part of our analysis for each of the 2011 quarterly comparisons, 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). When calculating the volume-weighted AMP for a HCPCS code with partial AMP data, we excluded any NDCs without AMPs; however, we did not exclude those NDCs from the corresponding volume-weighted ASP. This means that the volume-weighted AMP for a HCPCS code with partial AMP data is based on fewer NDCs than the volume-weighted ASP for that same code. Appendix B describes in more detail the methods used to calculate volume-weighted AMPs for HCPCS codes using complete or partial AMP data.

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<sup>32</sup> 77 Fed. Reg. 44722, 45057 (July 30, 2012).

<sup>33</sup> ASP and crosswalk data from the first through fourth quarters of 2011 were current as of June 2011, September 2011, December 2011, and March 2012, respectively. AMP data from the first through fourth quarters of 2011 were current as of May 2011, August 2011, November 2011, and April 2012, respectively.

## Comparing Volume-Weighted ASPs and AMPs for 2011

In each of our 2011 quarterly comparisons, we compared the volume-weighted ASPs and AMPs and identified HCPCS codes with ASPs that exceeded the AMPs by at least 5 percent when calculated using either complete or partial AMP data.<sup>34</sup> For each of the HCPCS codes that exceeded the 5-percent threshold in at least one quarter of 2011, we estimated the impact of lowering reimbursement to 103 percent of the AMP.<sup>35</sup>

As part of our 2011 annual overview, we merged the results of the four quarterly pricing comparisons to identify HCPCS codes with ASPs that exceeded AMPs by at least 5 percent in one or more quarters of 2011 when calculated using either complete or partial AMP data. To provide more accurate savings estimates, we recalculated the savings estimates for the codes that exceeded the threshold in one or more quarters of 2011 using recent Medicare payment amount and expenditures data that were not available when our quarterly pricing comparisons were originally performed. As a result, the estimated savings presented in this annual overview may differ from the savings presented in each of OIG's separate quarterly pricing comparisons. Appendix C describes in more detail the methods we used to estimate savings for HCPCS codes that exceeded the 5-percent threshold.

*Additional Analysis of HCPCS Codes With Complete AMP Data.* To examine the potential effect of CMS's proposed price substitution policy, each of our quarterly pricing comparisons for 2011 identified codes with complete AMP data that exceeded the 5-percent threshold in two consecutive or three of four quarters.<sup>36</sup>

As part of our 2011 annual overview, we merged the results of the four quarterly pricing comparisons to identify HCPCS codes that repeatedly

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<sup>34</sup> For those HCPCS codes that exceeded the 5-percent threshold, we reviewed the associated NDCs to verify the accuracy of the billing unit information for the quarter(s) in which the threshold was exceeded. If HCPCS codes had potentially inaccurate billing units, we excluded them from our findings.

<sup>35</sup> Section 1847A(d)(3)(C) of the Act directs the Secretary to replace payment amounts for drugs that exceed the 5-percent threshold with the lesser of the widely available market price (WAMP) for the drug (if any) or 103 percent of the AMP. For the purposes of this study, we used 103 percent of the AMP to estimate the impact of lowering reimbursement amounts. If WAMPs had been available for these drugs and had been lower than 103 percent of the AMP, the savings estimate presented in this report would have been greater.

<sup>36</sup> 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 2011 also examined quarterly results from 2010.

met this price substitution criterion.<sup>37</sup> In addition, we identified and excluded HCPCS codes in any quarter of 2011 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. We then totaled the estimated savings for the remaining HCPCS codes that would have had price reductions.<sup>38</sup>

*Additional Analysis of HCPCS Codes With Partial AMP Data.* For each of our 2011 quarterly comparisons, we identified HCPCS codes with partial AMP data that exceeded the 5-percent threshold only because AMP data were missing or unavailable.<sup>39</sup> As mentioned previously, the volume-weighted AMP for a HCPCS code with partial AMP data is based on fewer NDCs than the volume-weighted ASP for that same code. Therefore, there may be a disparity between the volume-weighted ASP and AMP that would not exist if AMP data were available for the full set of NDCs. In other words, the volume-weighted ASP for the HCPCS code could exceed the volume-weighted AMP by at least 5 percent only because AMPs for certain NDCs were not represented.

To determine whether NDCs without AMPs unduly influenced the results of our pricing comparisons, we reanalyzed pricing data after accounting for the missing and unavailable AMP values. Specifically, we replaced each missing or unavailable value with its corresponding ASP and recalculated the volume-weighted AMPs using those imputed prices.<sup>40</sup> We then compared those new volume-weighted AMPs to the volume-weighted ASPs originally calculated by CMS.

If a HCPCS code no longer exceeded the 5-percent threshold in a given quarter, we concluded that the missing and unavailable AMPs were likely

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<sup>37</sup> 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 will be necessary for OIG to complete its pricing comparison, there will be a three-quarter lag between the ASP reporting period and the effective date of the price substitutions. Therefore, AMP-based price substitutions based on pricing data from the first through fourth quarters of 2011 would have applied in the fourth quarter of 2011 through the third quarter of 2012, respectively.

<sup>38</sup> We did not determine whether any of the remaining drugs were identified by FDA as being in short supply during the applicable quarters.

<sup>39</sup> For the purposes of this study, an AMP was considered “missing” if the manufacturer had a Medicaid rebate agreement in 2011 but did not submit a price for the quarter. An AMP was considered “unavailable” for an NDC if the manufacturer did not have a Medicaid rebate agreement and was therefore not required to submit AMP data to CMS. To determine whether a manufacturer had a rebate agreement in 2011, we consulted the list of participating drug companies posted on CMS’s Web site.

<sup>40</sup> Although an NDC’s ASP is not usually the same as its AMP, ASPs in 2011 were within 3 percent of the AMPs at the median. Therefore, we believe that ASP acts as a reasonable proxy for AMP, ensuring that the NDC is represented in both the volume-weighted ASP and the volume-weighted AMP for the HCPCS code.

responsible for the HCPCS code's having initially exceeded the threshold in that quarter, as opposed to an actual disparity between ASPs and AMPs in the marketplace. If a HCPCS code continued to exceed the 5-percent threshold in a given quarter, we concluded that missing and unavailable AMPs had little impact on the results of our pricing comparison for that quarter. For these cases, the HCPCS codes likely exceeded the threshold as a result of actual pricing differences between ASPs and AMPs.

As part of our 2011 annual overview, we merged the results of the four quarterly pricing comparisons to identify HCPCS codes with partial AMP data that exceeded the 5-percent threshold in one or more quarters of 2011 because of an actual pricing disparity. Because price substitutions for these HCPCS codes may be warranted, we estimated the monetary impact of lowering reimbursement for these codes to 103 percent of the new volume-weighted AMPs.<sup>41</sup>

### **Analyzing HCPCS Codes With No AMP Data in 2011**

In each of our pricing comparisons for 2011, we excluded HCPCS codes that had missing or unavailable AMP data for all of the NDCs CMS used to calculate Medicare reimbursement. To identify the total number of HCPCS codes that were excluded from OIG pricing comparisons in 2011, we merged the results from each of the four quarterly reports. We then identified the number of HCPCS codes that were never included in OIG's pricing comparisons in 2011 because of missing or unavailable AMP data.

### **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 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.

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<sup>41</sup> We did not determine whether any of these drugs were identified by FDA as being in short supply during the applicable quarters.

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## FINDINGS

### **In 2011, 58 HCPCS codes exceeded the 5-percent threshold in 1 or more quarters when complete AMP data were used**

Consistent with sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act, OIG compared ASPs with AMPs to identify instances in which the ASP for a particular drug exceeded the AMP by a threshold of 5 percent. Of the 472 HCPCS codes examined during 2011, 58 exceeded this 5-percent threshold in at least one quarter when complete AMP data were used.<sup>42</sup> Appendix D lists the 58 HCPCS codes, including the quarter(s) during which the codes exceeded the threshold.

Pursuant to section 1847A(d)(3) of the Act, the Secretary may disregard the ASP for a drug that exceeds the 5-percent threshold and shall substitute the payment amount with the lesser of either the WAMP or 103 percent of the AMP. We estimate that if reimbursement amounts for the 58 codes with complete AMP data had been lowered to 103 percent of the AMPs during the applicable quarters, Medicare expenditures would have been reduced by \$14.4 million between the fourth quarter of 2011 and the third quarter of 2012.<sup>43, 44</sup>

### ***Under CMS's proposed price substitution policy, reimbursement amounts for over 40 percent of the 58 HCPCS codes would have been reduced, resulting in an estimated savings of almost \$7 million over 1 year***

If CMS's proposed price substitution policy had been in effect during 2011, reimbursement amounts for 24 of the 58 HCPCS codes would have been reduced in at least one quarter. These 24 HCPCS codes had complete AMP data and exceeded the 5-percent threshold in two consecutive or three of four quarters. In addition, the AMP-based substitution amounts for these 24 codes were less than the ASP-based payment amounts for the quarter(s) in which the substitutions would have

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<sup>42</sup> Three of the 58 codes also exceeded the 5-percent threshold in at least one quarter when partial AMP data were used.

<sup>43</sup> As mentioned previously, AMP-based price substitutions calculated using pricing data from the first through fourth quarters of 2011 would have been applied in the fourth quarter of 2011 through the third quarter of 2012, respectively.

<sup>44</sup> Of the 58 HCPCS codes, 7 had AMP-based substitution amounts that were higher than the ASP-based reimbursement amounts in every quarter in which the substitutions would have occurred; therefore, we excluded these codes from our savings estimate. We were unable to estimate savings for an additional three HCPCS codes because they did not have any allowed services listed in the 2011 PBAR file.

been applied.<sup>45</sup> If reimbursement amounts for the 24 codes had been based on 103 percent of the AMPs during the applicable quarters, Medicare expenditures would have been reduced by an estimated \$6.9 million between the fourth quarter of 2011 and the third quarter of 2012. Appendix D includes a list of the 24 HCPCS codes and the quarter(s) during which those codes would have met CMS's price substitution criteria.

### **In 2011, 24 HCPCS codes exceeded the 5-percent threshold in 1 or more quarters when partial AMP data were used**

Of the 472 HCPCS codes examined during 2011, 24 exceeded the 5-percent threshold in at least 1 quarter when partial AMP data were used.<sup>46</sup>

#### ***For over 60 percent of the HCPCS codes, missing and unavailable AMPs likely had little influence on the outcome of the pricing comparisons***

When we accounted for missing and unavailable AMPs, 15 of the 24 HCPCS codes continued to exceed the threshold in at least 1 quarter of 2011, suggesting that the pricing comparisons for these codes were accurately capturing underlying market trends even though AMP data were not available for the full set of NDCs. Because missing and unavailable AMP data had seemingly little influence on the pricing comparison results for these 15 HCPCS codes, price substitutions may be legitimately warranted in these cases. We estimate that if reimbursement amounts for the 15 codes had been based on 103 percent of the AMPs during the applicable quarters, Medicare expenditures would have been reduced by \$485,000 between the fourth quarter of 2011 and the third quarter of 2012.<sup>47</sup> Appendix E lists the 15 HCPCS codes, including the quarter(s) during which the codes exceeded the 5-percent threshold after accounting for missing and unavailable AMP values.

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<sup>45</sup> Two additional HCPCS codes had complete AMP data and exceeded the 5-percent threshold in two consecutive or three of four quarters; however, the AMP-based substitution amounts for these codes were higher than the ASP-based reimbursement amounts in every quarter in which the substitutions would have occurred.

<sup>46</sup> Three of the twenty-four codes also exceeded the 5-percent threshold in at least one quarter when complete AMP data were used.

<sup>47</sup> Of the 15 HCPCS codes, 3 had AMP-based substitution amounts that were higher than the ASP-based reimbursement amounts in every quarter in which the substitutions may have occurred; therefore, we excluded these codes from our savings estimate. We were unable to estimate savings for one additional HCPCS code because the code did not have any allowed services listed in the 2011 PBAR file.

For the remaining 9 of 24 HCPCS codes, ASPs no longer exceeded the AMPs in any quarter, indicating that these codes initially exceeded the threshold because of missing AMP data rather than a genuine pricing disparity between the ASPs and AMPs.

### **Because of NDCs without AMP data, the number of pricing comparisons performed in 2011 was reduced by at least 9 percent in each quarter**

If a HCPCS code had no AMPs for any of its associated NDCs, we could not evaluate that code pursuant to sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act. In 2011, from 9 to 10 percent of HCPCS codes were excluded from OIG's pricing comparisons in each quarter because AMP data were missing or unavailable for all of the associated NDCs.<sup>48, 49</sup> Table 1 lists the number and percentage of HCPCS codes in each quarter that were excluded from our analysis and specifies the number of codes that were based on unavailable NDCs, missing NDCs, or a combination of both.

In total, 55 HCPCS codes were excluded from OIG's pricing comparisons in 1 or more quarters of 2011 because AMP data were missing or unavailable for all of the NDCs that CMS used to calculate Medicare reimbursement for that quarter. For most of these codes (44 of 55), we were never able to perform pricing comparisons in 2011 because AMPs were always missing or unavailable for all of the associated NDCs. Seventy percent of the 44 HCPCS codes (31 of 44) would never have been subject to our pricing comparisons because they were associated exclusively with NDCs for which manufacturers were not required to report AMP data. In 2011, Medicare and its beneficiaries spent \$119 million on these 31 drugs.

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<sup>48</sup> Relative to the total number of HCPCS codes in each quarter with Medicare reimbursement amounts based on the ASP payment methodology.

<sup>49</sup> As mentioned previously, for the purposes of this study, an AMP was considered "missing" if the manufacturer had a Medicaid rebate agreement in 2011 but did not submit an AMP for the quarter. An AMP was considered "unavailable" for an NDC if the manufacturer did not participate in the Medicaid drug rebate program and was therefore not required to submit AMP data.

**Table 1: HCPCS Codes That Were Excluded From 2011 Pricing Comparisons**

<b>Quarter in 2010</b>	<b>Number Excluded Because None of the Corresponding NDCs Had AMP Data</b>	<b>Percentage Excluded Because None of the Corresponding NDCs Had AMP Data *</b>
<b>First</b>	<b>51</b>	<b>10%</b>
Codes with unavailable AMPs only	37	
Codes with missing AMPs only	12	
Codes with a mix of missing and unavailable AMPs	2	
<b>Second</b>	<b>49</b>	<b>10%</b>
Codes with unavailable AMPs only	36	
Codes with missing AMPs only	10	
Codes with a mix of missing and unavailable AMPs	3	
<b>Third</b>	<b>47</b>	<b>9%</b>
Codes with unavailable AMPs only	34	
Codes with missing AMPs only	10	
Codes with a mix of missing and unavailable AMPs	3	
<b>Fourth</b>	<b>48</b>	<b>9%</b>
Codes with unavailable AMPs only	36	
Codes with missing AMPs only	9	
Codes with a mix of missing and unavailable AMPs	3	

\* Relative to the total number of HCPCS codes in each quarter with reimbursement amounts based on the ASP payment methodology.  
 Source: OIG analysis of ASP and AMP data from the first through fourth quarters of 2011.

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## 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 payment amounts based on ASPs. Specifically, the ASP statute mandates that OIG monitor ASPs by comparing them with AMPs and WAMPs 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 issuing 28 comparisons between ASPs and AMPs, each of which identified Part B drugs that would have been eligible for price reductions under the law. However, CMS has yet to lower reimbursement in response to OIG's findings and recommendations.

This report identified 58 drug codes that exceeded the 5-percent threshold in 1 or more quarters of 2011 when complete AMP data were used. If reimbursement amounts for these 58 codes had been lowered to 103 percent of the AMP during the applicable quarter(s), Medicare expenditures would have been reduced by an estimated \$14.4 million over 1 year. Under CMS's price substitution policy, reimbursement amounts for over 40 percent of these codes would have been reduced, saving an estimated \$7 million over 1 year. An additional 24 HCPCS codes exceeded the 5-percent threshold when partial AMP data were used. We found that missing and unavailable AMPs for the majority of these codes likely had little influence on the outcome of the pricing comparisons; therefore, price substitution may be legitimately warranted in these cases. We also found that 31 HCPCS codes were never subject to pricing comparisons in 2011 because they were associated exclusively with NDCs for which manufacturers were not required to report AMP data.

Mandated pricing comparisons enable CMS to make responsive, short-term payment adjustments that prevent Medicare and its beneficiaries from overspending. Although the savings associated with such adjustments may be modest relative to total expenditures for Part B drugs, significant savings would have accrued had CMS taken action immediately after OIG issued its first pricing comparison. In the long term, savings achieved through price substitution could reduce waste and conserve taxpayer funds at a time when increased focus has been placed on rising health care costs and fiscal responsibility. Therefore, we recommend that CMS:

### **Finalize the price substitution policy in the proposed rule and lower Medicare reimbursement amounts for drugs that exceed the 5-percent threshold**

CMS's most recent proposed policy represents a step toward meeting statutory price substitution requirements and addressing the gap between ASPs and AMPs for certain Part B drugs. We recommend that CMS move forward with finalizing and applying this policy.

### **Consider expanding the price substitution policy to include all HCPCS codes with complete AMP data**

CMS has expressed concern that price substitutions based on results from a single quarter will not appropriately or accurately account for temporary fluctuations in market prices that would be corrected in a subsequent quarter; therefore, the agency plans to lower reimbursement amounts only for those codes with complete AMP data that exceed the 5-percent threshold in two consecutive or three of four quarters. However, this cautious approach would have drastically reduced the effectiveness of ASP monitoring in 2011, cutting potential savings by more than half.

Temporary fluctuations in ASPs and AMPs may nevertheless 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 suggest that CMS consider including 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.

### **Consider expanding the price substitution policy to include certain HCPCS codes with partial AMP data**

Because CMS believes that volume-weighted AMPs based on partial AMP data may not adequately account for market-related drug price changes and may lead to artificially low price substitutions, codes that exceed the 5-percent threshold when partial AMP data are used would not be eligible for price reduction under CMS's proposed price substitution policy. However, for 15 HCPCS codes with partial AMP data in 2011, missing and unavailable AMPs likely had little influence on the outcome of the pricing comparisons. When we accounted for missing AMPs, these 15 HCPCS codes continued to exceed the threshold, indicating that the pricing comparisons were accurately capturing underlying market trends even though AMP data were not available for the full set of NDCs. Because the risk of substituting ASP-based reimbursement with an artificially low volume-weighted AMP is greatly diminished for these types of HCPCS codes, we suggest that CMS consider including in its

price substitution policy HCPCS codes identified by OIG as meeting the threshold when missing AMPs have been imputed.

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 applying its substitution policy to at least certain HCPCS codes with partial AMP data.

### **Consider seeking a legislative change to require manufacturers of Part B-covered drugs to submit both ASPs and AMPs**

During 2011, at least 34 HCPCS codes in each quarter could not be included in OIG's pricing comparisons because all of the associated NDCs belonged to manufacturers that did not have Medicaid rebate agreements and were therefore not required to provide AMP data to CMS. Thirty-one HCPCS codes had unavailable AMP data in all four quarters of 2011. Although Medicare and its beneficiaries spent over \$100 million for these drugs during that year, payment amounts for the drugs could not be monitored through pricing comparisons with AMPs. To ensure that payment amounts are subject to regular price monitoring and reflect market trends for all drugs reimbursed on the basis of ASP, CMS could seek a legislative change requiring manufacturers of such Part B-covered drugs to submit ASPs and AMPs, regardless of whether they have rebate agreements. OIG is planning a study that will determine the number of Part B drugs associated with manufacturers that do not have rebate agreements and therefore are not required to report ASP data.

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## **AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

CMS concurred with our recommendation to finalize the price substitution policy and lower Medicare reimbursement amounts for drugs that exceed the 5-percent threshold. CMS noted that the price substitution policy and threshold were finalized in a November 2012 rule and will go into effect in 2013.<sup>50</sup> CMS also stated that this policy will not be applied to any drugs that are identified by FDA as being in short supply. CMS believes that this policy will safeguard its ability to achieve cost savings while protecting access to drugs and preventing inadvertent payment reductions.

CMS did not concur with our recommendation to consider expanding the price substitution policy to include all HCPCS codes with complete AMP data that met the threshold in a single quarter. CMS stated that the policy applies only to HCPCS codes with complete AMP data where the ASP

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<sup>50</sup> 77 Fed. Reg. 68892, 69140-2 (November 16, 2012).

exceeds the AMP by more than 5 percent in two consecutive quarters or three of the previous four quarters immediately preceding the quarter to which the price substitution would be applied. CMS also stated that the November 2012 final rule includes the requirement that the applicable threshold must be exceeded in two consecutive or three of four quarters. Further, CMS noted that it has maintained a cautious approach to implementing the policy and that public comments have supported such an approach.

CMS did not concur with our recommendation to consider expanding the price substitution policy to include certain HCPCS codes with partial AMP data. CMS stated that it continues to believe that a distinction between complete and partial data is necessary because of concerns that partial AMP data comparisons do not adequately account for market-related drug price changes and may lead to the substitution of incomplete and inaccurate prices. Further, CMS stated that substitutions based on this approach may impact physician and beneficiary access to drugs and that it has not received additional information that would persuade it to revise this position.

CMS also did not concur with our recommendation at this time to consider seeking legislative change to require all manufacturers of Part B-covered drugs to submit both ASPs and AMPs. CMS stated that the President's budget for 2013 does not include any proposals specific to this issue.

In response to CMS's comments, we continue to note that CMS's cautious approach to expanding the price substitution policy (by not including price substitutions based on results from a single quarter) would have drastically reduced the effectiveness of ASP monitoring in 2011, cutting potential savings by more than half. Also, missing and unavailable AMPs likely had little influence on the outcome of the pricing comparisons for the 15 HCPCS codes with partial AMP data. Further, we reiterate that by excluding from its policy all codes with partial AMP data, CMS may inadvertently provide drug manufacturers with a disincentive to submit timely AMPs. To ensure that CMS can make appropriate and timely adjustments to reimbursement once the price substitution policy has been implemented, we will continue to issue quarterly pricing reports comparing ASPs and AMPs.

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

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## APPENDIX A

### **The Equation Used by the Centers for Medicare & Medicaid Services To Calculate Volume-Weighted Average Sales Prices**

A volume-weighted average sales price (ASP) is calculated for the dosage amount associated with the Healthcare Common Procedure Coding System (HCPCS) code. In the following equation, the “number of billing units” represents the number of HCPCS code doses that are contained in a national drug code (NDC).

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

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## APPENDIX B

### **Detailed Methodology for Calculating Volume-Weighted Average Manufacturer Prices for 2011**

Before computing quarterly volume-weighted average manufacturer prices (AMP) for 2011, it was necessary to identify the national drug codes (NDC) that should be included in each quarter's calculations. To ensure that the broadest range of drug codes would be subject to the Office of Inspector General's pricing comparisons, we examined Healthcare Common Procedure Coding System (HCPCS) codes with complete AMP data (i.e., HCPCS codes with AMP data for every NDC that was used to calculate Medicare reimbursement), as well as HCPCS codes with partial AMP data (i.e., HCPCS codes with AMP data for only some of the NDCs that were used to calculate Medicare reimbursement).<sup>51</sup>

#### ***Calculating Converted AMPs***

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). In contrast, an ASP is reported for the entire amount of the drug contained in the NDC (e.g., for 50 milliliters, for 100 tablets). To ensure that AMPs would be comparable to ASPs, it was necessary to convert the AMPs for each NDC in each quarter so that they represented the total amount of the drug contained in that NDC.

To calculate "converted AMPs" for the NDCs included in each of our quarterly reports, we multiplied the AMP by the total amount of the drug contained in each NDC, as identified by sources such as CMS's crosswalk file, manufacturer Web sites, Thomson Reuters' *Red Book*, and the Food and Drug Administration's NDC directory.

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.

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<sup>51</sup> We excluded NDCs without AMPs when calculating volume-weighted AMPs for HCPCS codes with partial AMP data; however, the corresponding average sales prices (ASP) were not excluded from the volume-weighted ASPs as determined by the Centers for Medicare & Medicaid Services (CMS). Volume-weighted ASPs remained the same, regardless of the availability of AMP data.

*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 removed only the NDCs with problematic AMP conversions. However, 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***

Using the remaining NDCs with successful AMP conversions, we calculated a volume-weighted AMP for each of the corresponding HCPCS codes, consistent with the revised methodology for calculating volume-weighted ASPs.

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## APPENDIX C

### **Detailed Methodology for Estimating Savings for Drug Codes That Exceeded the 5-Percent Threshold in 2011**

If the average sales price (ASP) for a Healthcare Common Procedure Coding System (HCPCS) code exceeded the average manufacturer price (AMP) by at least 5 percent in any quarter of 2011, we estimated the savings associated with substituting the reimbursement amount for that code with 103 percent of the AMP.

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 will be necessary for the Office of Inspector General (OIG) to complete its pricing comparison, there will be a three-quarter lag between the ASP reporting period and the effective date of the price substitutions. Therefore, AMP-based price substitutions based on pricing data from the first through fourth quarters of 2011 would have applied in the fourth quarter of 2011 through the third quarter of 2012, respectively.

#### ***Calculation of Savings Estimates in the Separate Quarterly Pricing Comparisons for 2011***

For each HCPCS code that exceeded the 5-percent threshold in each quarter, we calculated 103 percent of the volume-weighted AMP and subtracted this amount from the reimbursement amount. Because we performed our quarterly pricing comparisons before reimbursement amounts were available for the quarters in which the price substitutions would have occurred, we used the reimbursement amounts in effect at the time of our analysis. For example, for each code that exceeded the threshold in the first quarter of 2011, we subtracted 103 percent of the volume-weighted AMP from the published reimbursement amount for the third quarter of 2011.

To estimate the financial effect for each quarter, we multiplied the difference between the reimbursement amount and 103 percent of the AMP by one-fourth of the number of services that were allowed by Medicare for each HCPCS code, as reported in the Centers for Medicare & Medicaid Services' (CMS) Part B Analytics and Reports (PBAR). Savings estimates for codes that exceeded the threshold in the first through third quarters were based on CMS's PBAR data from 2010, whereas savings estimates for codes in the fourth quarter were based on PBAR data from 2011.

### ***Calculation of Savings Estimates in the Annual Overview for 2011***

For each of the HCPCS codes that exceeded the 5-percent threshold in a given quarter of 2011, 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. For example, for each code that exceeded the threshold in the first quarter of 2011, we subtracted 103 percent of the volume-weighted AMP from the published reimbursement amount for the fourth quarter of 2011.<sup>52</sup>

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 2011, as reported in the PBAR.

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<sup>52</sup> If the AMP-based substitution amount for a given code was higher than the ASP-based reimbursement amount for the quarter in which the substitution would have occurred, we excluded that code from our savings estimate for that quarter.

## APPENDIX D

### Fifty-Eight Drug Codes That Exceeded the 5-Percent Threshold in 2011 When Complete Average Manufacturer Price Data Were Used

Drug Code	Description	Drug Code Dosage	Quarter(s) in Which the Codes Exceeded the 5-Percent Threshold			
			First Quarter	Second Quarter	Third Quarter	Fourth Quarter
A9583	Gadofosveset trisodium injection	1 mL		X		
J0130	Abciximab injection	10 mg	X	X*		
J0287	Amphotericin b lipid complex injection	10 mg	X*			
J0456	Azithromycin injection	500 mg				X
J0470	Dimecaprol injection	100 mg		X		
J0500	Dicyclomine injection	20 mg			X	X*
J0515	Benztropine mesylate injection	1 mg				X
J0595	Butorphanol tartrate injection	1 mg				X
J0610	Calcium gluconate injection	10 mL				X
J0670	Mepivacaine HCl injection	10 mL				X
J0713	Ceftazidime injection	500 mg		X	X*	X*
J0720	Chloramphenicol sodium injection	1 g	X			
J0744	Ciprofloxacin for intravenous infusion injection	200 mg			X	
J0770	Colistimethate sodium injection	150 mg				X
J0780	Prochlorperazine injection	10 mg			X	
J1070	Testosterone cypionate injection	100 mg		X	X	X*
J1120	Acetazolamide sodium injection	500 mg		X		
J1205	Chlorothiazide sodium injection	500 mg	X	X*	X*	X*
J1240	Dimenhydrinate injection	50 mg		X		
J1364	Erythromycin lactobionate injection	500 mg	X*			
J1557	Gammaplex injection	500 mg			X	
J1570	Ganciclovir sodium injection	500 mg	X	X*	X*	
J1580	Garamycin gentamicin injection	80 mg	X			
J1644	Heparin sodium injection	1,000 units		X		
J1650	Enoxaparin sodium injection	10 mg	X*	X*	X*	X*
J1742	Ibutilide fumarate injection	1 mg			X	X*
J1756	Iron sucrose injection	1 mg				X
J1955	Levocarnitine injection	1 g	X*			X
J2360	Orphenadrine injection	60 mg			X	
J2440	Papaverin HCl injection	60 mg			X	
J2501	Paricalcitol injection	1 µg		X	X*	X*
J2545	Pentamidine isethionate inhalation solution	300 mg	X	X*		
J2675	Progesterone injection	50 mg			X	X*
J2780	Ranitidine HCl injection	25 mg		X	X*	X*

## APPENDIX D (CONTINUED)

Drug Code	Description	Drug Code Dosage	Quarter(s) in Which the Codes Exceeded the 5-Percent Threshold			
			First Quarter	Second Quarter	Third Quarter	Fourth Quarter
J2916	Sodium ferric gluconate complex injection	12.5 mg	X			
J2993	Retepase injection	18.1 mg		X		
J3303	Triamcinolone hexacetonl injection	5 mg		X	X*	X
J3411	Thiamine HCl injection	100 mg				X
J7507	Tacrolimus, oral	1 mg		X	X	
J7620	Albuterol and ipratropium bromide, noncompounded	2.5 mg/0.5 mg		X	X*	X
J7631	Cromolyn sodium, noncompounded, unit dose form	10 mg				X
J8510	Busulfan, oral	2 mg				X
J9045	Carboplatin injection	50 mg			X	X*
J9060	Cisplatin injection	10 mg	X*			
J9065	Cladribine injection	1 mg		X		X
J9100	Cytarabine HCl injection	100 mg	X			
J9150	Daunorubicin injection	10 mg		X	X*	
J9171	Docetaxel injection	1 mg		X		
J9190	Fluorouracil injection	500 mg		X		
J9211	Idarubicin HCl injection	5 mg			X	X*
J9214	Interferon alfa-2b injection	1 million units	X*	X*	X*	X*
J9218	Leuprolide acetate injection	1 mg		X*		
J9280	Mitomycin injection	5 mg				X
J9293	Mitoxantrone HCl injection	5 mg				X
J9370	Vincristine sulfate injection	1 mg	X*			
Q0166	Granisetron HCL, oral	1 mg		X	X	
Q0167	Dronabinol, oral	2.5 mg				X
Q0169	Promethazine HCl, oral	12.5 mg		X		

\* Pricing comparisons for quarters marked with an asterisk would have triggered a price substitution based on criteria proposed by the Centers for Medicare & Medicaid Services (CMS) (i.e., the drug code exceeded the 5-percent threshold in two consecutive or three of four quarters and had a substitution amount that was less than the payment amount for the quarter in which the substitution would have occurred). In 2011, a total of 24 drug codes would have been subject to price substitution under CMS's proposed criteria.

Source: Office of Inspector General analysis of average sales price and average manufacturer price data from 2011.

## APPENDIX E

### Fifteen Drug Codes With Partial Average Manufacturer Price Data for Which Price Substitutions May Be Warranted

Drug Code	Description	Drug Code Dosage	Quarter(s) in Which the Codes Exceeded the 5-Percent Threshold			
			First Quarter	Second Quarter	Third Quarter	Fourth Quarter
J0290	Ampicillin injection	500 mg		X		
J1020	Methylprednisolone injection	20 mg	X			
J1644	Heparin sodium injection	1000 units	X			
J2930	Methylprednisolone injection	125 mg				X
J7509	Methylprednisolone, oral	4 mg	X	X		
J7608	Acetylcysteine inhalation solution, noncompounded	1 g		X	X	
J9045	Carboplatin injection	50 mg	X			
J9190	Fluorouracil injection	500 mg	X			
J9206	Irinotecan injection	20 mg	X			
J9390	Vinorelbine tartrate injection	10 mg		X		
Q0162	Ondansetron, oral	1 mg			X	X
Q0163	Diphenhydramine HCl injection	50 mg	X	X	X	X
Q0164	Prochlorperazine maleate, oral	5 mg	X		X	X
Q0165	Prochlorperazine maleate, oral	10 mg	X	X		X
Q0179	Ondansetron HCl, oral	8 mg	X	X		

Source: Office of Inspector General analysis of average sales price and average manufacturer price data from 2011.

## APPENDIX F

### Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator  
Washington, DC 20201

**DATE:** DEC 07 2012

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

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

**SUBJECT:** Office of Inspector General (OIG) Draft Report: "Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2011" (OEI-03-12-00670)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on OIG's Draft Report entitled, "Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2011" (OEI-03-12-00670). 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.

The OIG stated that the objectives for this report were to identify drugs with an ASP that exceeded AMP by at least 5 percent in any quarter of 2011, and examine the impact of missing and unavailable data on the OIG's 2010 pricing comparisons. The 2011 overview found that 58 Healthcare Common Procedure Coding System (HCPCS) codes with complete data (i.e., AMP data was available for all national drug codes (NDC) used in the ASP calculation for a code) met the 5 percent threshold in at least one quarter of 2011. OIG stated that of these 58 codes, 24 would have been subject to the price substitution policy that CMS proposed in July 2012. The application of the price substitution policy to these 24 HCPCS codes would have reduced Medicare expenditures by an estimated \$6.9 million over a four-quarter period. This is a much higher amount than the 2010 savings estimate.<sup>1</sup> OIG also found that another 24 HCPCS codes with partial data (i.e., AMP data was only available for some of the NDCs used in the ASP calculation for a code) met the 5 percent threshold, and OIG determined that missing data for 15 of these codes appeared to have little influence on the outcome of the comparison because the available data accurately captured underlying market trends. OIG also noted that 55 HCPCS codes were excluded from the comparison in one or more quarters due to missing or unavailable AMP data.

<sup>1</sup> CMS believes that the higher value may be associated with HCPCS J7620, a bronchodilator combination that is administered by nebulizer for the treatment of chronic airway disease, which is a heavily utilized drug. Several other heavily utilized drugs, including J9171 docetaxel - an injectable chemotherapeutic agent, also exceeded the threshold for at least one quarter. We note that it has been unusual for heavily utilized drugs to exceed the substitution threshold.

## Agency Comments (continued)

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### **OIG Recommendation 1**

The OIG recommends that CMS finalize the price substitution policy in the proposed rule and lower Medicare reimbursement amounts for drugs that exceed the 5-percent threshold.

### **CMS Response**

The CMS concurs with this recommendation. The thresholds and price substitution policy finalized in the *Federal Register* at 77 FR 68892, 69140-2 (Nov. 16, 2012) and 77 FR 68892, 69368 (Nov. 16, 2012) will go into effect in 2013. As discussed in the report, the 2013 policy includes safeguards that were proposed in 2012 and adds a safeguard that prevents the policy from being applied to any drugs that are identified by the Food and Drug Administration to be in short supply. CMS believes that the thresholds and price substitution policy will safeguard our ability to achieve cost savings while protecting access to drugs and preventing any inadvertent payment reduction that could result in payment amounts that are less than acquisition cost.

### **OIG Recommendation 2**

The OIG recommends that CMS consider expanding the price substitution policy to include all HCPCS codes with complete AMP data.

### **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 the previous four quarters immediately preceding the quarter to which the price substitution would be applied. OIG is recommending that we 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 policy finalized for 2013 includes all safeguards proposed in 2012, including the requirement that the applicable threshold must be exceeded in two consecutive or three of four quarters. As CMS discussed in the November 16, 2012 final rule (referenced above) and previous rules, we have maintained a cautious approach regarding the implementation of this policy. Public comments have supported such an approach, including the use of safeguards to provide assurances that the price substitution policy will be applied only when appropriate and will not affect access to the affected drugs by inadvertently lowering the payment amount to a level that is below providers' acquisition cost.

### **OIG Recommendation 3**

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

## Agency Comments (continued)

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### CMS Response

The CMS does not concur with this recommendation. As we have discussed in rulemaking on this issue, most recently in the 2013 physician fee schedule final rule referenced above, we will limit substitution to only those situations where ASP and AMP comparisons are based on the same set of NDCs for a billing code. We continue to believe that a distinction between “complete” and “partial” data is necessary because we remain concerned that partial AMP data comparisons do not adequately account for market-related drug price changes and may lead to the substitution of incomplete and inaccurate volume-weighted prices because different sets of NDCs’ sales are used in partial data comparisons. Substitutions based on this approach may impact physician and beneficiary access to drugs. We have not received additional information that would persuade us to revise our position.

### OIG Recommendation 4

The OIG recommends that CMS consider seeking a legislative change to directly require all manufacturers of Part B-covered drugs to submit both ASPs and AMPs.

### CMS Response

The CMS does not concur with this recommendation at this time. The President’s budget for fiscal year 2013 does not include any proposals specific to this issue.

The CMS thanks OIG for their efforts on this draft report.

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## 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 Kevin Manley and Debra Roush.

# Office of Inspector General

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The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

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## **Office of Investigations**

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

## **Office of Counsel to the Inspector General**

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.