

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**DRUG MANUFACTURERS'  
NONCOMPLIANCE WITH  
AVERAGE MANUFACTURER PRICE  
REPORTING REQUIREMENTS**



Daniel R. Levinson  
Inspector General

September 2010  
OEI-03-09-00060

---

## OBJECTIVES

1. To determine whether manufacturers submitted 2008 average manufacturer prices (AMP) to the Centers for Medicare & Medicaid Services (CMS) within the timeframes specified by Federal requirements.
2. To determine whether CMS has taken action against manufacturers that did not submit AMP data within the timeframes specified by Federal requirements.

---

## BACKGROUND

The Social Security Act sets forth price reporting obligations for certain manufacturers, including the obligation to report AMP data to CMS. During 2008, AMP was generally defined by statute to be 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. Manufacturers must provide CMS with the AMP for each of their covered outpatient drugs within 30 days after the end of each month and each quarter.

Manufacturer-reported AMPs play a critical role in Government payments for prescription drugs. Currently, AMPs provided by manufacturers on a quarterly basis are used to calculate the rebate amounts owed to States under the Medicaid drug rebate program. Quarterly AMPs are also used to establish ceiling prices in the 340B program, which is a prescription drug discount program administered by the Health Resources and Services Administration.

In addition, consistent with the Deficit Reduction Act of 2005 (DRA) and the Patient Protection and Affordable Care Act, AMPs reported on a monthly basis are to be used to establish Federal upper limit amounts in the Medicaid program. The DRA also requires CMS to disclose AMP data to State Medicaid programs, which would enable States to use monthly AMP data when setting Medicaid reimbursement rates for prescription drugs. Although an injunction currently prohibits CMS from using AMPs in a way that affects Medicaid reimbursement rates and from disclosing AMPs to States, AMP data could be used for these purposes in the future.

According to statute, manufacturers that fail to provide timely AMP data may be subject to civil money penalties and/or termination from the drug rebate program. Because the responsibility to impose civil

money penalties has been delegated to the Office of Inspector General (OIG), CMS may refer noncompliant manufacturers to OIG for the purpose of imposing such penalties in appropriate cases. CMS also has authority to terminate the rebate agreements of drug manufacturers that fail to meet price reporting requirements.

For this study, we obtained manufacturer-reported drug product data and AMP data for each month and quarter of 2008, including the dates on which the AMPs were initially certified by manufacturers. For each drug product included in our study, we determined the months and quarters for which AMPs were submitted late or not at all. We then summarized the results for each month and quarter to identify manufacturers that (1) had missing data, i.e., submitted no AMP data for any of their drug products; (2) had late AMP data, i.e., submitted AMP data for all of their drug products after the deadline; or (3) had incomplete AMP data, i.e., submitted at least some of their AMPs by the deadline but submitted the remaining AMPs either late or not at all or submitted a portion of their AMPs late and never submitted the remaining AMPs.

We also determined whether manufacturers that failed to submit timely monthly or quarterly AMP data during 2008 were terminated by CMS or referred by CMS to OIG for potential civil money penalties.

---

## FINDINGS

**In 2008, more than half of manufacturers did not fully comply with quarterly submission requirements for AMP data.** Of the 592 manufacturers that were required to submit quarterly AMP data during 2008, 313 (53 percent) failed to provide pricing data by the statutorily defined due date.

Sixteen of the manufacturers under review had missing AMP data for all of their drug products in multiple quarters. Forty-eight of the manufacturers under review submitted late AMP data for all of their drug products in multiple quarters. One hundred twenty of the manufacturers under review submitted incomplete AMP data in multiple quarters.

**In 2008, more than three-fourths of manufacturers did not fully comply with monthly submission requirements for AMP data.** Of the 579 manufacturers that were required to submit monthly AMP data during 2008, 453 (78 percent) failed to provide pricing data by the statutorily defined due date.

## E X E C U T I V E   S U M M A R Y

Forty of the manufacturers in our review had missing AMP data for all of their drug products in multiple months. One hundred forty-eight of the manufacturers under review had late AMP data for all of their drug products in multiple months. Two hundred twenty-seven of the manufacturers under review had incomplete AMP data in multiple months.

**CMS took action against some manufacturers for failure to comply with quarterly AMP reporting requirements but took no action for failure to comply with monthly reporting requirements.** In total, 78 manufacturers were referred to OIG and/or terminated by CMS for failure to comply with quarterly AMP reporting requirements in 2008. Of these 78 manufacturers, 52 were only referred to OIG, 4 were only terminated by CMS, and the remaining 22 were both referred to OIG and subsequently terminated by CMS. Although CMS tracks manufacturers that report either no monthly AMP data or less than 90 percent of their monthly AMP data, it does not refer or terminate those manufacturers. However, some noncompliant manufacturers are referred or terminated by CMS because they also have missing or late quarterly AMP data.

---

### RECOMMENDATIONS

Because AMP data currently play such a critical role in Government payments for prescription drugs and may play an even greater role in the future, CMS should ensure that action is taken against noncompliant manufacturers. Drug manufacturers must also do their part by reporting both quarterly and monthly AMP data to CMS in a timely and accurate way.

To promote compliance with quarterly and monthly AMP reporting requirements and to help ensure that Medicaid and covered 340B entities do not overpay for prescription drugs, we recommend that CMS:

**Take action against manufacturers that submit incomplete quarterly AMP data.**

**Take action against manufacturers that fail to submit monthly AMP data in a timely manner.**

---

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

CMS concurred with both recommendations and stated that it will begin referring manufacturers that submit incomplete quarterly and monthly data to OIG for civil money penalty consideration. OIG looks forward to expanding its collaboration with CMS regarding administrative remedies for noncompliance with AMP reporting requirements.



# T A B L E O F C O N T E N T S

EXECUTIVE SUMMARY .....	i
INTRODUCTION .....	1
FINDINGS .....	10
In 2008, more than half of manufacturers did not fully comply with quarterly submission requirements for AMP data .....	10
In 2008, more than three-fourths of manufacturers did not fully comply with monthly submission requirements for AMP data ...	12
CMS took action against some manufacturers for failure to comply with quarterly AMP reporting requirements but took no action for failure to comply with monthly reporting requirements .....	14
RECOMMENDATIONS .....	18
Agency Comments and Office of Inspector General Response ...	19
APPENDIXES .....	20
A: Current and Future Uses of Average Manufacturer Price Data in Federal Health Care Programs .....	20
B: Manufacturers With Missing and Late Quarterly Average Manufacturer Price Data .....	24
C: Manufacturers With Missing and Late Monthly Average Manufacturer Price Data .....	25
D: Agency Comments .....	26
ACKNOWLEDGMENTS .....	28

---

## OBJECTIVES

1. To determine whether manufacturers submitted 2008 average manufacturer prices (AMP) to the Centers for Medicare & Medicaid Services (CMS) within the timeframes specified by Federal requirements.
2. To determine whether CMS has taken action against manufacturers that did not submit AMP data within the timeframes specified by Federal requirements.

---

## BACKGROUND

The Social Security Act (the Act) and Federal regulations set forth price reporting obligations for certain drug manufacturers, including the obligation to report AMP data to CMS on quarterly and monthly bases.<sup>1</sup> During 2008, AMP was generally defined by statute to be 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.<sup>2, 3</sup>

Manufacturer-reported AMPs play a critical role in Government payments for prescription drugs. Currently, AMPs provided by manufacturers on a quarterly basis are used to calculate the rebate amounts owed to States under the Medicaid drug rebate program. Quarterly AMPs are also used to establish ceiling prices in the 340B program, which is a prescription drug discount program for covered entities that is administered by the Health Resources and Services Administration (HRSA).

In addition, consistent with the Deficit Reduction Act of 2005 (DRA) and the Patient Protection and Affordable Care Act (Affordable Care Act),<sup>4</sup> monthly AMPs are to be used to establish Federal upper limit (FUL)

---

<sup>1</sup> Section 1927(b)(3) of the Act and 42 CFR §§ 447.510(a) and (d). Price reporting obligations apply to manufacturers that participate in the Medicaid drug rebate program.

<sup>2</sup> Section 1927(k)(1) of the Act.

<sup>3</sup> 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 as measured by one of eight unit types: capsule, tablet, milliliter, gram, each, suppository, transdermal patch, and injectable antihemophilic factor unit. For example, an AMP might be submitted for 1 tablet, 1 milliliter, or 1 gram.

<sup>4</sup> P.L. 109-171 and P.L. 111-148, respectively.

amounts in the Medicaid program.<sup>5</sup> The DRA also requires CMS to disclose AMP data to State Medicaid programs, which would enable States to use monthly AMP data when setting Medicaid reimbursement rates for prescription drugs.<sup>6</sup> Although a preliminary injunction from a Federal district court currently prohibits CMS from using AMPs in a way that affects Medicaid reimbursement rates and from disclosing AMPs to States, AMP data could be used for these purposes in the future.<sup>7</sup>

If quarterly and monthly AMPs are not reported in a timely manner, (1) CMS may not have complete data on which to base Medicaid rebates and future FUL amounts,<sup>8</sup> (2) HRSA may be unable to establish ceiling prices under the 340B program, and (3) States may be unable to use AMPs for Medicaid reimbursement purposes.<sup>9</sup> As a result, the Medicaid program and covered entities participating in the 340B program could potentially overpay for prescription drugs.

For more detailed information about the current and future uses of AMP data in Federal health care programs, see Appendix A.

### **AMP Reporting Requirements**

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 of Health & Human Services (the Secretary) and pay quarterly rebates to State Medicaid agencies.<sup>10</sup>

---

<sup>5</sup> Prior to the DRA, manufacturers were required to submit only quarterly AMPs. However, section 6001 of the DRA and section 2503(b)(1)(A) of the Affordable Care Act expanded manufacturers' reporting requirements to include, respectively, monthly AMPs and the total number of units used to calculate those monthly AMPs. Section 2503(a)(1)(B) of the Affordable Care Act establishes monthly AMPs as the new basis for FUL amounts.

<sup>6</sup> Section 6001 of the DRA.

<sup>7</sup> *National Association of Chain Drug Stores, et al., v. U.S. Department of Health & Human Services, et al.*, Civil Action No. 1:07cv02017, order dated December 19, 2007.

<sup>8</sup> If a manufacturer does not submit timely or complete AMP data, the manufacturer must manually calculate rebate amounts and send rebate payments to States. Therefore, although CMS cannot calculate a rebate amount, States may nonetheless receive rebate payments for drug products with missing AMPs.

<sup>9</sup> According to a 2007 Office of Inspector General (OIG) report entitled *States' Use of New Drug Pricing Data in the Medicaid Program* (OEI-03-06-00490), most States had yet to decide as of October 2006 whether to use AMP data for Medicaid drug reimbursement. Some States raised concerns about missing AMP data, AMP outliers, and the correlation between AMPs and acquisition costs. Undecided States would like assurances from CMS that the AMP data are accurate and valid.

<sup>10</sup> Sections 1927(a)(1) and (b)(1) of the Act.

Under these rebate agreements and pursuant to the Act, manufacturers must make regular reports to CMS of the AMPs for each of their covered outpatient drugs.<sup>11, 12</sup> Originally, manufacturers were required to calculate and report AMPs on a quarterly basis only, with submissions due 30 days after the end of each quarter. However, pursuant to the DRA, manufacturers must also calculate monthly AMPs, with submissions due 30 days after the end of each month.<sup>13, 14</sup> If a drug product has been discontinued, the manufacturer must provide CMS with the product's termination date and continue reporting quarterly AMPs for the product for 1 full year after the termination date.<sup>15, 16</sup> The manufacturer may stop reporting monthly AMPs beginning the first month after the termination date of the drug.<sup>17</sup>

Manufacturers transmit drug product data and AMP data for each reporting period to CMS using the Drug Data Reporting for Medicaid system (DDR). First, manufacturers must enter drug product data for their covered 11-digit national drug codes (NDC), each of which identifies a specific manufacturer, product, and package size. Once the drug product data have been accepted by the system, manufacturers are able to submit AMPs for the corresponding NDCs. The DDR reviews manufacturers' AMP submissions for data errors, notifies manufacturers about potential problems, and may reject files with detected errors. The DDR also displays the number of NDCs entered

---

<sup>11</sup> Section 1927(b)(3) of the Act.

<sup>12</sup> Sections 1927(k)(2-3) of the Act provide the definition of a covered outpatient drug.

<sup>13</sup> Pursuant to section 6001(b)(1) of the DRA, manufacturers are required to report AMPs on a monthly basis. The applicable regulations at 42 CFR § 447.510 specify that quarterly pricing reports must include other information in addition to AMPs, such as customary prompt pay discounts and "best prices" for single-source or innovator multiple-source drugs.

<sup>14</sup> As specified in 42 CFR § 447.504(i), a quarterly AMP is now calculated as a weighted average of monthly AMPs in the quarter. However, the manufacturer must adjust the AMP for a quarter if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized.

<sup>15</sup> CMS, Medicaid Drug Rebate State Release Number 140 (March 15, 2006).

<sup>16</sup> According to CMS, a drug's termination date depends on the reason it is being discontinued by the manufacturer. If a drug product is removed from the shelf immediately because of a health or safety concern, the termination date is the date removed. Otherwise, the termination date is the shelf life of the last batch sold.

<sup>17</sup> Specifically, 42 CFR § 447.510(d)(5) states that manufacturers should not report monthly AMPs for terminated drug products beginning with the first month after the expiration date of the last lot sold (i.e., the termination date).

into the system for which AMP data have yet to be reported.<sup>18</sup> After resolving data errors (if any), manufacturers certify the AMP data in the DDR.

AMP data must be certified within 30 days after the end of each month and each quarter. Certified monthly data are uploaded to CMS's FUL database, whereas certified quarterly data are uploaded to the Medicaid Drug Rebate (MDR) database. Information about the dates on which AMPs were certified and uploaded is maintained in the DDR.

### **Penalties for Failure To Report Timely AMP Data**

Manufacturers that fail to provide AMP data on a timely basis may be subject to civil money penalties and/or termination from the drug rebate program. Pursuant to section 1927(b)(3)(C)(i) of the Act, the Secretary is authorized to impose a civil money penalty that increases by \$10,000 for each day that the required information (including quarterly and monthly AMP data) has not been provided after applicable deadlines. This section of the Act also specifies that if the required prices are not reported within 90 days of the deadline, the manufacturer's rebate agreement will be suspended until the date that the pricing information is reported.<sup>19</sup>

The responsibility to impose penalties pursuant to section 1927(b)(3)(C)(i) of the Act has been delegated to OIG by the Secretary.<sup>20</sup> In the second quarter of 2006, CMS began referring noncompliant manufacturers to OIG for the purpose of imposing civil money penalties.<sup>21</sup> In response to CMS's referrals, OIG has proposed that civil money penalties be levied against manufacturers that fail to comply with price reporting requirements.

CMS also has authority to terminate the rebate agreements of manufacturers that fail to comply with AMP reporting requirements.<sup>22</sup>

---

<sup>18</sup> The DDR also allows the manufacturers themselves to run a missing data report, which lists the NDCs that have no pricing data in the current period or any other period going back to 1991.

<sup>19</sup> Pursuant to section 1927(b)(3)(C)(i) of the Act, rebate agreements must be suspended for no less than 30 days.

<sup>20</sup> 59 Fed. Reg. 52967 (Oct. 20, 1994).

<sup>21</sup> CMS began referring noncompliant manufacturers to OIG in response to a 2005 report entitled *Deficiencies in the Oversight of the 340B Drug Pricing Program* (OEI-05-02-00072). As part of this report, OIG recommended that CMS consider referring manufacturers whose pricing data submissions do not comply with reporting requirements to OIG so that penalties could be imposed in appropriate cases.

<sup>22</sup> Section 1927(b)(4)(B) of the Act.

Specifically, CMS may terminate a rebate agreement “for violation of the requirements of the agreement or other good cause shown.”<sup>23</sup> If a rebate agreement is terminated by CMS, the manufacturer may not enter into another rebate agreement for at least one quarter (with certain exceptions).<sup>24, 25</sup>

### **Previous OIG Work**

Several OIG studies have found that some manufacturers may not be submitting quarterly AMP data for all of their NDCs by the statutory deadline. In one report, OIG found that almost 20 percent of 340B ceiling prices in the first quarter of 2005 could not be calculated because of missing AMP data.<sup>26</sup> Another OIG report identified 1,431 NDCs with no AMP data during one or more quarters of 2008.<sup>27</sup> Manufacturers for almost 60 percent of these NDCs participated in the MDR program in 2008 and were therefore generally required to submit AMP data.

---

## **METHODOLOGY**

### **Scope**

For this study, we examined both monthly and quarterly AMP data from 2008 as reported in the MDR and FUL databases.

Rebate agreements are established by labeler code, which is a five-digit number that identifies the manufacturer of a given drug product. Drug companies and their subsidiaries may have one or more labeler codes. For the purposes of this report, we consider each labeler code to be a “manufacturer.”

### **Data Sources and Data Collection**

We obtained from CMS a list of manufacturers that participated in the Medicaid drug rebate program during 2008, including the effective dates of the manufacturers’ rebate agreements and the termination

---

<sup>23</sup> Pursuant to section 1927(b)(4)(B) of the Act, such termination shall not be effective earlier than 60 days after the date of notice for the termination.

<sup>24</sup> Section 1927(b)(4)(C) of the Act.

<sup>25</sup> If, after one quarter, a manufacturer wants to reenter the program, CMS will begin the reinstatement process. As part of that process, manufacturers must report all missing pricing data to CMS and pay any outstanding rebate amounts (including interest) to States.

<sup>26</sup> OIG, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072, October 2005.

<sup>27</sup> OIG, *Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2008*, OEI-03-09-00350, February 2010.

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

dates (if any).<sup>28</sup> Using this list, we identified 592 manufacturers that should have submitted AMP data for one or more quarters of 2008, and 579 manufacturers that should have submitted AMP data for 1 or more months of 2008. (In 2008, more manufacturers were required to submit quarterly AMPs than monthly AMPs because manufacturers of terminated NDCs must continue reporting quarterly AMPs for 1 year after the termination dates but need not report monthly AMPs after the termination dates.) The number of manufacturers that were required to submit AMP data in each individual month and quarter of 2008 is specified in Table 1.

CMS also provided us with Medicaid drug product data for 2008, as reported by manufacturers with rebate agreements. The data include information such as the name and NDC of each covered outpatient drug, the date each drug entered the market, and the termination date for the drug (if applicable). Using the data provided by CMS, we identified active NDCs for each month and quarter of 2008. Because CMS requires manufacturers to report quarterly AMPs for a year after a drug's termination date, we also identified NDCs that were terminated prior to 2008 but for which AMP data for one or more quarters of 2008 were still required. Table 1 shows the number of NDCs in each month and quarter for which AMP data were required.

CMS additionally provided us with AMP data for each month and quarter of 2008, including the dates on which the AMPs were initially certified by manufacturers. All AMP data were current as of July 16, 2009.

To determine whether CMS has taken action against manufacturers that do not comply with AMP reporting requirements, we interviewed CMS staff members who are responsible for monthly and quarterly AMP data. We asked them to identify manufacturers that were either terminated or referred to OIG for failure to comply with AMP reporting requirements during 2008.<sup>29, 30</sup>

---

<sup>28</sup> Only manufacturers on CMS's list are required to submit AMP data. Manufacturers with no valid drug product data on file with CMS were excluded from our review.

<sup>29</sup> Termination and referral data provided by CMS were current as of March 2010.

<sup>30</sup> CMS referred or terminated manufacturers based on quarterly AMP data that were available at the time of CMS's own analyses.

Table 1: Number of NDCs in Each Month and Quarter for Which Average Manufacturer Price Data Were Required

Quarter in 2008	Number of Manufacturers	Number of NDCs	Month in 2008	Number of Manufacturers	Number of NDCs
First	564	38,940	January	546	35,515
			February	547	35,544
			March	549	35,545
Second	555	37,565	April	540	34,436
			May	542	34,416
			June	545	34,426
Third	561	38,603	July	543	34,451
			August	546	35,533
			September	551	35,579
Fourth	565	38,271	October	549	35,261
			November	551	35,246
			December	555	35,252

Source: OIG analysis of manufacturers, NDCs, and AMP data from all four quarters of 2008.  
 Note: More manufacturers were required to submit quarterly AMPs for more NDCs than monthly AMPs because manufacturers of terminated NDCs must continue reporting quarterly AMPs for 1 year after the termination dates but need not report monthly AMPs after the termination dates.

**Analysis of AMP Submissions**

For each NDC included in our study, we determined the months and quarters in 2008 for which AMPs were either not submitted or submitted late. To accomplish this, we compared the AMP certification date for each period to the due date of the data (i.e., 30 days after the end of each period). Data without certification dates were considered missing. Data certified after the due dates were considered late. If AMP data were submitted late, we calculated the number of days that elapsed between the due dates and the certification dates. We also identified NDCs with missing or late AMP data in multiple months/quarters. Using 2008 Medicaid utilization data posted on CMS’s Web site, we also calculated Medicaid’s total expenditures for each NDC during the period(s) for which that NDC’s AMP was missing or late.<sup>31</sup>

For each month and quarter in 2008, we then summarized results at the NDC level to identify manufacturers with the following problems:

<sup>31</sup> To estimate Medicaid expenditures for an NDC without AMP data in a given month, we divided the total reimbursement amounts for the corresponding quarter by three.

- Missing AMP data. Manufacturers with missing AMP data submitted no AMP data for any of their NDCs during the month/quarter.
- Late AMP data. Manufacturers with late AMP data submitted AMP data for all of their NDCs after the deadline.
- Incomplete AMP data. Manufacturers with incomplete AMP data fell into one of two categories: (1) manufacturers that submitted at least some of their AMPs by the deadline but submitted the remaining AMPs for the month/quarter either late or not at all or (2) manufacturers that submitted a portion of their AMPs late and never submitted the remaining AMPs for the month/quarter.

We then identified manufacturers that had missing, late, or incomplete AMPs in multiple months or quarters.

We also identified manufacturers that CMS terminated or referred to OIG for failure to submit monthly or quarterly data by the statutory deadline. We then determined whether the manufacturers identified by our analysis as having missing, late, or incomplete quarterly or monthly AMP data were terminated by CMS or referred to OIG.

### **Limitations**

We did not verify whether the NDCs provided by manufacturers for each reporting period and subsequently listed in CMS's drug product file met the definition of a covered outpatient drug.<sup>32</sup> We also did not examine whether AMP data initially reported by the applicable deadline were later corrected and resubmitted by the manufacturers.

For NDCs with missing and late AMPs, we did not determine whether manufacturers manually calculated rebate amounts and paid rebates to States accordingly.<sup>33</sup> States may have received appropriate rebates from manufacturers, even when those manufacturers did not comply with quarterly reporting requirements. We also did not determine whether NDCs with missing and late AMPs had Medicaid utilization in 2008.

Furthermore, we did not contact the manufacturers of NDCs with missing AMPs to determine whether they discontinued the NDCs but neglected to report termination dates to CMS. If NDCs with missing

---

<sup>32</sup> As defined by sections 1927(k)(2-3) of the Act.

<sup>33</sup> See Appendix A for a more detailed description of rebate calculations.

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

AMPs were, in fact, discontinued and no longer required AMPs, the number of manufacturers with missing and incomplete data in our report may be overestimated.

OIG's determinations of missing and late AMP data for a given period were not always the same as those made by CMS for that same period. This may have resulted from a number of factors. For instance, OIG identified manufacturers as having late data if the data were submitted any time after the due dates, whereas CMS identified manufacturers as having late data if the data were submitted after the rebate amounts were calculated. Also, CMS terminated or referred manufacturers based on AMP data that were current at the time of CMS's analysis, whereas OIG analyzed more recently updated data.

### **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

### **In 2008, more than half of manufacturers did not fully comply with quarterly submission requirements for AMP data**

In 2008, 53 percent of manufacturers that participated in the Medicaid drug rebate program (313 of 592) failed to submit at least

some of their quarterly AMPs within the timeframes specified by Federal requirements. These manufacturers had missing, late, or incomplete AMP data during one or more quarters of 2008. When manufacturers do not comply with quarterly reporting requirements, CMS does not have complete data on which to base Medicaid rebates and HRSA may be unable to establish ceiling prices under the 340B program.

Manufacturers that repeatedly failed to comply with quarterly AMP requirements did not always have the same problems (i.e., missing, late, and incomplete data) with the same NDCs in each period. Some manufacturers had different problems in different quarters. As a result, those manufacturers were included in more than one of the missing, late, and incomplete quarterly AMP categories described below.<sup>34</sup>

#### **Five percent of manufacturers failed to submit any quarterly AMP data in one or more quarters of 2008**

Of the 592 manufacturers under review, 31 (5 percent) did not submit AMP data for any of their NDCs during at least one quarter of 2008. More than half of these 31 manufacturers repeatedly failed to provide the required AMP data during 2008. Specifically, 2 manufacturers did not submit AMP data in 2 quarters, 11 did not submit AMP data in 3 quarters, and an additional 3 did not submit AMP data in all 4 quarters. Medicaid paid \$3.8 million during the applicable quarters of 2008 for NDCs belonging to the 31 manufacturers that did not submit the required AMP data.

Table B-1 in Appendix B lists the number and percentage of manufacturers with no AMP data in each quarter, as well as the number of NDCs associated with those manufacturers.

#### **Almost one-fourth of manufacturers submitted all of their quarterly AMP data after the deadline in one or more quarters of 2008**

In 2008, 24 percent of manufacturers (144 of 592) submitted quarterly AMP data for all of their NDCs after the deadline in at least one

---

<sup>34</sup> Because manufacturers could have different problems in different quarters, the number of manufacturers in each subfinding sums to more than the total number of manufacturers that did not fully comply with quarterly AMP reporting requirements.

quarter. One-third of these manufacturers (48 of 144) submitted late AMP data in multiple quarters, with one manufacturer submitting prices after the deadline in all four quarters.

The amount of time that passed before overdue AMPs were submitted by these manufacturers varied by quarter. In the second and third quarters of 2008, at least 80 percent of overdue AMPs were submitted within 5 days of the deadline and no more than 5 percent of overdue AMPs were more than 30 days late. However, manufacturers with late AMPs in the first and last quarters of 2008 were slower to provide their outstanding data. A little more than half of the overdue AMPs in the first quarter were submitted within 5 days of the deadline, and only 20 percent of overdue AMPs in the fourth quarter were submitted within 5 days. Furthermore, over one-third of the overdue AMPs in each of these quarters were more than 30 days late.

CMS typically calculates Medicaid rebate amounts about 3 to 5 days after the due date for the AMP data. If manufacturers submit AMP data beyond that point, CMS cannot calculate the quarterly rebate amounts for the corresponding NDCs.<sup>35</sup> It then becomes the responsibility of the manufacturers to manually calculate the rebate amounts and send the rebate payments to the States.

Table B-2 in Appendix B lists the number and percentage of manufacturers that submitted all of their AMP data after the deadline in each quarter, as well as the number of NDCs associated with those manufacturers.

**Almost one-third of manufacturers submitted incomplete quarterly AMP data in one or more quarters of 2008**

In 2008, 30 percent of manufacturers (180 of 592) submitted incomplete AMP data in at least one quarter of 2008. Two-thirds of these manufacturers (120 of 180) submitted incomplete data in multiple quarters. As mentioned previously, manufacturers with incomplete AMP data fell into one of two categories: (1) manufacturers that submitted at least some of their AMPs by the deadline but submitted the remaining AMPs for the quarter either late or not at all or (2) manufacturers that submitted a portion of their AMPs late and never submitted the remaining AMPs. For manufacturers in the first category, an average of 60 percent of the outstanding AMPs in each

---

<sup>35</sup> Overdue AMP data submitted after rebate amounts have been calculated for the quarter are included with the following quarter's transmission of rebate data from CMS to States.

quarter were never submitted. However, for manufacturers in the second category, an average of only 3 percent of the outstanding AMPs in each quarter were never submitted. Overall, the vast majority of AMPs associated with manufacturers in the second category were eventually provided to CMS.

**In 2008, more than three-fourths of manufacturers did not fully comply with monthly submission requirements for AMP data**

In 2008, 78 percent of the manufacturers that were required to submit monthly AMP data (453 of 579) failed to do so within the timeframes specified

by Federal requirements. These manufacturers had missing, late, or incomplete AMP data during 1 or more months of 2008. Because CMS is currently prohibited from disclosing AMPs to States and from using AMPs in a way that affects Medicaid reimbursement, problematic monthly AMP submissions have little effect at this time.<sup>36</sup> In the future, however, monthly AMPs may be used by CMS to establish FUL amounts and by States to set Medicaid reimbursement amounts. If manufacturers continue to report monthly AMPs either late or not at all, CMS may be unable to establish appropriate future FUL amounts and States may be unable to use AMPs to set future Medicaid reimbursement rates.

Manufacturers that repeatedly failed to comply with monthly reporting requirements did not always have the same problems for the same NDCs in each period. Some manufacturers had different problems in different months. As a result, those manufacturers were included in more than one of the missing, late, and incomplete monthly AMP categories described below.<sup>37</sup>

**Ten percent of manufacturers failed to submit any monthly AMP data in 1 or more months of 2008**

Of the 579 manufacturers under review, 57 (10 percent) did not submit AMP data for any of their NDCs during at least 1 month of 2008. Forty of these fifty-seven manufacturers repeatedly failed to provide the

<sup>36</sup> Currently, CMS uses monthly AMP data only for internal calculations of AMP-based FUL amounts.

<sup>37</sup> Because manufacturers could have different problems in different months, the number of manufacturers in each subfinding sums to more than the total number of manufacturers that did not fully comply with monthly AMP reporting requirements.

## F I N D I N G S

required AMP data during 2008, with 21 failing to submit AMP data in 7 or more months and 5 failing to submit monthly AMP data for all 12 months. Medicaid paid \$29.4 million during the applicable months of 2008 for NDCs belonging to manufacturers that did not submit any of the required AMP data.

Table C-1 in Appendix C lists the number and percentage of manufacturers with no AMP data in each month, as well as the number of NDCs associated with those manufacturers.

### **Over 40 percent of manufacturers submitted all of their monthly AMP data after the deadline in 1 or more months of 2008**

In 2008, 41 percent of manufacturers (235 of 579) submitted monthly AMP data for all of their NDCs after the deadline in at least 1 month. Almost two-thirds of these manufacturers (148 of 235) submitted late AMP data in multiple months, with 23 manufacturers submitting prices after the deadline in 6 or more months.

The amount of time that passed before these manufacturers submitted their overdue AMPs varied from month to month. During 2008, the percentage of late AMPs submitted within 5 days of each month's deadline ranged from 4 percent to 74 percent, with an average of 48 percent. The percentage of late AMPs submitted more than 30 days after each month's deadline ranged from 5 percent to 64 percent, with an average of 31 percent.

Table C-2 in Appendix C lists the number and percentage of manufacturers that submitted all of their AMP data after the deadline in each month, as well as the number of NDCs associated with those manufacturers.

### **Almost half of manufacturers submitted incomplete monthly AMP data in 1 or more months of 2008**

In 2008, 46 percent of manufacturers (268 of 579) submitted incomplete AMP data in at least 1 month. Of these manufacturers, 85 percent (227 of 268) submitted incomplete AMP data in multiple months. As with the quarterly data, manufacturers with incomplete monthly AMP data fell into one of two categories: (1) manufacturers that submitted at least some of their AMPs by the deadline but submitted the remaining AMPs for the month either late or not at all or (2) manufacturers that submitted a portion of their AMPs late and never submitted the remaining AMPs. For manufacturers in the first category, an average of 77 percent of the outstanding AMPs in each month were never submitted. However, for manufacturers in the second category, an

average of only 6 percent of the outstanding AMPs in each month were never submitted. Typically, the vast majority of monthly AMPs associated with manufacturers in the second category were eventually provided to CMS.

**CMS took action against some manufacturers for failure to comply with quarterly AMP reporting requirements but took no action for failure to comply with monthly reporting requirements**

Although CMS has instituted procedures to penalize manufacturers with consistently missing and late quarterly AMP data, CMS has

no such procedures to penalize manufacturers with consistently missing and late monthly AMP data.

**CMS referred to OIG and/or terminated 78 manufacturers that failed to comply with quarterly AMP reporting requirements in 2008**

CMS staff take a number of actions against manufacturers with missing and late quarterly AMP data. About 1 to 2 weeks after the due date, a staff member emails manufacturers that missed the quarterly deadline, prompting them to report the outstanding prices. Manufacturers with missing data in at least two of the four previous quarters are terminated by CMS. Manufacturers with late AMP submissions in at least two of the four previous quarters are referred to OIG for potential civil money penalties.<sup>38</sup> According to staff, CMS has the resources to pursue only manufacturers that have missing or late data for all of their NDCs. Although staff can compile reports identifying manufacturers with incomplete AMP data, they do not currently have the resources to pursue those manufacturers.

In total, 78 manufacturers were referred to OIG and/or terminated by CMS for failure to comply with AMP reporting requirements in 2008. Of these 78 manufacturers, 52 were only referred to OIG, 4 were only terminated by CMS, and the remaining 22 were both referred to OIG and subsequently terminated by CMS.<sup>39</sup>

*CMS effectively took action against manufacturers identified by OIG as having missing quarterly AMP data.* As shown in Table 2, CMS referred

<sup>38</sup> CMS considers late data to be data submitted after the MDR database has been shut down for the calculation of rebate amounts.

<sup>39</sup> CMS's actions were based on missing and late AMP submissions during all of the four-quarter periods between the second quarter of 2007 and the third quarter of 2009. Each of these four-quarter periods included at least one quarter of 2008.

F I N D I N G S

or terminated a large majority of the manufacturers that OIG identified as having no AMP data in at least one quarter of 2008. In fact, CMS took action against all but one of the manufacturers we identified as having no AMP data in multiple quarters.

CMS also took action against manufacturers identified by OIG as having late quarterly data, but to a lesser extent. Consistent with its policy to penalize manufacturers that repeatedly submit late AMPs, CMS was more likely to refer manufacturers identified by OIG as having multiple quarters of late data. CMS penalized only 16 percent of the manufacturers with late data in just one quarter. However, as shown in Table 2, it took action against 48 percent of manufacturers with late data in multiple quarters.

CMS took action against few manufacturers identified by OIG as having incomplete data. Because CMS does not specifically pursue manufacturers that submit incomplete quarterly AMPs, most of the manufacturers that we identified as having incomplete quarterly data were not penalized. However, as shown in Table 2, a small portion of these manufacturers were nonetheless referred or terminated.<sup>40</sup>

Table 2: Manufacturers With Problematic Quarterly AMP Data That Were Referred or Terminated by CMS

Description of Problematic Quarterly AMP Data According to OIG Analysis	Total Number of Manufacturers	Total Number Penalized	Percentage Penalized	Action		
				Number Referred Only	Number Terminated Only	Number Referred, Then Terminated
<b>Missing AMP data</b>	<b>31</b>	<b>27</b>	<b>87%</b>	<b>5</b>	<b>3</b>	<b>19</b>
In multiple quarters	16	15	94%	1	2	12
<b>Late AMP data</b>	<b>144</b>	<b>38</b>	<b>26%</b>	<b>34</b>	<b>0</b>	<b>4</b>
In multiple quarters	48	23	48%	22	0	1
<b>Incomplete AMP data</b>	<b>180</b>	<b>19</b>	<b>11%</b>	<b>14</b>	<b>1</b>	<b>4</b>
In multiple quarters	120	12	10%	10	1	1

Source: OIG analysis of AMP data from the first through fourth quarters of 2008 and CMS data regarding terminated and referred manufacturers, 2009.

Note: Because manufacturers could have different problems in different quarters and because the problems for which CMS terminated or referred manufacturers may not be the same as those identified by OIG in this study, the number of manufacturers that were terminated or referred in each problem category does not sum to the total number of manufacturers that were terminated or referred by CMS.

<sup>40</sup> These manufacturers may have been referred or terminated because they had untimely data in other quarters of 2008 or because CMS had different product or pricing information at the time it conducted its analysis.

**CMS took no direct action against manufacturers that failed to comply with monthly AMP reporting requirements in 2008**

CMS staff track manufacturers that report less than 90 percent of their monthly AMP data; however, staff do not follow up with noncompliant manufacturers unless those manufacturers contact CMS for another reason.<sup>41</sup> If a manufacturer contacts CMS, staff will check to see whether that manufacturer has been reporting monthly AMPs. Manufacturers that have reported less than 90 percent of their AMP data during at least 2 months are then instructed to report the outstanding data.<sup>42</sup> CMS does not refer or terminate manufacturers that fail to comply with monthly AMP reporting requirements.

Because monthly AMP data are currently used only for internal calculations, CMS staff stated that they see no immediate need to terminate manufacturers that fail to comply with monthly reporting requirements.

Although CMS does not directly penalize manufacturers with missing, late, or incomplete monthly AMPs, some of these noncompliant manufacturers were referred or terminated by CMS because they also had missing or late quarterly AMP data.

As shown in Table 3, more than half of manufacturers identified by OIG as having missing monthly AMP data were referred or terminated by CMS. Manufacturers with late and incomplete monthly data were much less likely to be penalized.

---

<sup>41</sup> Although CMS receives monthly reporting data on all manufacturers, it tracks only manufacturers that have 30 or more NDCs.

<sup>42</sup> Months of missing data do not need to be consecutive. They can be any 2 months of data since October 2007, when manufacturers first started reporting monthly AMPs.

F I N D I N G S

Table 3: Manufacturers With Problematic Monthly AMP Data That Were Referred or Terminated Because They Also Had Problematic Quarterly Data

Description of Problematic Monthly AMP Data According to OIG Analysis	Total Number of Manufacturers	Total Number Penalized	Percentage Penalized	Action		
				Number Referred Only	Number Terminated Only	Number Referred, Then Terminated
<b>No AMP data</b>	<b>57</b>	<b>33</b>	<b>58%</b>	<b>11</b>	<b>3</b>	<b>19</b>
In multiple months	40	28	70%	7	3	18
<b>Late AMP data</b>	<b>235</b>	<b>38</b>	<b>16%</b>	<b>29</b>	<b>3</b>	<b>6</b>
In multiple months	148	28	19%	23	1	4
<b>Incomplete AMP data</b>	<b>268</b>	<b>22</b>	<b>8%</b>	<b>19</b>	<b>0</b>	<b>3</b>
In multiple months	227	17	7%	15	0	2

Source: OIG analysis of AMP data from all 12 months of 2008 and CMS data regarding terminated and referred manufacturers, 2009.

Note: Because manufacturers could have different problems in different months, the number of manufacturers that were terminated or referred in each problem category does not sum to the total number of manufacturers that were terminated or referred by CMS.

In 2008, more than half of the manufacturers that were required to submit quarterly AMP data failed to comply with reporting requirements in at least one quarter. Manufacturers were even less likely to comply with monthly AMP reporting requirements, with more than three-quarters having missing, late, or incomplete AMPs in at least 1 month of 2008.

CMS takes action against manufacturers with missing and late quarterly AMP data, including reminding noncompliant manufacturers to submit quarterly data, terminating manufacturers that repeatedly fail to submit quarterly AMPs, and referring manufacturers with consistently late quarterly data to OIG for potential civil money penalties.

However, CMS does not take any such action against manufacturers with missing and late monthly AMPs. Although CMS tracks manufacturers with no monthly AMP data, staff remind noncompliant manufacturers to submit overdue data only if those manufacturers initiate contact. Furthermore, CMS has yet to terminate or refer any manufacturer for failure to comply with monthly AMP reporting requirements.

Because AMP data play such a critical role in Government payments for prescription drugs, CMS must ensure that action is taken against noncompliant manufacturers. Drug manufacturers must also do their part by reporting both quarterly and monthly AMP data to CMS in a timely and accurate way.

To promote full compliance with quarterly and monthly AMP reporting requirements and to help ensure that Medicaid and covered 340B entities do not overpay for prescription drugs, we recommend that CMS:

**Take action against manufacturers that submit incomplete quarterly AMP data**

Although CMS staff acknowledge that incomplete data are a problem, they state that they do not currently have the resources to pursue manufacturers that submit only some of their AMPs. CMS should ensure that action is taken against manufacturers with incomplete quarterly AMP data. To that end, we will provide CMS with more detailed information about the manufacturers in this study with incomplete quarterly AMP data.

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

### **Take action against manufacturers that fail to submit monthly AMP data in a timely manner**

Shortly after each monthly deadline, CMS should contact manufacturers that fail to comply with monthly reporting requirements and ask them to submit outstanding data. If manufacturers repeatedly fail to report monthly AMP data or repeatedly submit them late, those manufacturers should be either terminated by CMS or referred to OIG for potential civil money penalties. Manufacturers with incomplete monthly AMPs should also be addressed. These proactive steps will signal the importance of complying with monthly AMP requirements and help to ensure that CMS has complete monthly AMP data. This in turn will enable CMS to better gauge the potential impact of AMP-based FULs and to ensure the integrity of future FUL amounts.

---

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

CMS concurred with both recommendations and stated that it will begin referring manufacturers that submit incomplete quarterly and monthly data to OIG for civil money penalty consideration. OIG looks forward to expanding its collaboration with CMS regarding administrative remedies for noncompliance with AMP reporting requirements.

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

## **Current and Future Uses of Average Manufacturer Price Data in Federal Health Care Programs**

Average manufacturer price (AMP) data play a critical role in Government payments for prescription drugs. Quarterly AMPs are currently used in both the Medicaid drug rebate program and the 340B drug discount program, and monthly AMPs may be used in the future for the purposes of Medicaid reimbursement.

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

The Medicaid rebate amount for any given drug generally depends on the quarterly AMP submitted by the manufacturer, as well as on whether the drug is a brand-name or generic. For the purposes of the Medicaid drug rebate program, drugs are classified as one of three types: single-source, innovator multiple-source, or noninnovator multiple-source. Manufacturers provide the Centers for Medicare & Medicaid Services (CMS) with the drug type for each of their national drug codes (NDC), in conjunction with AMP data. Manufacturers must also provide a “best price” for each of their single-source and innovator multiple-source drugs on a quarterly basis.<sup>43</sup> Using these data, CMS calculates a unit rebate amount (URA) for each NDC and transmits that information to States.

Manufacturers pay a higher Medicaid rebate for innovator drugs (i.e., brands) than for noninnovator drugs (i.e., generics). From 1996 through 2009, the URA for single-source and innovator multiple-source drugs was the greater of 15.1 percent of the AMP or the difference between the AMP and best price.<sup>44, 45</sup> For noninnovator multiple-source drugs, the URA was 11 percent of the AMP.<sup>46</sup>

---

<sup>43</sup> Sections 1927(b)(3)(A)(i)(II) and (c)(1)(C) of the Social Security Act (the Act). Generally speaking, best price is defined as the lowest price available from the manufacturer to any purchaser in the United States, with certain exceptions.

<sup>44</sup> Section 1927(c) of the Act.

<sup>45</sup> Effective January 2010, section 2501(a) of the Patient Protection and Affordable Care Act (Affordable Care Act), P.L. 111-148, increases the URA for single-source and innovator multiple-source drugs to the greater of 23.1 percent of the AMP or the difference between AMP and best price (with certain exceptions).

<sup>46</sup> Effective January 2010, section 2501(b) of the Affordable Care Act increases the URA for noninnovator multiple-source drugs to 13 percent.

If the pricing data result in a URA of zero<sup>47</sup> or if a manufacturer does not submit timely or complete pricing data, the manufacturer must manually calculate the URA and send a rebate payment to the States.<sup>48</sup>

### **The 340B Drug Discount Program and AMPs**

In 1992, Congress amended the Public Health Service Act (PHS Act) to include a new section entitled *Limitation on Prices of Drugs Purchased by Covered Entities*. This change created the 340B program, which is a discount drug program administered by the Health Resources and Services Administration (HRSA). Under the 340B program, a manufacturer agrees to sell covered outpatient drugs at or below a specified ceiling price to qualified entities. These entities include federally qualified health centers, Ryan White grantees, and disproportionate share hospitals, among others.<sup>49</sup>

The 340B discount is calculated using the same component information that Medicaid uses to calculate rebates.<sup>50</sup> Specifically, the 340B discount is equal to the AMP reduced by Medicaid's URA.<sup>51</sup> Under an intraagency agreement with CMS, HRSA calculates 340B ceiling prices using quarterly AMP and URA data supplied by CMS.

### **Potential Uses of Monthly AMPs in the Medicaid Program**

Currently, all 50 States and the District of Columbia (hereinafter referred to as States) offer prescription drug coverage under Medicaid. Medicaid beneficiaries typically obtain covered drugs from pharmacies, which bill and are reimbursed by State Medicaid agencies using NDCs. In 2008, Medicaid payments for prescription drugs totaled approximately \$24 billion.<sup>52</sup>

---

<sup>47</sup> According to CMS staff, if the quarterly AMP submitted by a manufacturer is 400 percent greater or 400 percent less than the previous quarter's AMP, then an alert is sent to the manufacturer and the URA is sent to the States as zero.

<sup>48</sup> CMS, *Medicaid Drug Rebate Data Guide for Labelers*, p. 15.

<sup>49</sup> For more information about covered entities, see HRSA, *Introduction to 340B Drug Pricing Program*, accessed at <http://www.hrsa.gov> on December 11, 2009.

<sup>50</sup> HRSA, *Glossary of Pharmacy-Related Terms*, accessed at <http://www.hrsa.gov> on December 11, 2009.

<sup>51</sup> Sections 340B(a)(1-2) of the PHS Act.

<sup>52</sup> This total was calculated using national summary data for 2008, which were downloaded from CMS's Web site on July 30, 2009. This amount includes both Federal and State payments. Rebates collected by States under the Medicaid drug rebate program were not subtracted from this figure. Data for some States may not have been complete at the time of extraction. Therefore, the 2008 drug expenditures presented in this report may underestimate Medicaid's actual expenditures.

Federal regulations require, with certain exceptions, that each State Medicaid agency's reimbursement for covered outpatient drugs not exceed (in the aggregate) the lower of the estimated acquisition cost plus a reasonable dispensing fee or the provider's usual and customary charge to the public for the drugs.<sup>53</sup> CMS allows States the flexibility to define estimated acquisition cost, with most States basing their calculations on a drug's average wholesale price discounted by a certain percentage. For certain drugs, States also use the Federal upper limit (FUL) or State maximum allowable cost programs in setting reimbursement amounts.<sup>54</sup>

To reduce Medicaid prescription drug expenditures, the Deficit Reduction Act of 2005 (DRA)<sup>55</sup> and the Affordable Care Act enacted a number of changes that expand the role of AMPs in Medicaid payments for prescription drugs. For example, the DRA requires CMS to disclose AMP data to State Medicaid programs on a monthly basis, which would enable States to use AMP data when setting Medicaid reimbursement rates for prescription drugs.<sup>56</sup> In addition, the DRA and the Affordable Care Act specify that AMPs are to be used to establish FUL amounts for certain multiple-source drugs in the Medicaid program. Specifically, FUL amounts under the Affordable Care Act are to be no less than 175 percent of the weighted average of the most recently reported monthly AMPs.<sup>57, 58</sup>

However, CMS has yet to disclose AMP data to States or use those prices when establishing FUL amounts. On December 19, 2007, the U.S. District Court for the District of Columbia preliminarily enjoined CMS from disclosing AMP data to States and from using AMP for purposes of Medicaid reimbursement. Although CMS may not currently

---

<sup>53</sup> 42 CFR § 447.512(b).

<sup>54</sup> The FUL and State maximum allowable cost programs serve to control spending for multiple-source drugs. CMS has established FUL amounts for more than 700 drugs. In addition, almost all States have implemented maximum allowable cost programs to limit reimbursement amounts for certain drugs.

<sup>55</sup> P.L. 109-171.

<sup>56</sup> Section 6001(b) of the DRA. Prior to the DRA, section 1927(b)(3)(D) of the Act broadly guaranteed the confidentiality of AMP data reported by manufacturers (with certain limited exceptions).

<sup>57</sup> Section 2503(a)(1)(B) of the Affordable Care Act.

<sup>58</sup> Section 6001(a)(2) of the DRA included a provision setting the FUL amount at 250 percent of the lowest reported AMP. The Affordable Care Act revised this provision, setting the FUL amount at no less than 175 percent of the weighted average of the most recently reported monthly AMPs.

A P P E N D I X ~ A

implement AMP-based FULs, it calculates AMP-based FULs each month for internal purposes.

**Manufacturers With Missing and Late Quarterly Average Manufacturer Price Data**

Table B-1: Manufacturers That Failed To Submit Any Quarterly AMP Data

Quarter in 2008	Manufacturers		Corresponding NDCs			
	Number With No AMP Data	Percentage With No AMP Data	Number of NDCs	Average per Manufacturer	Median per Manufacturer	Total Reimbursed
First	13	2.3%	331	25	10	\$670,141
Second	16	2.9%	373	23	11	\$924,055
Third	16	2.9%	382	24	11	\$728,141
Fourth	19	3.4%	204	11	7	\$1,511,500
<b>Total</b>						<b>\$3,833,836</b>

Source: Office of Inspector General (OIG) analysis of average manufacturer price (AMP) data from the first through fourth quarters of 2008.

Note: Reimbursement totals and average national drug codes (NDC) were rounded to the nearest whole number. Percentages were rounded to the nearest tenth.

Table B-2: Manufacturers That Submitted Late Quarterly AMP Data for All of Their NDCs

Quarter in 2008	Manufacturers		Corresponding NDCs						
	Number With Late AMP Data	Percentage With Late AMP Data	Number of NDCs	Average per Manufacturer	Median per Manufacturer	Up to 5 Days Late	Between 6 and 30 Days Late	More Than 30 Days Late	Total Reimbursed
First	48	8.5%	1,232	26	9.5	51.6%	9.8%	38.6%	\$88,758,970
Second	54	9.7%	2,008	37	11	81.8%	16.5%	1.7%	\$144,625,672
Third	56	10.0%	1,792	32	11.5	90.1%	5.1%	4.9%	\$250,565,315
Fourth	47	8.3%	1,629	35	11	20.0%	44.6%	35.5%	\$145,141,051
<b>Total</b>									<b>\$629,091,008</b>

Source: OIG analysis of AMP data from the first through fourth quarters of 2008.

Note: Reimbursement totals and average NDCs were rounded to the nearest whole number. Percentages were rounded to the nearest tenth. Totals may not add to 100 percent because of rounding.

▶ A P P E N D I X ~ C

**Manufacturers With Missing and Late Monthly Average Manufacturer Price Data**

Table C-1: Manufacturers That Failed To Submit Any Monthly AMP Data

Month in 2008	Manufacturers		Corresponding NDCs			
	Number With No AMP Data	Percentage With No AMP Data	Number of NDCs	Average per Manufacturer	Median per Manufacturer	Total Reimbursed
January	21	3.8%	2,721	130	10	\$491,470
February	19	3.5%	464	24	10	\$341,543
March	15	2.7%	409	27	10	\$255,732
April	25	4.6%	854	34	10	\$3,249,378
May	22	4.1%	547	25	9.5	\$2,472,201
June	23	4.2%	545	24	10	\$2,440,754
July	24	4.4%	556	23	10	\$3,932,949
August	26	4.8%	579	22	10.5	\$2,171,715
September	24	4.4%	569	24	10.5	\$2,135,650
October	24	4.4%	336	14	8.5	\$4,677,283
November	26	4.7%	398	15	9	\$4,375,819
December	21	3.8%	384	18	10	\$2,809,279
<b>Total</b>						<b>\$29,353,773</b>

Source: Office of Inspector General (OIG) analysis of average manufacturer price (AMP) data from all 12 months of 2008.  
 Note: Reimbursement totals and average national drug codes (NDC) were rounded to the nearest whole number. Percentages were rounded to the nearest tenth.

Table C-2: Manufacturers That Submitted Late Monthly AMP Data for All of Their NDCs

Month in 2008	Manufacturers		Corresponding NDCs						Total Reimbursed
	Number With Late AMP Data	Percentage With Late AMP Data	Number of NDCs	Average per Manufacturer	Median per Manufacturer	Up to 5 Days Late	Between 6 and 30 Days Late	More Than 30 Days Late	
January	74	13.6%	3,101	42	13.5	73.0%	6.2%	20.8%	\$152,026,066
February	102	18.6%	2,552	25	7.5	73.6%	5.4%	21.0%	\$111,996,285
March	30	5.5%	539	18	9	48.4%	19.7%	31.9%	\$3,817,121
April	42	7.8%	1,188	28	6	29.7%	6.3%	64.0%	\$28,587,091
May	41	7.6%	1,052	26	8	3.9%	35.6%	60.6%	\$24,665,287
June	32	5.9%	1,118	35	9.5	68.6%	17.7%	13.7%	\$24,430,127
July	79	14.5%	2,472	31	9	70.7%	4.1%	25.2%	\$142,456,629
August	40	7.3%	1,438	36	8	34.9%	60.0%	5.1%	\$13,982,617
September	28	5.1%	433	15	10	64.9%	19.9%	15.2%	\$52,592,634
October	83	15.1%	2,334	28	11	61.0%	11.2%	27.8%	\$89,580,991
November	35	6.4%	1,398	40	11	24.3%	42.9%	32.8%	\$14,785,657
December	35	6.3%	1,098	31	8	21.7%	29.7%	48.6%	\$42,879,873
<b>Total</b>									<b>\$701,800,378</b>

Source: OIG analysis of AMP data from all 12 months of 2008.  
 Note: Reimbursement totals and average NDCs were rounded to the nearest whole number. Percentages were rounded to the nearest tenth. Totals may not add to 100 percent because of rounding.

**Agency Comments**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator  
Washington, DC 20201

JUL 07 2010

**DATE:**

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

**FROM:** Marilyn Tavenner */S/*  
Acting Administrator and Chief Operating Officer

**SUBJECT:** Office of Inspector General (OIG) Draft Report: "Timely Submission of Average Manufacturer Price Data" (OEI-03-09-00060)

Thank you for the opportunity to review and comment on the subject OIG draft report. In this report, the OIG sought to determine whether manufacturers submitted 2008 Average Manufacturer Prices (AMPs) to the Centers for Medicare & Medicaid Services (CMS) within the time frames specified by Federal requirements, and whether CMS has taken action against manufacturers that did not submit AMP data within those specified timeframes.

Section 1927 of the Social Security Act (the Act) sets forth price reporting requirements for manufacturers that participate in the Medicaid Drug Rebate Program, including the requirement for manufacturers to report both quarterly and monthly AMPs to CMS. Quarterly AMPs are used to calculate rebate amounts that are owed to the States by the manufacturers, and are also used to establish ceiling prices in the 340B program administered by the Health Resources and Services Administration. Although the use of monthly AMPs to calculate the Federal Upper Limits (FULs) under 42 CFR 447.514 is currently prohibited by a court injunction, the Affordable Care Act revises the methodology of the FULs program, but continues to use manufacturer submitted monthly AMPs to calculate the FUL.

Section 1927 of the Act states that manufactures that fail to provide the required AMP data by the specified deadlines may be subject to civil monetary penalties and/or termination from the Medicaid Drug Rebate Program. The report notes that the authority to issue civil monetary penalties against non-compliant manufacturers has been-delegated to the OIG.

**OIG Findings**

The OIG found that, in 2008, more than half of manufacturers did not fully comply with quarterly submission requirements for AMP data and more than three-fourths of manufacturers did not fully comply with monthly AMP submission requirements.

In addition, the OIG found that CMS took action against some manufacturers for failing to comply with quarterly AMP reporting requirements, but took no action for failing to comply with monthly reporting requirements. In total, 78 manufacturers were referred to the OIG and/or terminated by CMS for failing to comply with quarterly reporting requirements in 2008.

Page 2 – Daniel Levinson

However, although CMS tracks manufacturers that do not comply with monthly reporting requirements, those compliance violations resulted in no OIG referrals or terminations during 2008.

**OIG Recommendations**

- CMS should take action against manufacturers that submit incomplete quarterly AMP data.
- CMS should take action against manufacturers that fail to submit monthly AMP data in a timely manner.

**CMS Response**

We concur with both recommendations. We plan to begin referring manufacturers that submit incomplete AMP data to the OIG for civil monetary penalty consideration. We look forward to working with the OIG to implement this additional referral process, and believe that we will be able to begin providing the OIG with a report of manufacturers with incomplete quarterly and monthly AMP submissions in the near future.

Again, we appreciate the opportunity to review and comment on this draft report.



## 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.

Lauren McNulty served as the team leader for this study. Central office staff who contributed include Natasha Franklin and Rita Wurm.

# *Office of Inspector General*

<http://oig.hhs.gov>

---

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:

## *Office of Audit Services*

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.

## *Office of Evaluation and Inspections*

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

## *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.