

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**AVERAGE SALES PRICES:  
MANUFACTURER REPORTING  
AND CMS OVERSIGHT**



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## E X E C U T I V E S U M M A R Y

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### **OBJECTIVES**

1. To determine whether manufacturers that reported average sales price (ASP) data to the Centers for Medicare & Medicaid Services (CMS) did so within the timeframe required by Federal law.
2. To review CMS's oversight procedures for the submission of ASP data.
3. To quantify the number of manufacturers that provided ASPs to CMS but were not required to do so under the current system.

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### **BACKGROUND**

CMS continues to cover a limited number of outpatient prescription drugs under its Part B benefit. Since January 2005, CMS has been paying for most Part B-covered drugs using a payment methodology based on ASP. ASP is defined as 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.

Section 1927 of the Social Security Act (the Act) sets forth ASP reporting requirements for manufacturers. Pursuant to section 1927 of the Act, manufacturers with Medicaid drug rebate agreements in effect must, among other things, provide CMS with pricing information, including the ASPs for their Part B-covered drugs. However, drug coverage under Medicaid differs from drug coverage under Medicare Part B. Therefore, Medicaid rebate agreements may not be applicable for certain manufacturers given the differences in coverage.

Manufacturers that report ASPs are required to submit them to CMS no later than 30 days after the close of the previous quarter. As a result, there is a two-quarter lag between the time when sales reflected in the ASP occur and the time when these sales become the basis for Medicare payment amounts.

To fulfill their reporting requirements, manufacturers typically mail a floppy or compact disc containing ASP data to CMS. CMS staff manually enter all ASP data received from manufacturers into quarterly ASP files prior to calculating the Medicare payment amounts for Part B-covered drugs. CMS posts the payment amounts on its public Web site 2 weeks before the start of the applicable quarter (i.e., approximately 6 to 7 weeks after the submission deadline).

## E X E C U T I V E   S U M M A R Y

For 2007 and the first two quarters of 2008, we used CMS tracking spreadsheets, ASP pricing files, a list of labeler codes associated with manufacturers required to submit drug-pricing data, an interview with CMS, and a review of relevant documents to accomplish our three objectives.

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### FINDINGS

**Each quarter, over 40 percent of manufacturers submitted ASPs late; most late submissions were within 10 days of the deadline.**

For each quarter under review, between 41 and 52 percent of manufacturers provided ASPs after the statutorily defined due date. However, at least 95 percent of manufacturers submitted ASP data to CMS within 10 days after the deadline. Further, no more than 2 percent of manufacturer submissions each quarter were more than 30 days late. Late submissions did not seem to have an effect on the Medicare payment amount because there is a 6- to 7-week period between the date ASP data are due and the publication of the payment amounts.

**CMS implemented oversight procedures for ASP data; however, CMS's data collection and analysis methods introduce the potential for inefficiency and errors.** CMS has implemented several oversight procedures related to payment for Part B-covered drugs. From the time it receives a manufacturer's submission to the time payment amounts are posted on the Web site, CMS performs multiple quality assurance checks. CMS is also coordinating with the Office of Inspector General (OIG) to identify manufacturers that do not submit ASP data in a timely fashion.

However, other CMS practices related to ASP data may inhibit efficiency and result in potential errors. For example, although CMS uses an automated system to collect average manufacturer prices (AMP) for the Medicaid program, it relies on manual processes for ASP data. In addition, CMS does not track which manufacturers are required to report ASPs, receives substantial amounts of ASP data for non-Part B-covered drugs, and does not receive the underlying data that form the basis of manufacturer ASP submissions.

**Almost one-fifth of labeler codes with reported ASPs were associated with manufacturers that were not required to provide these prices under the current system.** Approximately 200 unique labeler codes were associated with ASP data submissions for

Part B-covered drugs during each of the quarters under review. Nearly one-fifth of these codes belonged to manufacturers that were not required to provide ASP data under the current system because they did not have Medicaid drug rebate agreements in effect for that quarter.

Some drug codes were associated only with manufacturers that did not have Medicaid drug rebate agreements in place. If these manufacturers chose not to report ASPs, CMS would be unable to calculate ASP-based Medicare payment amounts for these drug codes.

In addition, there were also manufacturers of Part B-covered drugs that did not have rebate agreements and did not provide ASP data to CMS. Because CMS does not have pricing or utilization data for these drugs, we are unable to quantify the impact this may have had on Medicare payment amounts.

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## RECOMMENDATIONS

When setting payment amounts for drugs covered under Medicare Part B, CMS relies on ASP data reported by manufacturers. This report identifies several potential issues with the current ASP reporting process, including (1) the timeliness of manufacturer reporting, (2) the largely manual process used by CMS to collect and analyze manufacturer-reported data, and (3) the legal requirements for manufacturer reporting. Each of these issues introduces the potential for inefficiency and errors. To ensure that Medicare payments for Part B-covered drugs are accurate, timely, and reflective of all Part B-covered drug sales, we recommend that CMS:

**Develop an automated system for the collection of ASP data.** CMS has developed an automated system for manufacturers to submit AMPs and could use that system as a template for establishing an automated ASP system. Many manufacturers that submit ASPs already submit AMPs; therefore, these manufacturers are familiar with the concept of an automated price-reporting system. An automated system would potentially limit the possibility of data entry errors, reduce the amount of time it takes to calculate ASP-based payment amounts and adjust ASP payment limits, and enable CMS to track ASPs with greater ease.

**Seek a legislative change to directly require all manufacturers of Part B-covered drugs to submit ASPs.** CMS could work with Congress to develop legislation that would directly require all manufacturers of Part B-covered drugs to submit ASPs, regardless of whether the manufacturers

have Medicaid drug rebate agreements. This would ensure that Medicare payment amounts were reflective of all Part B-covered drugs.

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

In its comments on the draft report, CMS agreed that certain refinements to the ASP reporting process are desirable to ensure that Medicare payments for Part B-covered drugs are accurate and timely.

CMS concurred with OIG's recommendation that it develop an automated system for the collection of ASP data and agreed that an automated system would be an improvement over the present one. CMS also stated that it is working with contractors to improve the efficiency of ASP-related processes.

CMS did not concur at this time with OIG's recommendation that it seek a legislative change to directly require all manufacturers of Part B-covered drugs to submit ASPs. However, CMS stated that it will consider this recommendation as it continues to monitor the effects of current payment policies. We continue to support our recommendation that CMS seek a legislative change to the ASP reporting requirements as a way to ensure that Medicare payment amounts are reflective of all Part B-covered drugs.

▶ **T A B L E O F C O N T E N T S**

**EXECUTIVE SUMMARY**..... i

**INTRODUCTION** ..... 1

**FINDINGS** ..... 11

    Each quarter, over 40 percent of manufacturers submitted ASPs late; most late submissions were within 10 days of the deadline. .... 11

    CMS implemented oversight procedures for ASP data; however, CMS’s data collection and analysis methods introduce the potential for inefficiency and errors ..... 11

    Almost one-fifth of labeler codes with reported ASPs were associated with manufacturers that were not required to provide these prices under the current system ..... 13

**RECOMMENDATIONS** ..... 16

    Agency Comments and Office of Inspector General Response ..... 18

**APPENDIX** ..... 19

    Agency Comments ..... 19

**ACKNOWLEDGMENTS** ..... 21

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## OBJECTIVES

1. To determine whether manufacturers that reported average sales price (ASP) data to the Centers for Medicare & Medicaid Services (CMS) did so within the timeframe required by Federal law.
2. To review CMS's oversight procedures for the submission of ASP data.
3. To quantify the number of manufacturers that provided ASPs to CMS but were not required to do so under the current system.

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## BACKGROUND

Medicare and its beneficiaries paid over \$11 billion for Part B-covered drugs in 2008.<sup>1</sup> ASPs serve as the basis of Medicare payment for Part B-covered drugs. Therefore, inaccurate, incomplete, and late ASP data could have adverse effects on beneficiary and Federal Government payments. This study examined the timeliness of manufacturer ASP submissions, CMS's oversight as it relates to ASP data, and ASP reporting requirements.

### Medicare Part B Coverage of Prescription Drugs

Although Medicare Part D covers most outpatient prescription drugs, CMS continues to cover a limited number of outpatient prescription drugs and biologicals (hereinafter referred to as drugs) under its Part B benefit. Part B-covered drugs generally fall into the following categories: drugs furnished incident to a physician's services (e.g., injectable drugs used in connection with the treatment of cancer); drugs explicitly covered by statute (e.g., some vaccines and oral anticancer drugs); and drugs used in conjunction with durable medical equipment (e.g., inhalation drugs).<sup>2</sup>

### Medicare Part B Payments for Prescription Drugs

To obtain Medicare payment for Part B-covered drugs, physicians and suppliers submit claims to claims-processing contractors using Healthcare Common Procedure Coding System (HCPCS) codes. The HCPCS codes provide a standardized system for describing the specific items and services provided in the delivery of health care. In the case of

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<sup>1</sup> Medicare expenditures for Part B drugs in 2008 were calculated using CMS's Part B Analytics and Reports (PBAR). PBAR data were downloaded on July 8, 2009.

<sup>2</sup> 68 Fed. Reg. 50428, 50429 (Aug. 20, 2003).

prescription drugs, each HCPCS code defines the drug name and billing unit size but does not specify the manufacturer or package size.

### **Payment Methodology for Part B Drugs and Biologicals**

CMS pays for most Part B-covered drugs using a methodology based on ASPs. Section 1847A(c) of the Social Security Act (the Act), as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), P.L. No. 108-173, defines an ASP as 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. 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>3</sup> Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid drug rebate program.<sup>4, 5</sup>

Medicare payment amounts for most Part B-covered prescription drugs are equal to 106 percent of the volume-weighted ASPs for the HCPCS codes. Medicare beneficiaries are responsible for 20 percent of this amount in the form of coinsurance.

There is a two-quarter lag between the time when sales reflected in the ASP occur and the time when these sales become the basis for Medicare payment amounts. For example, first-quarter 2008 ASP data from manufacturers served as the basis for third-quarter 2008 Medicare payment amounts for most Part B-covered drugs.

### **Manufacturer Reporting Requirements**

ASP data. Section 1927 of the Act sets forth ASP reporting requirements for manufacturers. This section originally pertained only to the Medicaid program but was modified by the MMA to include requirements under Medicare Part B as well. The current provisions of section 1927 of the Act thus link the ASP reporting

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

<sup>4</sup> Pursuant to section 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>5</sup> Section 1847A(c)(2) of the Act.

## I N T R O D U C T I O N

requirements to a manufacturer's entry into a Medicaid drug rebate agreement. More specifically, pursuant to section 1927(b)(3) of the Act, manufacturers with rebate agreements in effect must, among other things, provide CMS with pricing information, including the ASP for each of their Part B-covered drugs and average manufacturer price (AMP) for each of their Medicaid-covered drugs, on a quarterly basis.<sup>6</sup> However, Medicare Part B and Medicaid cover different types of drugs. As a result, Medicaid rebate agreements may not be applicable for certain manufacturers given the differences in coverage.

Manufacturers report ASPs for Part B-covered drugs by national drug codes (NDC), an 11-digit numeric code divided into three segments identifying (1) the firm that manufactures, distributes, or repackages<sup>7</sup> the drug product (i.e., the labeler code); (2) the specific strength, dosage form, and formulation of the product; and (3) the product's package size. According to section 1927(b)(3) of the Act and 42 CFR § 414.804(a)(5), manufacturers are required to provide CMS with the ASP and volume of sales for each NDC on a quarterly basis, with submissions due 30 days after the close of each quarter. Because Medicare payment for Part B-covered 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 posts the payment amounts on its public Web site 2 weeks before the start of the applicable quarter (i.e., 6 to 7 weeks after the submission deadline).<sup>8</sup> CMS provides the Office of Inspector General (OIG) with quarterly ASP data 2 to 3 days after the payment files are posted to the Web site. See Table 1 on page 4 for details on the ASP reporting timeline.

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<sup>6</sup> ASPs are not actually used in the calculation of Medicaid rebates.

<sup>7</sup> A repackager purchases drugs from the manufacturer and typically repackages them into smaller quantities.

<sup>8</sup> CMS posts the quarterly ASP files to <http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/>.

I N T R O D U C T I O N

Table 1: ASP Reporting Timeline

Sales Period	ASP Data Due to CMS	Payment Amounts Posted on CMS Web Site*	Payment Amounts Provided to OIG and Sent to Contractors for Claims Processing and Payment*	Payment Amounts Take Effect
January 1–March 31	April 30	June 15	June 17	July 1
April 1–June 30	July 30	September 15	September 17	October 1
July 1–September 30	October 30	December 15	December 17	January 1
October 1–December 31	January 30	March 15	March 17	April 1

Source: OIG analysis of ASP reporting requirements.

\*Denotes approximate dates.

CMS provides manufacturers a template to use when submitting ASP data for Part B-covered drugs. In this template, manufacturers provide data including the NDC, the manufacturer’s ASP for the drug, and the number of units sold.<sup>9</sup> Manufacturers are not required to report the underlying data (e.g., total sales, rebates, and price concessions) or the exact methods used to calculate the ASP. Each ASP submission must be certified by the manufacturer’s Chief Executive Officer or Chief Financial Officer or an individual who has been delegated the authority.<sup>10</sup> This certification verifies that the reported ASPs were calculated accurately and that all information and statements made in the submission are true, complete, and current to the best of the signatory’s knowledge.<sup>11</sup> If a manufacturer determines that a previous quarter’s submission was in error, it may resubmit quarterly ASP data to CMS, which will, in turn, revise the Medicare payment amount.<sup>12</sup>

Manufacturers typically mail a floppy or compact disc containing ASP data to CMS to fulfill their reporting requirements. CMS staff manually enter all ASP data received from manufacturers into the quarterly ASP files prior to calculating the Medicare payment amounts for Part B-covered drugs.<sup>13</sup>

<sup>9</sup> 69 Fed. Reg. 17935, 17940 (Apr. 6, 2004).

<sup>10</sup> 42 CFR § 414.804(a)(6).

<sup>11</sup> 69 Fed. Reg. 17935, 17941 (Apr. 6, 2004).

<sup>12</sup> At times, CMS may make changes to Medicare payment amounts from past quarters based on revised data submissions from manufacturers.

<sup>13</sup> Manual data entry refers to both typing and using the “copy and paste” function.

Manufacturers may face civil money penalties or suspension of their rebate agreements if they knowingly provide false information about their ASPs or fail to report ASP data in the required timeframe.<sup>14</sup> The penalties associated with late submissions may be increased by up to \$10,000 for each day the ASP data are not provided.<sup>15, 16</sup>

**AMP data.** As part of their Medicaid rebate agreements, and for Federal payments to be authorized for covered outpatient drugs provided under Medicaid, manufacturers must report AMPs to CMS. As generally defined in section 1927(k)(1) of the Act, AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. The AMP is generally calculated as a weighted average of prices for a manufacturer's package sizes of a drug sold during a given quarter and is reported for the lowest identifiable quantity of the drug.

Manufacturers electronically transmit AMP pricing and product data for each reporting period to CMS using the automated Drug Data Reporting for Medicaid system (DDR). First, manufacturers must enter drug product data for each of their covered NDCs into the system. Once the drug product data have been accepted by the system, manufacturers are able to submit AMPs for those drugs. The DDR electronically reviews manufacturers' pricing submissions for data errors, notifies manufacturers about potential problems, and may reject files with detected errors. After resolving data errors (if any), manufacturers certify the pricing data in the DDR. CMS provides OIG with quarterly AMP data approximately 2 weeks after the submission deadline (i.e., approximately 6 to 7 weeks before the next quarter).

### **OIG Mandate To Monitor ASP**

Sections 1847A(d)(1) and (2) of the Act, as added by the MMA, direct OIG to undertake studies that compare ASPs to AMPs and widely

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<sup>14</sup> Sections 1927(b)(3)(C)(i) and (ii) of the Act.

<sup>15</sup> Section 1927(b)(3)(C)(i) of the Act.

<sup>16</sup> OIG is coordinating with CMS to identify manufacturers that do not submit ASP or other required drug pricing data (e.g., AMP) in a timely fashion. OIG has initiated actions against certain manufacturers that fail to satisfy their pricing data submission requirements.

available market prices.<sup>17</sup> Related to this requirement, OIG has completed numerous reports comparing ASPs to AMPs, two reports comparing ASPs to widely available market prices, and one report examining Medicare payment for drugs with newly available generic versions.<sup>18, 19</sup> Although CMS has acknowledged the authority of the Secretary of the Department of Health and Human Services (the Secretary) to adjust ASP-based payment limits based on the results of these studies, the agency has yet to make any changes as a result of OIG's work. Additionally, OIG had completed eight audits of manufacturer ASP data submissions as of December 2009.

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## METHODOLOGY

### Scope and Data Collection

For this study, we used CMS tracking spreadsheets, ASP pricing files, a list of labeler codes associated with manufacturers required to submit drug-pricing data, an interview with CMS, and a review of relevant documents for 2007 and the first two quarters of 2008.

CMS uses one system (i.e., the tracking spreadsheet) to track the submission of ASP data by manufacturers and a different system (i.e., the background file) to compile the actual ASPs. For the purposes of this study, we conducted separate analyses on each of these files. To examine the timeliness of ASP submissions, we analyzed the tracking spreadsheets. To determine how many labeler codes were associated with manufacturers that actually reported ASPs but were not required to provide these prices under the current system, we analyzed the quarterly ASP background files in conjunction with the Medicaid participating drug manufacturer files.

*CMS tracking spreadsheets.* CMS provided us with tracking spreadsheets containing the manufacturer names, the dates the ASP

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<sup>17</sup> Section 1847A(d)(5) of the Act generally defines widely available market price to be the price that a prudent physician or supplier would pay for the drug, net of any routinely available price concessions.

<sup>18</sup> OEI-03-04-00430, April 2006; OEI-03-06-00370, July 2006; OEI-03-07-00140, July 2007; OEI-03-07-00530, September 2007; OEI-03-08-00010, December 2007; OEI-03-08-00130, May 2008; OEI-03-08-00340, August 2008; OEI-03-08-00450, December 2008; OEI-03-08-00530, December 2008; OEI-03-09-00050, February 2009; OEI-03-09-00150, April 2009; OEI-03-09-00340, August 2009; OEI-03-09-00490, August 2009; OEI-03-09-00640, January 2010.

<sup>19</sup> OEI-03-05-00430, June 2006; OEI-03-07-00190, July 2008; OEI-03-08-00310, August 2008.

# I N T R O D U C T I O N

submissions were recorded as received by CMS, and manufacturer contact information. The tracking spreadsheets are organized by manufacturer name and do not contain ASPs or NDCs (or, therefore, labeler codes); they are files compiled by CMS and used primarily to document the status of manufacturer submissions and to identify manufacturers that require follow-up calls to request data.

We collected tracking spreadsheets from CMS that recorded manufacturer submission dates for 175 manufacturers. However, seven manufacturers listed on these spreadsheets did not provide ASP submissions to CMS during any of the quarters under review and were excluded from our analysis. These manufacturers did not submit ASPs during the period under review because they either merged with or were purchased by other manufacturers or do not sell Part B-covered drugs. Therefore, 168 manufacturers submitted ASPs during at least one of the quarters under review and were included in our analysis.

However, not all of these 168 manufacturers submitted ASP data in each of the quarters under review. Manufacturers without a submission date for a quarter were excluded from that quarter’s analysis. According to CMS, some reasons manufacturers did not submit ASP data every quarter include the following: manufacturers merged with or were purchased by other manufacturers (as previously mentioned), manufacturers did not have Medicaid rebate agreements in effect, and manufacturers did not sell Part B-covered drugs during a particular quarter. See Table 2 for the number of manufacturers that submitted ASP data each quarter, according to CMS’s tracking spreadsheets.

Table 2: ASP Submissions From CMS’s Tracking Spreadsheets

Quarter and Year	Number of Manufacturers That Submitted ASP Data
1 <sup>st</sup> Quarter 2007 <sup>20</sup>	152
2 <sup>nd</sup> Quarter 2007	152
3 <sup>rd</sup> Quarter 2007	151
4 <sup>th</sup> Quarter 2007	154
1 <sup>st</sup> Quarter 2008	157
2 <sup>nd</sup> Quarter 2008	157

Source: OIG analysis of CMS tracking spreadsheets.

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<sup>20</sup> We excluded one manufacturer from our analysis of first quarter 2007 ASP data because we could not determine the manufacturer’s submission date. However, CMS’s background file indicates that the manufacturer did submit ASP data to CMS.

# I N T R O D U C T I O N

*CMS interview and document review.* We conducted an interview with CMS staff and reviewed relevant policy documents to gather information about oversight procedures regarding ASP data submissions. The interview and document review sought to identify the way in which CMS collects, verifies, and analyzes data; CMS oversight procedures; potential vulnerabilities to the ASP system; and the way in which ASP reporting requirements relate to AMP reporting requirements.

*ASP data.* CMS uses the tracking spreadsheets to record ASP submission dates; it uses a different set of files (called background files) to compile ASPs. The background files contain manufacturer submissions for Part B-covered drugs, their billing codes, and ASPs; they are updated each quarter. CMS provided us with the background files for 2007 and the first two quarters of 2008. Data in these files include the NDC; the manufacturer’s ASP for the drug (which factors in total sales, price concessions, and sales volume); and the number of units sold. These files also contain information on which NDCs are included in the calculation of Medicare payment amounts. See Table 3 for the number of labeler codes associated with ASP data submissions for each quarter under review.

Table 3: Labeler Codes Associated With ASP Data Submissions

Quarter and Year	Number of Labeler Codes Associated With ASP Data Submissions
1 <sup>st</sup> Quarter 2007	198
2 <sup>nd</sup> Quarter 2007	192
3 <sup>rd</sup> Quarter 2007	193
4 <sup>th</sup> Quarter 2007	199
1 <sup>st</sup> Quarter 2008	202
2 <sup>nd</sup> Quarter 2008	207

Source: OIG analysis of NDC-level ASP submissions and participating drug manufacturer file.

We also collected CMS’s crosswalk files for the quarters under review. These files link NDCs to HCPCS billing codes and could help identify

Part B-covered drugs for which manufacturers did not submit ASP data.<sup>21</sup>

Medicaid participating drug manufacturer file. We obtained the list of manufacturers that participated in the Medicaid drug rebate program during the quarters under review from CMS. This list contains participating manufacturer information, including the manufacturer's name; the labeler code (i.e., the first five digits of the NDC); and the date the rebate agreement went into effect. Manufacturers of Part B-covered drugs that have rebate agreements in effect are required to report ASP data. One manufacturer may have multiple labeler codes.

#### **Data Analysis**

Timeliness of ASP submissions. Using CMS's tracking spreadsheets, we compared manufacturer submission dates to the statutorily defined deadline to determine the number of manufacturers that submitted late ASP data. In addition, we calculated the number of days that elapsed before each manufacturer submitted ASP data.

CMS oversight. We reviewed the transcript from our interview with CMS as well as relevant policy documents to determine how CMS collects ASP data, how CMS verifies and analyzes ASP data, how CMS implements oversight processes for ASP data, and to what extent vulnerabilities exist in the ASP system.

Manufacturer submission requirements. Using NDC-level ASP data from the background files, we identified all labeler codes (i.e., the first five digits of the NDC) associated with data submissions during each of the quarters under review. We identified the labeler codes only for NDCs deemed valid by CMS (i.e., the NDCs included in the calculation of the Medicare payment amount). For each quarter under review, we compared these labeler codes to the list of labeler codes associated with manufacturers that participate in the Medicaid drug rebate program and were required to provide ASPs under the current system (see Table 3 on page 8 for the number of labeler codes associated with ASP data submissions).

From this comparison, we determined how many labeler codes with reported ASPs were associated with manufacturers that were not required to provide these prices under the current system. We also

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<sup>21</sup> In several of its ASP files, CMS notes that the absence or presence of a particular drug does not indicate whether the drug is actually covered by Medicare Part B.

## I N T R O D U C T I O N

determined whether any HCPCS codes had Medicare payment amounts that were based solely on NDCs from manufacturers without rebate agreements. In addition, using the crosswalk files, background files, and files containing labeler codes of manufacturers that participate in the Medicaid drug rebate program, we identified manufacturers of Part B-covered drugs that did not provide ASPs and also did not have rebate agreements during the quarters under review.

### **Limitations**

We did not verify the accuracy or completeness of CMS's pricing data, tracking file, or the list of manufacturers participating in the Medicaid drug rebate program. In addition, we did not analyze the background files to determine whether there were specific data entry errors.

### **Standards**

This study was conducted in accordance with the "Quality Standards for Inspections" approved by the Council of the Inspectors General on Integrity and Efficiency.

## ► FINDINGS

### Each quarter, over 40 percent of manufacturers submitted ASPs late; most late submissions were within 10 days of the deadline

For each quarter under review, between 41 and 52 percent of manufacturers provided ASPs after the statutorily defined due date. However, at least 95 percent of manufacturers submitted ASP data to CMS within 10 days after the deadline. Further, no more than 2 percent of manufacturer submissions each quarter were more than 30 days late. See Table 4 for a description of manufacturer submissions according to the dates recorded by CMS in its tracking spreadsheets. Late submissions did not seem to have an effect on the Medicare payment amount because there is a 6- to 7-week period between the ASP due date and the publication of the payment amounts.

Table 4: Manufacturer ASP Data Submissions From CMS’s Tracking Spreadsheets

Quarter and Year	Percentage of Manufacturer Submissions Received Before the Deadline*	Late Manufacturer Submissions*		
		Percentage of Manufacturer Submissions 10 or Fewer Days Late	Percentage of Manufacturer Submissions More Than 10 Days Late and Fewer Than 30 Days Late	Percentage of Manufacturer Submissions 30 or More Days Late
1 <sup>st</sup> Quarter 2007	53	43	3	2
2 <sup>nd</sup> Quarter 2007	53	44	3	1**
3 <sup>rd</sup> Quarter 2007	48	47	5	1**
4 <sup>th</sup> Quarter 2007	48	50	2	0
1 <sup>st</sup> Quarter 2008	59	38	2	1
2 <sup>nd</sup> Quarter 2008	48	52	1	0

Source: OIG analysis of CMS ASP tracking spreadsheets.

\*Between 151 and 157 manufacturers submitted ASP data according to CMS’s tracking spreadsheet. See Table 2 on page 7 for additional detail.

\*\*These late submissions were from the same manufacturer.

Note: Totals may not add up to 100 because of rounding.

### CMS implemented oversight procedures for ASP data; however, CMS’s data collection and analysis methods introduce the potential for inefficiency and errors

CMS has implemented several oversight procedures related to payment for Part B-covered drugs. From the time it receives a manufacturer’s submission of ASP data to the time payment amounts are posted on its Web site, CMS performs multiple quality assurance checks, including:

- monitoring when manufacturers submit data,
- contacting late manufacturers to remind them to submit ASP data,

## F I N D I N G S

- identifying the appropriate ASP data to be included in the Medicare payment amount,
- identifying new drugs or billing codes that may be needed for the upcoming quarter, and
- determining whether the Medicare payment amount for specific HCPCS codes underwent dramatic changes from quarter to quarter.

CMS also posts the quarterly Medicare payment amounts to its Web site several days before providing the payment files to the claims-processing contractor. This step allows manufacturers to review the Medicare payment amounts and resubmit pricing data if manufacturers identify errors before the contractor can download the new prices to its payment system. CMS believes this process has reduced the need to revise and retract payment files because manufacturers can identify errors before the prices go into effect. Finally, CMS is coordinating with OIG to identify manufacturers that do not submit ASP or other required drug pricing data (e.g., AMP) in a timely fashion.

### **CMS's methods for collecting and analyzing ASP data could reduce efficiency and lead to potential errors**

Although CMS has implemented oversight procedures related to payment for Part B-covered drugs, it relies on manual data entry, does not proactively identify which manufacturers are required to report ASPs, receives substantial amounts of ASP data for non-Part B-covered drugs, and does not receive the underlying data that form the basis of manufacturer ASP submissions.<sup>22</sup> These factors may inhibit efficiency and result in potential errors.

*Manual data entry.* Unlike its system for reporting AMP data, CMS does not have an automated system for entering ASP data; staff manually enter every data element from manufacturer submissions into the ASP files, a process that could introduce errors. Previous OIG work with ASP data identified multiple errors that needed to be corrected before any analysis could be conducted, including:

- NDCs missing the first few digits (generally this applies only to NDCs where the first digit is zero),

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<sup>22</sup> Manufacturers are not obligated to report the underlying data used to arrive at their ASPs.

## FINDINGS

- NDCs with extra or missing digits, and
- NDCs that contain a dash or other incorrect text.<sup>23</sup>

In addition, manual data entry is time consuming and increases the amount of time between when manufacturers submit ASPs and when CMS calculates the Medicare payment amounts.

*Tracking methods.* CMS does not maintain a comprehensive list of manufacturers that are required to submit ASP data; it tracks only those that actually make submissions. The tracking spreadsheets include only manufacturers that made at least one quarterly ASP submission. This method of tracking is based on previous submissions; it does not take into account the manufacturers that are required to submit ASPs. In addition, CMS would not have any information in its tracking spreadsheet on manufacturers without a rebate agreement that did not submit ASP data.

*Data for non-Part B-covered drugs.* According to CMS, drug manufacturers submitted ASP data for over 8,100 NDCs each quarter; in any given quarter, 3,000 of these NDCs were not actually included in the calculation of Medicare payment amounts. These extra data further complicate the process because CMS staff spend substantial time determining which of these NDCs are Part B-covered drugs (typically using manual methods). In contrast, the automated system used to collect AMP data requires manufacturers to submit and certify valid product data for NDCs prior to providing pricing data.

*Data transparency.* Manufacturers are under no obligation to report to CMS the underlying data that form their ASP submissions. CMS receives only the ASP, the NDC, the number of units, and some product information. Manufacturers are not required to provide any data on total sales, price concessions, or type of customer. Therefore, CMS is unable to verify how manufacturers arrive at the ASPs they submit.

**Almost one-fifth of labeler codes with reported ASPs were associated with manufacturers that were not required to provide these prices under the current system**

Approximately 200 unique labeler codes were associated with ASP data submissions for Part B-covered drugs during each of the quarters under review. Nearly one-fifth of these

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<sup>23</sup> OIG identified these errors during analysis for the reports comparing ASPs to AMPs. See page 6 for these reports.

## FINDINGS

codes belonged to manufacturers that did not have to provide ASP data under the current system because they did not have a Medicaid drug rebate agreement in effect for that quarter. See Table 5 for the percentage of labeler codes associated with manufacturers that submitted ASP data but were not required to do so under the current system.

Table 5: Manufacturer Requirements for Reporting ASPs

Quarter and Year	Percentage of Labeler Codes Associated With Manufacturers That Submitted ASPs but Were Not Required To Do So Under the Current System*
1 <sup>st</sup> Quarter 2007	17
2 <sup>nd</sup> Quarter 2007	17
3 <sup>rd</sup> Quarter 2007	17
4 <sup>th</sup> Quarter 2007	18
1 <sup>st</sup> Quarter 2008	18
2 <sup>nd</sup> Quarter 2008	17

\*There were between 192 and 207 labeler codes with ASP data submissions for the quarters under review. See Table 3 on page 8 for additional detail.

Source: OIG analysis of manufacturers participating in the Medicaid drug rebate program and ASP data.

### **Some HCPCS codes were crosswalked only to NDCs of manufacturers that were not required to report ASPs under the current system**

Medicare payment amounts in the third quarter of 2008 for some HCPCS codes (one version of immune globulin, for example) were based solely on NDCs from manufacturers that did not have rebate agreements in effect in the first quarter of 2008. If these manufacturers chose not to report ASPs, CMS would be unable to calculate ASP-based Medicare payment amounts for these HCPCS codes.<sup>24</sup>

### **A number of manufacturers of Part B-covered drugs were not required to report ASPs and did not provide ASP data to CMS**

We identified between 66 and 82 labeler codes during the quarters under review that were associated with manufacturers that had products listed in the background and crosswalk files (i.e., were Part B-covered drugs) but (1) did not report ASP data for a particular quarter and (2) did not have a rebate agreement in effect for that quarter. Approximately one-third of these labeler codes were associated with repackagers (i.e., companies that repackage drugs purchased from

<sup>24</sup> According to CMS, in the absence of reported ASP data, it still calculates a Medicare payment amount to ensure timely and efficient claims processing. In these cases, CMS uses other published sources of pricing data.

## F I N D I N G S

manufacturers into smaller quantities). Because CMS does not have pricing or utilization data for these drugs, we are unable to quantify the impact this may have had on Medicare payment amounts.

## ► R E C O M M E N D A T I O N S

When setting payment amounts for drugs covered under Medicare Part B, CMS relies on ASP data reported by manufacturers. This report identifies several potential issues with the current ASP reporting process, including (1) the timeliness of manufacturer reporting, (2) the largely manual process used by CMS to collect and analyze manufacturer-reported data, and (3) the legal requirements for manufacturer reporting.

For example, over 40 percent of manufacturers failed to submit ASPs by the statutorily defined deadline each quarter. Although this did not seem to have a significant impact on Medicare payment amounts during the quarters under review, CMS's ability to calculate appropriate payment amounts is reliant upon timely manufacturer data submissions.

In addition, CMS's process for data collection and analysis could lead to inefficiency and errors. Unlike the system CMS uses to collect AMP data, the agency does not have an automated process to collect ASPs. An automated system could reduce the time required to calculate payment amounts, validate that manufacturers are submitting data for Part B-covered drugs, and develop a more comprehensive list of manufacturers required to report ASPs.

Finally, a number of manufacturers that currently report ASPs do not have Medicaid rebate agreements in place and therefore are not required to do so under the current system. Other manufacturers with Part B-covered drugs are not reporting ASPs at all. Therefore, for certain drugs, Medicare payment amounts may not include ASPs for all drugs on the market.

Each of these issues introduces the potential for inefficiency and errors. To ensure that Medicare payment for Part B-covered drugs is accurate, timely, and reflective of all Part B-covered drug sales, we recommend that CMS:

### **Develop an automated system for the collection of ASP data**

CMS has developed an automated system for manufacturers to submit AMPs and could use that system as a template for establishing an automated ASP system. Many manufacturers that submit ASPs already submit AMPs; therefore, these manufacturers are familiar with the concept of an automated price-reporting system. An automated system could limit the possibility of data entry errors, reduce the

## R E C O M M E N D A T I O N S

amount of time it takes to calculate ASP-based payment amounts and adjust ASP payment limits, and enable CMS to track ASPs with greater ease.

An automated system would make the process more efficient and could help ensure data quality. Similar to the AMP system, an automated system for ASP collection would include manufacturer submission and certification of NDCs prior to accepting the associated pricing data.

The increased efficiency resulting from the implementation of an automated system could facilitate the adjustment of Medicare payment amounts based on the results of OIG ASP-to-AMP price comparisons. CMS has acknowledged the Secretary's authority to adjust ASP-based payment limits based on the results of these studies.<sup>25</sup> However, the agency has yet to make any changes as a result of OIG's work, citing the timing of OIG pricing comparisons as one potential obstacle to adjusting payment amounts.<sup>26</sup> Therefore, if OIG can provide the results of its pricing comparisons to CMS sooner, it could enable the adjustment of Medicare payment amounts based on these comparisons.

### **Seek a legislative change to directly require all manufacturers of Part B-covered drugs to submit ASPs**

During the quarters under review, almost one-fifth of labeler codes with reported ASP data were associated with manufacturers that were not required to provide ASPs under the current system because they did not have Medicaid rebate agreements in place. Also, there may be additional manufacturers of Part B-covered drugs that are not submitting ASP data because they do not have a rebate agreement in effect, yet their products are potentially eligible for Part B payments. CMS could work with Congress to develop legislation that would directly require all manufacturers of Part B-covered drugs to submit ASPs, regardless of whether the manufacturers have Medicaid drug rebate agreements. This would ensure that Medicare payment amounts were reflective of all Part B-covered drugs.

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<sup>25</sup> OEI-03-04-00430, April 2006.

<sup>26</sup> OEI-03-07-00140, July 2007.

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

In its comments on the draft report, CMS agreed that certain refinements to the ASP reporting process are desirable to ensure that Medicare payments for Part B-covered drugs are accurate and timely.

CMS concurred with OIG's recommendation that it develop an automated system for the collection of ASP data and agreed that an automated system would be an improvement over the present one. CMS noted that it recognized the risks with the current system and understands the need to develop an automated solution. CMS also stated that it is working with contractors to improve the efficiency of ASP-related processes.

CMS did not concur at this time with OIG's recommendation that it seek a legislative change to directly require all manufacturers of Part B-covered drugs to submit ASPs. However, CMS stated that it will consider this recommendation as it continues to monitor the effects of current payment policies. We continue to support our recommendation that CMS seek a legislative change to the ASP reporting requirements as a way to ensure that Medicare payment amounts are reflective of all Part B-covered drugs.

CMS also provided several technical comments. Based on these comments, we made a few minor revisions to the report, where appropriate. CMS's comments are provided in the Appendix.

▶ A P P E N D I X

**Agency Comments**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

*Administrator*  
Washington, DC 20201

NOV 25 2009

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

**FROM:** Charlene Frizzera */S/*  
Acting Administrator

**SUBJECT:** Office of Inspector General Draft Report (OIG): "Average Sales Prices:  
Manufacturer Reporting and CMS Oversight" (OEI-03-08-00480)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the OIG report entitled, "Average Sales Prices: Manufacturer Reporting and CMS Oversight." We appreciate the OIG's continuing efforts to examine payments made under the average sales price (ASP) methodology. The OIG report presents findings from a review of manufacturer submitted ASP data and of CMS internal procedures used to collect, array, and manage that data in order to calculate quarterly Part B drug payment limits.

The report had three objectives: 1) to determine whether manufacturers that reported ASP data to CMS did so within the timeframe required by Federal law; 2) to review CMS' oversight procedures for the submission of ASP data; and 3) to quantify the number of manufacturers that provided ASPs to CMS but were not required to do so under the current system.

The report had three major findings: 1) each quarter over 40 percent of manufacturers submitted ASPs late although most late submissions were submitted within 10 days of the deadline; 2) CMS implemented oversight procedures for ASP data but CMS' data collection and analysis methods introduce the potential for inefficiency and errors; and 3) almost one-fifth of labeler codes with reported ASPs were associated with manufacturers that were not required to provide these prices under the current system.

The OIG expressed concerns about the following aspects of the ASP reporting process: 1) the timeliness of manufacturer reporting; 2) the largely manual process used by CMS to collect and analyze manufacturer-reported data; and 3) the legal requirements for manufacturer reporting. The report finds that each of these issues introduces the potential for inefficiency and errors. To ensure that Medicare payments for Part B-covered drugs are accurate and timely, we agree that certain refinements to the process are desirable.

Page 2 – Daniel R. Levinson

**OIG Recommendation:**

Develop an automated system for the collection of ASP data.

**CMS Response:**

We concur with this recommendation. CMS has long recognized the risks inherent with any manual system and understands the need to pursue an automated solution. CMS is currently working with two contractors to improve the efficiency of both the ASP data intake and the data manipulation and price calculation processes. We agree that a fully automated system would be an improvement over the present system. Obstacles exist to prevent the rapid and complete implementation of a fully automated solution. Any automated solution that we ultimately adopt must be sophisticated enough to address the lack of compliance with reporting requirements by manufacturers (including improperly formatted national drug codes) or other product identifier formats, transposed fields, etc.), the ability to dynamically track changes to manufacturer submissions, provide a high level of data security and integrity, and have the capability to provide “real-time” editing and feedback to manufacturers and CMS.

**OIG Recommendation:**

Seek a legislative change to directly require all manufacturers of Part B-covered drugs to submit ASPs.

**CMS Response:**

We do not concur with this recommendation at this time. The President’s budget for fiscal year 2010 does not include any proposals to require manufacturers to submit ASPs regardless of whether they have a Medicaid drug rebate agreement. However, we will take this recommendation into consideration as we continue to monitor the effects of our current payment policies.

We thank OIG for presenting its findings and we appreciate their perspective on these issues. This report is in accord with our efforts to refine the data intake process and to migrate to a more automated process in the future. We would like to provide a number of technical comments on the report which are attached.

Attachment



## A C K N O W L E D G M E N T S

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director, Prescription Drug Pricing Unit.

Edward K. Burley served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to the report include Eric M. Biersmith; other central office staff who contributed include Scott Manley.

# *Office of Inspector General*

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