DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

DEC 12 2012

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Acting Administrator
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/S/

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SUBJECT: Memorandum Report: *Comparison of First-Quarter 2012 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2012*, OEI-03-12-00730

This review was conducted in accordance with the statutory mandate for the Office of Inspector General (OIG) to identify Medicare Part B prescription drugs with average sales prices (ASP) that exceed average manufacturer prices (AMP) by at least 5 percent. This review estimated the financial impact of lowering reimbursement amounts for drugs that met the 5-percent threshold to 103 percent of the AMPs, and also examined the potential effect of a November 2012 final rule that, among other things, specifies the circumstances under which the Centers for Medicare & Medicaid Services (CMS) will make AMP-based price substitutions.

SUMMARY

When Congress established ASP as the primary basis for Medicare Part B drug reimbursement, it also mandated that OIG compare ASPs with AMPs and directed CMS to lower reimbursement for drugs with ASPs that exceed AMPs by a threshold of 5 percent. Since the implementation of the ASP payment methodology in 2005, OIG has fulfilled its responsibility by issuing 26 reports comparing ASPs and AMPs. However, CMS has yet to lower reimbursement in response to OIG's findings and recommendations. This latest comparison examines drugs that exceeded the 5-percent threshold based on either complete or partial AMP data in the first quarter of 2012. Of the 385 drug codes with complete AMP data, 22 exceeded the 5-percent threshold. If reimbursement amounts for all 22 codes had been based on 103 percent of the AMPs in the third quarter of 2012, Medicare would have saved an estimated $739,000 in that quarter alone. Under CMS's price substitution policy, reimbursement amounts for 15 of the 22 drugs would have been reduced, saving an estimated $606,000 in the quarter. Of the 64 drug codes with partial AMP data, 6 exceeded the 5-percent threshold. CMS has

expressed concern that partial AMP data may not adequately reflect market trends and therefore will not apply its price substitution policy to drugs with partial AMP data. However, we found that pricing comparisons for two of the six codes with partial AMP data seemed to accurately capture market trends; therefore, price reductions may be appropriate in these cases. We could not perform pricing comparisons for an additional 52 drug codes because none of the associated drug products had corresponding AMP data. Manufacturers for 9 percent of the associated drug products had Medicaid drug rebate agreements and were therefore generally required to submit AMPs.

BACKGROUND

The Social Security Act (the Act) mandates that OIG compare ASPs to AMPs.[1] If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (currently 5 percent), the Act states that 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 that "… 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]

Medicare Part B Coverage of Prescription Drugs

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.

Medicare Part B Payments for Prescription Drugs

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 procedure codes. CMS established the Healthcare Common Procedure Coding System (HCPCS) to provide a standardized coding system for describing the specific items and services provided in the delivery of health care. 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 manufacturer or package size information.

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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 provides the Secretary with authority 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 over $12 billion for Part B drugs in 2011.[5] 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 and Biologicals

Medicare Part B pays for most covered drugs using a reimbursement methodology based on ASPs.[6] 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.[7] 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.[8] 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.[9, 10]

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.[11] 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 "crosswalks" manufacturers' NDCs to HCPCS codes. CMS uses information in this crosswalk file to calculate volume-weighted ASPs for covered HCPCS codes.

Calculation of Volume-Weighted ASPs

Third-quarter 2012 Medicare payments for most covered drug codes were based on first-quarter 2012 ASP submissions from manufacturers, which were volume weighted

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[5] 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.

[6] Several Part B drugs, including certain vaccines and blood products, are not paid for under the ASP methodology.

[7] Section 1847A(c) of the Act, as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173.

[8] Section 1847A(c)(3) of the Act.

[9] Section 1847A(c)(2) of the Act.

[10] 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.

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

using 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.[12] The amount of the drug contained in 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 that are in that NDC. For instance, an NDC may contain 10 milliliters of Drug A, but the corresponding HCPCS code may be defined as only 5 milliliters of Drug A. In this case, there are two billing units in the NDC. CMS calculates the number of billing units in each NDC when developing its crosswalk files.

Under the ASP pricing methodology, the Medicare allowance for most Part B drugs is equal to 106 percent of the volume-weighted ASP for the HCPCS code.[13] Medicare beneficiaries are generally responsible for 20 percent of this amount in the form of coinsurance.

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.[14] Under these rebate agreements and pursuant to the Act, manufacturers must provide CMS with the AMPs for each of their NDCs.[15] As further explained in regulation, manufacturers are required to submit AMPs within 30 days after the end of each quarter.[16]

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.[17, 18]

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[12] The equation that CMS currently uses to calculate volume-weighted ASPs is described in § 1847A(b)(6) of the Act. It is also provided in Appendix A.
[13] Section 1847A(b)(1) of the Act.
[14] Sections 1927(a)(1) and (b)(1) of the Act.
[15] Section 1927(b)(3) of the Act.
[16] 42 CFR § 447.510.
[17] Section 1927(k)(1) of the Act, as amended by § 2503 of the Patient Protection and Affordable Care Act, P.L. 111-148.
[18] 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.

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 money penalties and/or termination from the drug rebate program.[19, 20] Accordingly, CMS has terminated rebate agreements with a number of manufacturers for failure to report AMPs and, for the purposes of evaluating potential civil money 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.[21]

OIG's Monitoring of ASPs and AMPs

To comply with its statutory mandate, OIG has issued 22 quarterly pricing comparisons since the ASP reimbursement methodology for Part B drugs was implemented in January 2005. 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, respectively.

OIG has consistently recommended that CMS develop a price substitution policy and lower the reimbursement amounts 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, specifies the circumstances under which AMP-based price substitutions will occur beginning in 2013.[22, 23]

CMS's 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.[24] Because CMS believes that comparisons based on partial AMP data may not adequately reflect market trends,[25] the agency will lower reimbursement amounts only when ASP

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[19] Sections 1927(b)(3)(C)(i) and (4)(B)(i) of the Act.

[20] The Secretary delegated to OIG the responsibility to impose civil money penalties for violations of § 1927(b)(3)(C) of the Act in 59 Fed. Reg. 52967 (Oct. 20, 1994).

[21] OIG, *Special Advisory Bulletin: Average Manufacturer Price and Average Sales Price Reporting Requirements*, September 2010. Available online at http://www.oig.hhs.gov.

[22] 77 Fed. Reg. 68892, 69368 (Nov. 16, 2012).

[23] 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 based, in part, on 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 that final rule took effect in January 2012, CMS did not implement that policy in light of access concerns related to drug shortages.

[24] 77 Fed. Reg. 68892, 69368 (Nov. 16, 2012).

[25] 76 Fed. Reg. 73026, 73289 (Nov. 28, 2011).

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