

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**UNIT OF MEASURE  
INCONSISTENCIES IN THE  
MEDICAID PRESCRIPTION DRUG  
PROGRAM**



Daniel R. Levinson  
Inspector General

November 2007  
OEI-05-07-00050

# *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 all 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. Specifically, these evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness in departmental programs. To promote impact, the reports also present practical recommendations for improving program operations.

## *Office of Investigations*

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, 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 in OIG's internal operations. OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within HHS. OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.



---

## OBJECTIVE

- (1) To estimate the amount of inappropriate Medicaid rebate claims caused by unit of measure inconsistencies.
- (2) To determine how often States convert their Medicaid utilization data to correct for unit of measure inconsistencies.

---

## BACKGROUND

The Medicaid prescription drug program has two elements: reimbursements and rebates. State Medicaid agencies reimburse retail pharmacies for prescription drugs dispensed to Medicaid beneficiaries. Afterwards, State Medicaid agencies receive statutorily defined rebates from manufacturers for each unit of a drug for which they reimbursed pharmacies.

Although reimbursements and rebates are both elements of Medicaid's prescription drug program, each uses a different unit of measure standard. Medicaid reimbursements are based on the National Council for Prescription Drug Programs' (NCPDP) unit of measure standards. Medicaid rebates are based on the Centers for Medicare & Medicaid Services' (CMS) unit of measure standards.

In general, pharmacies request reimbursement from States based on NCPDP units, while States claim Medicaid rebates from manufacturers using CMS units. Therefore, States must convert utilization data from NCPDP units to CMS units before requesting rebates from manufacturers.

To determine how many drugs reimbursed by State Medicaid agencies have unit of measure inconsistencies, we compared NCPDP and CMS units of measure for drugs reimbursed by State Medicaid agencies during the first two quarters of 2006. To estimate the amount of Medicaid rebates inappropriately claimed, we subtracted the Medicaid rebates that States should have claimed, if they converted all utilization data, from the rebates that States actually claimed. To determine how often States convert their Medicaid utilization data to correct for unit of measure inconsistencies, we determined whether States reported utilization data in CMS units.

---

## FINDINGS

**Unit of measure inconsistencies resulted in an estimated \$11.8 million in inappropriately claimed Medicaid rebates during the first 6 months of 2006.** During the first two quarters of 2006, States inappropriately overclaimed an estimated \$8.1 million and underclaimed an estimated \$3.7 million in Medicaid rebates, for a total of \$11.8 million inappropriately claimed rebates. Inappropriately claimed rebates can lead to incorrect Medicaid rebate payments or disputes with manufacturers.

**Most unit of measure inconsistencies involve the unit type “each.”** Of 213 drugs identified with unit of measure inconsistencies, 193 have the NCPDP or CMS unit type “each.” The NCPDP and CMS have different guidance regarding the unit type “each.” For some product types, CMS guidance is not as specific as NCPDP guidance. For other product types, CMS and NCPDP guidance are in conflict.

**On average, States convert less than half of their utilization data for drugs with unit of measure inconsistencies.** We estimate that, on average, States converted utilization data for 45 percent of drugs with unit of measure inconsistencies. States convert a greater percentage of utilization data for drugs with larger dollar value discrepancies between rebate claims.

**States cannot efficiently detect or correct for unit of measure inconsistencies.** Because NCPDP and CMS package sizes are not always comparable, States cannot efficiently use package size comparisons to identify unit of measure inconsistencies. Additionally, incomplete guidance hinders States’ ability to convert unit of measure inconsistencies. Further, inaccurate reporting of the CMS package size by manufacturers may result in States incorrectly converting for unit of measure inconsistencies.

---

## RECOMMENDATIONS

To reduce the potential for inappropriately claimed Medicaid rebates because of unit of measure inconsistencies, we make the following recommendations:

**CMS should provide more specific guidance to manufacturers regarding the unit type “each.”**

Specifically, CMS could provide more detailed guidance for unit types where its standards are not as specific as NCPDP standards.

Additionally, CMS could provide further clarification for unit types where its standards are in conflict with NCPDP standards. Further, CMS could provide manufacturers with a detailed framework or analytic process to help them determine whether a drug should be an “each” or a different unit type.

**CMS should improve its guidance to States regarding detecting and converting unit of measure inconsistencies.**

Specifically, CMS could advise States about how to appropriately use CMS package size data to identify drugs with unit of measure inconsistencies and how to correctly convert utilization data. CMS could also encourage States to make systems enhancements to better detect and correct for unit of measure inconsistencies. Additionally, CMS could maintain a list of drugs with unit of measure inconsistencies on its Dispute Resolution Program Web site.

---

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

CMS disagreed with both recommendations. CMS does not believe (1) that unit of measure inconsistencies account for significant improper Medicaid rebate payments and (2) that the issue warrants further action beyond its current approach.

We recognize that inappropriate Medicaid rebate claims caused by unit of measure inconsistencies represent less than 1 percent of total rebate claims. However, as our analysis of NCPDP and CMS data shows, unit of measure inconsistencies remain a problem within the Medicaid prescription drug program with an estimated \$11.8 million in inappropriately claimed Medicaid rebates during a 6-month period. Further, the effects of unit of measure inconsistencies may grow as average manufacturer price data are increasingly used for Medicaid reimbursement.

We support the efforts already undertaken by CMS to prevent and correct for unit of measure inconsistencies. CMS has issued guidance to manufacturers and States regarding the issue. However, we maintain that CMS should implement the recommendations to assist manufacturers and States in resolving remaining unit of measure inconsistencies.



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

EXECUTIVE SUMMARY .....	i
INTRODUCTION .....	1
FINDINGS .....	10
States inappropriately claimed \$11.8 million in Medicaid rebates .....	10
Most inconsistencies involve the unit type “each” .....	10
States convert less than half of their utilization data .....	13
States cannot efficiently detect inconsistencies .....	14
RECOMMENDATIONS .....	17
Agency Comments and Office of Inspector General Response ...	18
APPENDIXES .....	22
A: Detailed Methodology .....	22
B: Detailed Examples Regarding Utilization Data Conversion ..	25
C: Agency Comments .....	27
ACKNOWLEDGMENTS .....	30

---

## OBJECTIVES

- (1) To estimate the amount of inappropriate Medicaid rebate claims caused by unit of measure inconsistencies.
- (2) To determine how often States convert their Medicaid utilization data to correct for unit of measure inconsistencies.

---

## BACKGROUND

Medicaid is a jointly funded Federal and State health insurance program for low-income and medically needy persons. Individual States establish eligibility requirements, benefit packages, and payment rates for their Medicaid programs under broad Federal standards administered by the Centers for Medicare & Medicaid Services (CMS). All State Medicaid programs have elected to include prescription drug coverage.

### **Medicaid Prescription Drug Payments**

The Medicaid prescription drug program has two elements: reimbursements and rebates. State Medicaid agencies reimburse retail pharmacies for prescription drugs dispensed to Medicaid beneficiaries. Afterwards, State Medicaid agencies receive statutorily defined rebates from manufacturers for each unit of drug for which they reimburse pharmacies.

*Medicaid Reimbursement.* CMS sets maximum drug reimbursement limits to ensure that the Federal Government acts as a prudent buyer.<sup>1</sup> Within these Federal parameters, each State determines its own pharmacy reimbursement formula.

For certain multiple source drugs with sufficient numbers of equivalent products, CMS sets specific Federal upper limit amounts. As of January 1, 2007, any drug with at least two therapeutically equivalent versions is included in the Federal upper limit list.<sup>2</sup> Additionally, Federal upper limit amounts are now based on 250 percent of the lowest reported average manufacturer price (AMP).<sup>3</sup>

---

<sup>1</sup> "Federal Upper Limits Overview." Available online at <http://www.cms.hhs.gov/FederalUpperLimits/>. Accessed on August 9, 2007.

<sup>2</sup> Section 6001(a)(1)(B) of the Deficit Reduction Act.

<sup>3</sup> Section 6001(a)(2) of the Deficit Reduction Act.

For a drug without a Federal upper limit, State Medicaid reimbursements do not exceed the lower of (1) its estimated acquisition cost (EAC) plus a dispensing fee or (2) the provider's usual and customary charge to the public for the drug.<sup>4</sup> Although CMS does not stipulate a method for calculating the EAC, States typically calculate the EAC based upon either the wholesaler acquisition cost (WAC) plus a markup percentage or average wholesale price (AWP) less a discount percentage. Both the WAC and the AWP are suggested list prices that are not necessarily based on actual sales.

*Medicaid Rebates.* The Omnibus Budget Reconciliation Act of 1990 created the Medicaid drug rebate program, which mandates that for a drug to be eligible for Medicaid reimbursement its manufacturer must enter into rebate agreements with the Secretary of the Department of Health and Human Services and pay quarterly rebates to State Medicaid agencies.<sup>5</sup>

The Medicaid unit rebate amount (URA) is the amount a manufacturer pays a State for each unit of a drug for which the State reimbursed pharmacies. The formula used to calculate the URA depends on whether the drug is a brand name or generic. The URA for brand name drugs is the greater of 15.1 percent of the AMP or the difference between the AMP and the Best Price (BP).<sup>6</sup> For generic drugs, the URA is 11 percent of the AMP. The AMP is the average price paid by wholesalers for products distributed to the retail class of trade. The BP is the lowest price available from the manufacturer to any purchaser (other than those excluded by law).<sup>7</sup>

Every quarter, CMS calculates the URA for each drug using AMP and BP data from manufacturers and provides the URA to State Medicaid agencies. To determine the total rebates due from manufacturers, a State multiplies the URA by the total number of units reimbursed by the State during the quarter. States send utilization data to

---

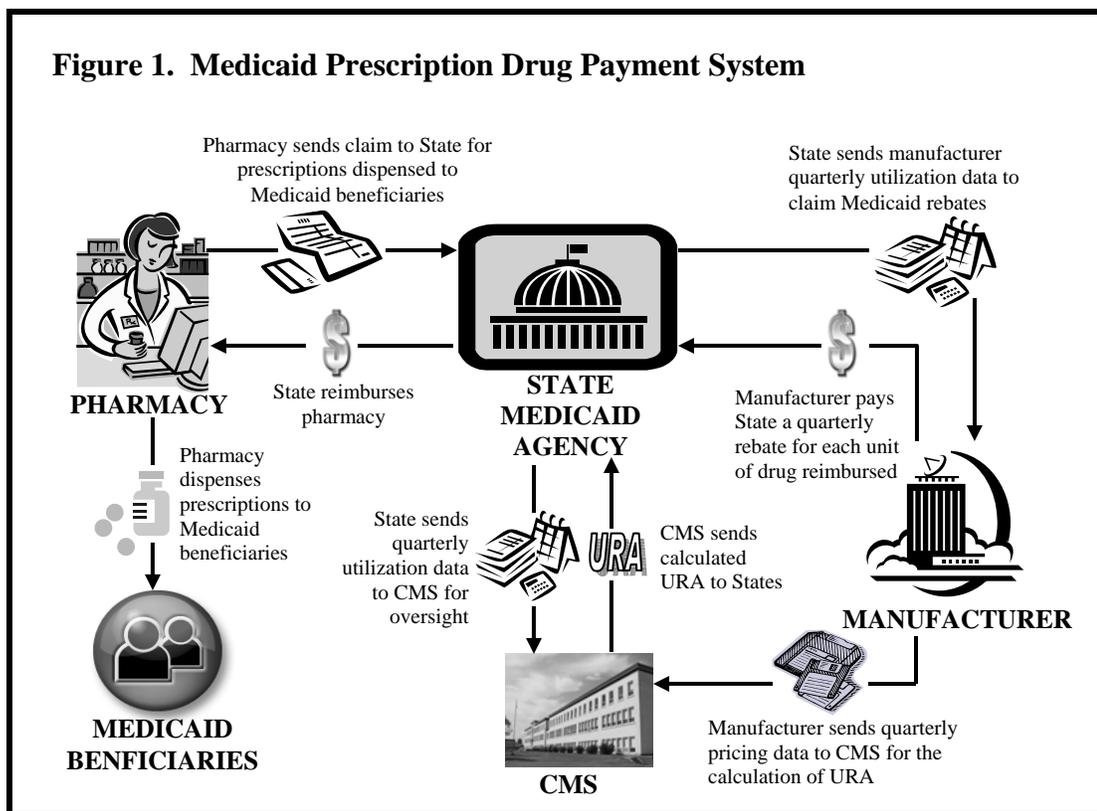
<sup>4</sup> 42 CFR § 447.331(b). On July 17, 2007, CMS issued a final rule (with an effective date of October 1, 2007) that removes 42 CFR § 447.331 but includes the substance of that section in a new section designated as 42 CFR § 447.512. 72 Fed. Reg. 39412, 39154.

<sup>5</sup> § 1927 of the Social Security Act (Act).

<sup>6</sup> This summary is not meant to capture the full complexity of the Federal Medicaid rebate formula for brand name drugs, which includes an additional calculation using an inflation factor.

<sup>7</sup> § 1927(c)(1)(C)(i) of the Act.

manufacturers to claim rebates and to CMS for oversight. Figure 1, below, illustrates the Medicaid prescription drug payment system.



Source: Office of Inspector General, 2007.

If a manufacturer disagrees with a State’s rebate claim, a manufacturer may dispute the rebate claim. A manufacturer may withhold payment for units in dispute. In 1994, CMS established the Dispute Resolution Program to address the problem of unpaid and disputed rebates.<sup>8</sup> As part of the program, CMS provides States and manufacturers with written guidance to prevent the most common disputes.

**Unit of Measure Standards**

How units are defined determines the number of units in a package, or package size. The unit of measure and package size are used together to calculate the per unit reimbursement and per unit rebate amounts used for Medicaid prescription drug payments. Although

<sup>8</sup> CMS, “Background of the Dispute Resolution Program.” Available online at <http://www.cms.hhs.gov/MedicaidDrugRebateDispR/downloads/drpbkgrnd.pdf>. Accessed on July 19, 2007.

reimbursements and rebates are both elements of Medicaid’s prescription drug payment system, each uses a different unit of measure standard.

*Retail Standards.* In 1993, the National Council for Prescription Drug Programs (NCPDP) developed unit of measure standards to facilitate uniform billing units in all retail transactions. According to NCPDP’s “Billing Unit Standards,” there are three possible unit types for which all drugs may be defined: each, milliliter, and gram.<sup>9</sup> Because Medicaid reimburses retail pharmacies for prescription drugs dispensed to beneficiaries, Medicaid bases reimbursements on NCPDP unit of measure standards.

*CMS Standards.* CMS developed unit of measure standards for use in the Medicaid drug rebate program. Because AMP and URA are calculated for the Medicaid drug rebate program, both are defined using CMS unit standards. CMS’s “Medicaid Drug Rebate Operational Guide” lists eight unit types: each, capsule, tablet, suppository, milliliter, antihemophilic, transdermal patch, and gram. In 1993, CMS agreed to align its standards with NCPDP standards when defining unit of measure for the Medicaid drug rebate program, with exceptions for specific packaging and dosage reasons.<sup>10</sup>

*Using Retail and CMS Standards.* Although NCPDP and CMS unit of measure standards serve their unique purposes, if used together, the inconsistencies between the two standards have potential financial implications for Medicaid reimbursements and rebates.

In general, pharmacies request reimbursement from States based on NCPDP units. But for States to claim the appropriate Medicaid rebate, States must use the CMS unit of measure to determine their utilization to report to manufacturers and CMS. For drugs with different unit of measure standards, States must convert their utilization data from NCPDP units to CMS units before requesting rebates from manufacturers. CMS’s “Dispute Resolution Program Best Practices”

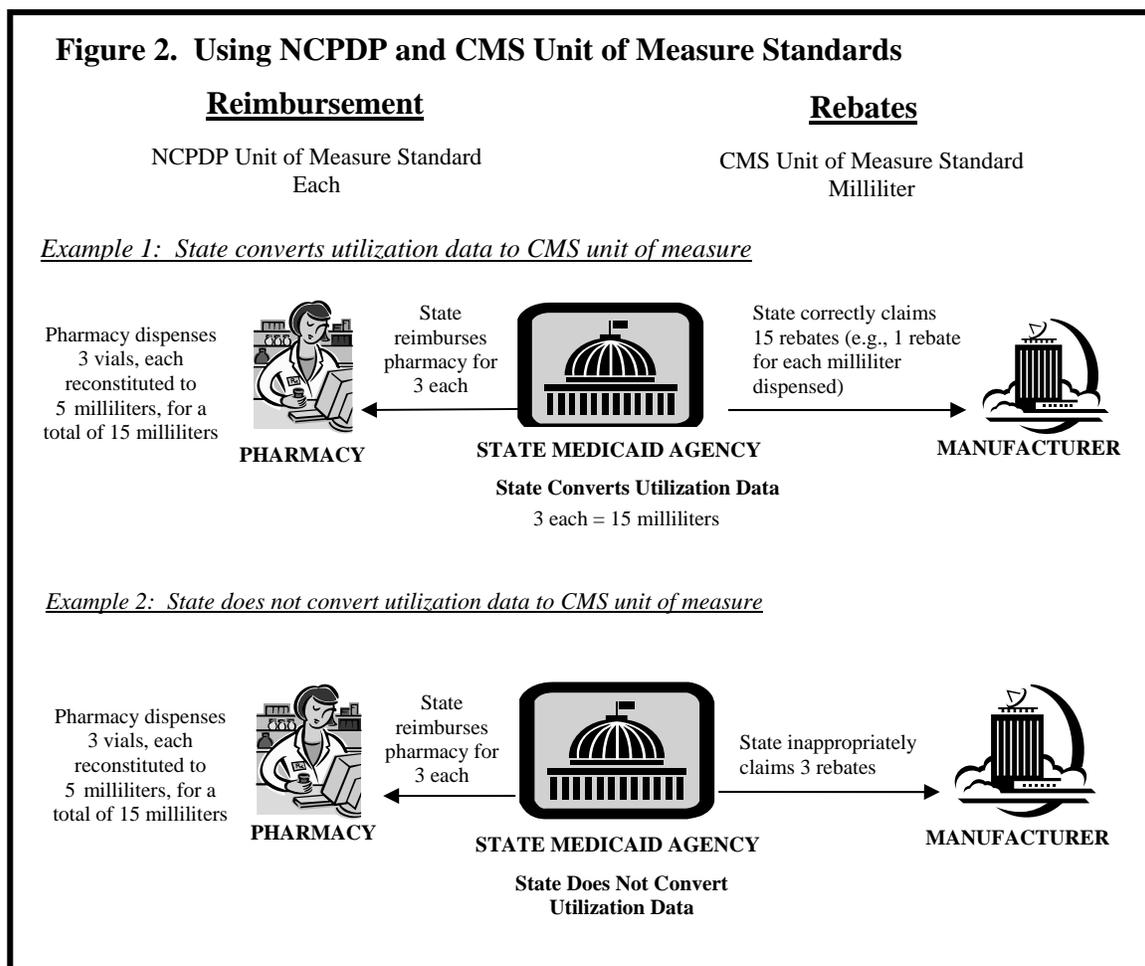
---

<sup>9</sup> National Council for Prescription Drug Programs, “Basic Guide to Standards.” Available online at [http://www.ncdp.org/PDF/Basic\\_guide\\_to\\_standards.pdf](http://www.ncdp.org/PDF/Basic_guide_to_standards.pdf). Accessed on April 26, 2007.

<sup>10</sup> “Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers,” Release Number 8. Available online at [http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03\\_DrugMfrReleases.asp](http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp). Accessed on August 3, 2007.

instructs States to ensure that utilization data are reported to manufacturers and CMS using the CMS unit of measure standard.<sup>11</sup>

Figure 2 provides theoretical examples of a State using NCPDP and CMS unit of measure standards in the Medicaid prescription drug program. In the first example, the State converts its utilization data to claim the appropriate number of Medicaid rebates. In the second example, the State does not convert its utilization data and underclaims Medicaid rebates.



Source: Office of Inspector General, 2007.

<sup>11</sup> "Dispute Resolution Best Practices." Available online at [http://www.cms.hhs.gov/MedicaidDrugRebateDispR/03\\_DRPBestPractices.asp#TopOfPage](http://www.cms.hhs.gov/MedicaidDrugRebateDispR/03_DRPBestPractices.asp#TopOfPage). Accessed on August 2, 2007.

### **Changes to Medicaid Prescription Drug Payments**

Over the last decade, the Office of Inspector General (OIG) has issued a series of reports that highlighted the deficiencies of using AWP and WAC as a basis for Medicaid's reimbursement amounts because of their disconnect from actual sales prices. These findings were presented during testimony before the Senate Committee on Finance.<sup>12</sup> Based in part on this work, the Deficit Reduction Act of 2005 (DRA) made a number of changes in how Medicaid drugs are reimbursed.<sup>13</sup> The DRA made the AMP available to the States. The AMP data provide States with a new source of pricing data for their reimbursement formulas. The DRA also mandated the use of AMP in the reimbursement formula for Federal upper limits.

With changes in Medicaid reimbursement, unit of measure inconsistencies may affect future Medicaid reimbursement. Because AMP uses CMS's unit of measure standards, using AMP to determine appropriate pharmacy payments will require that States convert reimbursement units into the NCPDP standards used in the retail market.

### **Related OIG Work**

In July 2006, OIG issued "Review of 340B Prices" (OEI-05-02-00073). During that review, we found that inconsistent drug pricing data produced incorrect Government ceiling prices. We identified instances in which the unit of measure differed between NCPDP and CMS. OIG recommended that the Health Resources and Services Administration work with CMS to identify drugs for which the unit of measure is captured differently by NCPDP and CMS.

In April 2007, the OIG report "States' Use of New Drug Pricing Data in the Medicaid Program" (OEI-03-06-00490) found that a majority of States surveyed have concerns about the accuracy of AMP data received from CMS. Specifically, five States described inconsistencies between the AMP units reported by CMS and the typical unit definition of the associated drug products. OIG recommended that CMS provide States

---

<sup>12</sup> Testimony of Robert A. Vito, Regional Inspector General IV Evaluations and Inspections, U.S. Department of Health and Human Services, before the Senate Committee on Finance (June 29, 2005). Available at <http://oig.hhs.gov/testimony/docs/2005/50629-vito-fin.pdf>. Accessed on May 23, 2007.

<sup>13</sup> Section 6001(b) of the DRA.

with the unit definition for drug products in AMP files distributed to States.

---

## METHODOLOGY

This study identifies drugs, by National Drug Code (NDC),<sup>14</sup> with inconsistencies between the NCPDP and CMS units of measure during the first and second quarters of 2006. This review only estimates the amount of inappropriate Medicaid rebate claims caused by unit of measure inconsistencies. This review does not determine the amount inappropriately paid because we did not determine the number of rebate claims disputed by manufacturers.

Below we provide an overview of our methodology. For further detail, see Appendix A.

### Data Collection

From CMS's Web site, we obtained Medicaid utilization data to produce a list of drugs reimbursed by State Medicaid agencies during the first half of 2006.<sup>15</sup>

From CMS, we obtained its units of measure and package sizes as well as AMP and URA for the first and second quarter of 2006. Because AMP and URA are calculated for the purpose of the Medicaid drug rebate program, both are provided per CMS unit.

From First DataBank, a third-party provider of drug pricing data, we obtained NCPDP units of measure and package sizes as well as product descriptions and drug pricing data. We obtained pricing data per package and per unit. Because pricing data from First DataBank are used in the retail market, per unit pricing data supplied by First DataBank are provided per NCPDP unit.

Further, to understand the challenges associated with detecting and correcting for unit of measure inconsistencies, we interviewed CMS staff. Additionally, we discussed unit of measure inconsistencies with four State Medicaid drug rebate directors and a fiscal intermediary, which operates Medicaid drug rebate programs for four States. We also

---

<sup>14</sup> An NDC is a three-segment universal product identifier that specifies a drug's manufacturer, product name, and package size.

<sup>15</sup> We included Medicaid utilization data from the District of Columbia. Additionally, we did not include Arizona in our analysis because Arizona does not participate in the Medicaid drug rebate program.

reviewed CMS’s “Medicaid Drug Rebate Operations Manual” and “Best Practices Guide to Dispute Resolution.”

### **Data Analysis**

We conducted our analysis in two stages. First, we compiled a list of all drugs with unit of measure inconsistencies. Second, for these drugs, we determined whether States reported utilization to manufacturers and CMS in the correct unit of measure.

*Determining Drugs With Unit of Measure Inconsistencies.* There were two scenarios that created unit of measure inconsistencies: the unit types did not match (e.g., milliliter versus each) or there were different interpretations of the same unit type.

To identify drugs for which the unit types did not match, we compared the NCPDP unit of measure to the CMS unit of measure. We counted drugs as having a unit of measure inconsistency when the NCPDP and CMS unit types did not match.

To identify drugs with different interpretations of the same unit type, we compared the NCPDP and CMS package sizes for drugs with the same unit type. If a drug was described with the same unit of measure by both NCPDP and CMS, but the package sizes were different, we concluded that this inconsistency was the result of different interpretations of the same unit type.

In cases in which we were unable to determine whether the drug had a unit of measure inconsistency, we were conservative in our analysis and assumed that the drug did not have a unit of measure inconsistency.

*Determining State Conversion of Utilization Data.* Because State utilization data sent to CMS do not contain unit of measure information, we determined whether States used the CMS unit of measure for rebates by comparing the actual per unit reimbursement to an estimated per unit cost in NCPDP units and an estimated per unit cost in CMS units. If the actual per unit reimbursement was closer to the estimate calculated with NCPDP units, we concluded that the State was using NCPDP units to report utilization and did not convert its utilization data. In cases in which we were unable to determine whether the actual unit cost was closer to the NCPDP or CMS per unit cost, we were conservative in our analysis and assumed that the State converted the units.

*Estimating Inappropriate Rebate Claims.* To estimate the amount of Medicaid rebates inappropriately claimed, we subtracted Medicaid rebates that States should have claimed, if they converted all utilization data, from rebates that States actually claimed.

### **Limitations**

We used States' estimated acquisition cost reimbursement formulas to determine per unit reimbursement from the aggregate data. Although State Medicaid reimbursement is typically based on estimated acquisition cost reimbursement formulas, it may also be based on other reimbursement methodologies.

According to CMS staff, States may request manufacturers to convert utilization data to correct for unit of measure inconsistencies. Because manufacturers may make these conversions after receiving rebate invoices from States, they are not reflected in the utilization data reported by States. However, the extent to which drugs are converted by manufacturers is unknown by CMS.

Because of these limitations, we present all of our data as estimates.

For 2,231 drugs, we were unable to determine if the drug had a unit of measure inconsistency because of different NCPDP and CMS definitions of package size. Additionally, for 332 drugs we were unable to determine if the drug had a unit of measure inconsistency because of possible errors in the package size data reported to CMS. In these cases, we were conservative in our analysis and assumed that the drug did not have an inconsistency. As a result, our estimates of inappropriately claimed Medicaid rebates may be low given our conservative methodological approach.

### **Standards**

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

## ► FINDINGS

### **Unit of measure inconsistencies resulted in an estimated \$11.8 million in inappropriately claimed Medicaid rebates during the first 6 months of 2006**

Unit of measure inconsistencies, if not converted, result in States inappropriately claiming Medicaid rebates. During the first two quarters of 2006, States

inappropriately overclaimed an estimated \$8.1 million and underclaimed an estimated \$3.7 million in Medicaid rebates, for a total of \$11.8 million inappropriately claimed rebates.

Overall, the amount of inappropriately claimed rebates because of unit of measure inconsistencies represents less than 1 percent of total rebate claims. However, regardless of the amount, inappropriately claimed Medicaid rebates can lead to incorrect Medicaid rebate payments or disputes with manufacturers.

Interviews with four State Medicaid drug rebate directors suggested that in their States, many rebate claims for drugs with unit of measure inconsistencies are disputed, especially for those inconsistencies that may lead to overclaiming. Overall, disputed claims can take months or years to resolve, tying up valuable resources and delaying rebate payments. Prior OIG work found that 15 States had inadequate dispute resolution and rebate collection processes.<sup>16</sup>

### **Most unit of measure inconsistencies involve the unit type “each”**

We identified 213 drugs with unit of measure inconsistencies during the first two quarters of 2006. Of the 213 drugs,

193 have the CMS or NCPDP unit type “each.” Of those, 112 drugs have the NCPDP unit type “each,” 52 drugs have the CMS unit type “each,” and 29 drugs have both the NCPDP and CMS unit type “each.”

Most drugs have a mismatch between the unit types “each” and milliliter or “each” and gram. A smaller percentage involves different interpretations of the unit type “each.” Table 1, on the next page, provides the number of drugs identified with unit of measure inconsistencies by NCPDP and CMS unit type.

---

<sup>16</sup> “Multistate Review of Medicaid Drug Rebate Programs,” A-06-03-00048. Available online at <http://oig.hhs.gov/oas/reports/region6/60300048.pdf>. Accessed on July 5, 2007.

<b>Table 1. Unit of Measure Inconsistencies by NCPDP and CMS Unit Type</b>			
<b>CMS Unit Type</b>	<b>NCPDP Unit Type</b>		
	<b>Each</b>	<b>Milliliter</b>	<b>Gram</b>
<b>Each</b>	29	47	5
<b>Milliliter</b>	56	8	0
<b>Gram</b>	48	6	6
<b>Suppository</b>	4	0	0
<b>Transdermal Patch</b>	4	0	0

Source: OIG analysis of State Medicaid utilization data, 2007.

Drugs with unit of measure inconsistencies involving the unit type “each” are continually added to the program. Of the 193 drugs that we identified involving the unit type “each,” 87 drugs entered the market between 2000 and 2006, with 25 of these new drugs in 2005 and 2006.

**NCPDP and CMS have different guidance regarding the use of the unit type “each”**

According to NCPDP guidance, there are three unit types: each, milliliter, and gram.<sup>17</sup> The unit type “each” is used for products that are not measured by volume or weight. Examples of products that must be defined as “each” according to NCPDP guidance include tablets, capsules, suppositories, transdermal patches, antihemophilic products, kits, powder-filled vials, and powdered packets. Additionally, packages with a quantity of less than one milliliter or gram should have the unit type “each.” Further, according to NCPDP guidance, liquid-filled vials, ampules, and syringes are not considered an “each” but rather use milliliters.

According to CMS guidance, there are eight unit types including each, milliliter, gram, transdermal patch, suppository, tablet, capsule, and antihemophilic factor.<sup>18</sup> Although CMS has five additional unit types, all five would have the NCPDP unit type “each.” CMS has not issued detailed guidance regarding specific use of the additional unit types.

<sup>17</sup> References to NCPDP guidance cite the NCPDP “Billing Unit Standard Implementation Guide” version 2.0, released in 2004.

<sup>18</sup> “Medicaid Drug Rebate Program Quarterly Pricing Data Definitions,” Medicaid Drug Rebate Operational Guide, page F7e.

## F I N D I N G S

According to CMS, the unit type “each” refers to drugs not identifiable by any other unit type.<sup>19</sup> In March 2006, CMS issued Manufacturer Release No. 73, which provided further guidance on use of the unit type “each.”<sup>20</sup> Within the release, CMS stated that the only product types for which manufacturers should use the unit type “each” include powder-filled vials, ampules, syringes, packets, and kits.

Even with the additional guidance in Manufacturer Release No. 73, differences between NCPDP and CMS guidance on the unit type “each” remain. For some product types, CMS guidance is not as specific as NCPDP guidance. For example, NCPDP guidance provides specific instructions for products supplied as liquid-filled vials (milliliter), while CMS guidance does not. Also, NCPDP guidance provides specific instructions regarding products supplied as a suppository (e.g., each suppository is a unit, not the package, which can contain more than one suppository), while CMS guidance does not provide any clarifying instructions. For other product types, CMS and NCPDP guidance are in conflict. For instance, products described as ampules or syringes have the unit type milliliter according to NCPDP guidance and the unit type “each” according to CMS guidance.<sup>21</sup>

Differences between NCPDP and CMS guidance are the result of different intended uses. NCPDP uses its unit of measure standards for calculating pricing data used in the retail pharmacy industry (i.e., AWP and WAC). These data are provided for each drug by unique package size. On the other hand, CMS uses its unit of measure standards for the calculation of the AMP and the URA for the Medicaid drug rebate program. The AMP and the URA must be weighted to account for all sales regardless of the package size. Thus, CMS calculates the AMP and the URA for each drug unit regardless of package size.

As a result of the required weighting for the AMP and the URA across package sizes, CMS staff advises manufacturers to give careful thought to the use of the unit type “each.”<sup>22</sup> CMS further advises manufacturers not to use the unit type “each” if a manufacturer has multiple package

---

<sup>19</sup> Ibid.

<sup>20</sup> “Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers,” Release Number 73. Available online at [http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03\\_DrugMfrReleases.asp](http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp). Accessed on August 2, 2007.

<sup>21</sup> Ibid.

<sup>22</sup> Ibid.

sizes or may launch a future package size of the drug.<sup>23</sup> In addition, manufacturers are encouraged to contact CMS in instances in which the unit type “each” may seem appropriate even though the drug does not fall into any of the product types CMS has designated as “each.” Despite this advice, CMS states in Manufacturer Release No. 73 that manufacturers continue to inaccurately report drugs as unit type “each.”

**On average, States convert less than half of their utilization data for drugs with unit of measure inconsistencies**

To deal with unit of measure inconsistencies, States must convert utilization data from NCPDP units to CMS units. We estimate that, on

average, States converted utilization data for 45 percent of drugs with unit of measure inconsistencies.

States that reimburse for a greater number of drugs overall do not convert utilization data for drugs with unit of measure inconsistencies at a higher rate. There is no relationship between the number of drugs reimbursed and the percentage of utilization data converted to CMS units by States.

The rates at which States converted their utilization data for drugs that lead to overclaiming and underclaiming were similar. On average, States converted 43 percent of drugs with unit of measure inconsistencies that would have led to overclaiming. States converted 46 percent, on average, of drugs with unit of measure inconsistencies that would have led to underclaiming.

**States convert a greater percentage of utilization data for drugs with larger dollar value discrepancies between rebate claims**

The larger the dollar value between rebate claims based on NCPDP units and rebate claims based on CMS units, the more often States convert utilization data for that drug. On average, States convert 18 percentage points more of the utilization data when the discrepancy is greater than \$100 per drug compared to when the discrepancy is less than \$10.

---

<sup>23</sup> Ibid.

F I N D I N G S

Table 2 provides the percentage of utilization data converted by the dollar value of the discrepancy.

<b>Table 2. Percentage of Utilization Data Conversions by the Dollar Value of the Discrepancy</b>		
<b>Dollar Value of the Discrepancy</b>	<b>Number of Drugs</b>	<b>Average Percentage of Utilization Data Converted to CMS Units</b>
Less than \$10	121	39%
\$10 - \$50	29	53%
\$50 - \$100	21	50%
Over \$100	42	57%
<b>Total</b>	<b>213</b>	<b>45%</b>

Source: OIG analysis of State Medicaid utilization data, 2007.

States may convert a greater percentage of utilization data for drugs with larger dollar value discrepancies because the unit of measure inconsistencies are easier to identify for more expensive drugs. According to the four State Medicaid drug rebate program directors we interviewed, one method for detecting unit of measure inconsistencies is to compare reimbursement amounts to rebate amounts. If a State claimed a rebate amount greater than total reimbursements or if the rebate amount is particularly small compared to total reimbursements, a State may suspect a unit of measure inconsistency. Because these comparisons are in the aggregate, identifying a unit of measure inconsistency is more difficult when the dollar difference would be relatively small.

**States cannot efficiently detect or correct for unit of measure inconsistencies**

CMS package size data are necessary to efficiently identify drugs with unit of measure

inconsistencies and to appropriately convert utilization data to CMS units. However, States have not received complete guidance regarding how to efficiently use CMS package size data to identify and convert unit of measure inconsistencies. Further, not all manufacturers correctly report the CMS package size to CMS.

The State Medicaid drug rebate program directors we interviewed suggested that because of problems with package size data, they must manually identify and correct for drugs with unit of measure inconsistencies. This requires them to engage in conversations with manufacturers and review product prescribing information. Manually

identifying drugs with unit of measure inconsistencies is an inefficient method given that, on average, States reimburse pharmacists for over 10,000 different drugs per quarter.

**Different interpretations of package size hinder States' ability to identify unit of measure inconsistencies**

Because NCPDP and CMS package sizes are not always comparable, States cannot efficiently use package size comparisons to identify unit of measure inconsistencies. Typically, unit of measure inconsistencies can be identified by comparing NCPDP and CMS unit type and NCPDP and CMS package size. However, identifying unit of measure inconsistencies by comparing NCPDP and CMS package sizes is difficult because NCPDP and CMS define package size differently. NCPDP package size data are defined as the number of units in the drug's package.<sup>24</sup> CMS package size data are defined as the number of units within the smallest dispensable amount.<sup>25</sup>

Because of different NCPDP and CMS interpretations of package size, we identified 2,231 drugs for which a package size comparison could not determine whether there was a unit of measure inconsistency. For these drugs, determining whether there is a unit of measure inconsistency is a labor intensive process requiring an indepth look into how each drug is packaged and dispensed.

**Incomplete guidance hinders States' ability to convert unit of measure inconsistencies**

CMS guidance on how to convert utilization data from NCPDP units to CMS units once a unit of measure inconsistency is detected does not account for all conversions. CMS guidance instructs States to claim rebates using the CMS unit of measure, reminding States to multiply the number of scripts by the CMS package size to determine total utilization.<sup>26</sup> However, this simple multiplication does not work in all circumstances. There are instances in which simple multiplication will result in an incorrect conversion. See Appendix C for detailed examples in which simple multiplication would result in incorrect conversions. In

---

<sup>24</sup> Definition of package size, National Drug Data File, First Bank.

<sup>25</sup> "Medicaid Drug Rebate Program Quarterly Pricing Data Definitions," Medicaid Drug Rebate Operational Guide, page F7e.

<sup>26</sup> "Medicaid Drug Rebate Program Letter to State Medicaid Directors," Release Number 61. Available online at [http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02\\_StateReleases.asp](http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02_StateReleases.asp). Accessed on August 2, 2007.

## F I N D I N G S

these cases, States would need to divide or use a conversion factor rather than multiplying.

### **Inaccurate reporting of the CMS package size by manufacturers may result in States incorrectly converting for unit of measure inconsistencies**

When package size is reported incorrectly, it can result in an apparent discrepancy between NCPDP and CMS package sizes when no actual discrepancy exists. Converting utilization data when there is not a real unit of measure inconsistency may cause incorrect Medicaid rebate claims and can delay rebate payments. Conversely, States may not convert utilization data for drugs that do have unit of measure inconsistencies because package sizes are reported as the same but are in fact different.

For example, the package size for one drug supplied as a powder to be reconstituted for injection was inaccurately reported to CMS. The drug is supplied as 20 milligrams in a single dose vial and is then reconstituted to 1 milliliter. The manufacturer reported the CMS unit type as milliliter but incorrectly reported package size as 20 to CMS. The correct CMS package size would be 1, for the 1 milliliter. In this case, the manufacturer reported the number of milligrams in the vial, not the number of milliliters.

We identified 332 drugs for which we were unable to determine whether there was a unit of measure inconsistency because of possible errors in the CMS package size reported by manufacturers.



---

We found that during the first two quarters of 2006, States inappropriately overclaimed an estimated \$8.1 million and underclaimed an estimated \$3.7 million in Medicaid rebates, for a total of \$11.8 million inappropriately claimed rebates.

Inappropriately claimed Medicaid rebates can lead to incorrect rebate payments or disputes with manufacturers. In addition, unit of measure inconsistencies have implications for future Medicaid reimbursement. With DRA's changes, CMS is using the AMP to calculate Federal upper limits and States may begin using the AMP to set pharmacy reimbursement in the future. Unit of measure inconsistencies may lead to errors in calculating reimbursement amounts based on the AMP.

Through a variety of actions, such as issuing written guidance for States, State Medicaid director letters, letters to manufacturers, and its Dispute Resolution Program, CMS has made important strides in improving the accuracy of rebate claims and reducing the number of disputes. However, unit of measure inconsistencies continue to affect the Medicaid prescription drug program. To reduce the potential for inappropriately claimed Medicaid rebates because of unit of measure inconsistencies, we recommend the following:

**CMS should provide more specific guidance to manufacturers regarding the unit type "each"**

Because most unit of measure inconsistencies involve the unit type "each," CMS should provide more specific guidance to manufacturers regarding the use of the unit type "each." Specifically, CMS could:

- Provide more detailed guidance for unit types where its standards are not as specific as NCPDP standards. For example, CMS could provide more detailed guidance for products described as a suppository.
- Provide further clarification for unit types where its standards are in conflict with NCPDP standards. For example, CMS could provide more detailed guidance for products described as ampules or syringes.
- Provide manufacturers with a detailed framework or analytic process to help them determine whether a drug should be an "each" or a different unit type. Because manufacturers are in the unique position to identify or

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

prevent unit of measure inconsistencies before they occur, manufacturers should carefully consider when a drug should have the unit type “each.”

As CMS staff advise, it is important that manufacturers choose the appropriate unit type from the beginning. As the number of drugs with complex drug packaging and marketing increases, CMS should continue to work with manufacturers to prevent future unit of measure inconsistencies.

### **CMS should improve its guidance to States regarding detecting and converting for unit of measure inconsistencies**

With States converting the utilization data for less than half of drugs with unit of measure inconsistencies, CMS should improve its guidance to States regarding unit of measure inconsistencies. More specifically, CMS could:

- Advise States about how to appropriately use CMS package size data to identify drugs with unit of measure inconsistencies.
- Advise States how to correctly convert utilization data. In particular, CMS could advise States about how to convert utilization data when they must be divided by the NCPDP package size or when a conversion factor must be used.
- Encourage States to make systems enhancements to better detect and correct for unit of measure inconsistencies.
- Maintain a list of drugs with unit of measure inconsistencies on its Dispute Resolution Program Web site. Updated periodically, the list could contain drugs identified by States, manufacturers, and CMS. Further, the list could contain the correct conversion factor to assist States when making conversions to utilization data. Beyond assisting States in claiming the correct rebates, the list could facilitate the use of the appropriate unit of measure with AMP data for reimbursement.

---

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

CMS disagreed with both recommendations. CMS does not believe (1) that unit of measure inconsistencies account for significant improper

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

Medicaid rebate payments and (2) that the issue warrants further action beyond its current approach.

We recognize that inappropriate Medicaid rebate claims caused by unit of measure inconsistencies represent less than 1 percent of total rebate claims. However, as our analysis of NCPDP and CMS data shows, unit of measure inconsistencies remain a problem within the Medicaid prescription drug program with an estimated \$11.8 million in inappropriately claimed Medicaid rebates during a 6-month period. Further, the effects of unit of measure inconsistencies may grow as AMP data are increasingly used for Medicaid reimbursement.

We support the efforts already undertaken by CMS to prevent and correct for unit of measure inconsistencies. CMS has issued guidance to manufacturers and States regarding the issue. However, we maintain that CMS should implement the recommendations to assist manufacturers and States in resolving remaining unit of measure inconsistencies.

A detailed discussion of CMS's specific comments is presented below. The full text of CMS's comments is presented in Appendix C.

### **Detailed Discussion of CMS's Comments**

Guidance to manufacturers. CMS disagreed with the recommendation that it should provide more specific guidance to manufacturers regarding the unit type "each." CMS stated that it has already provided guidance regarding the unit type "each" in Manufacturer Release No. 73, issued March 2006, and that changes resulting from this guidance were implemented subsequent to the time period we reviewed. We found that even with the additional release, differences between NCPDP and CMS guidance remain. We examined the unit types listed on CMS's Web site for the second quarter of 2007 for the drugs identified with unit of measure inconsistencies to determine whether the inconsistencies were resolved with the issuance of Manufacturer Release No. 73. Of the 163 drugs for which we could compare unit types, 158 had the same unit type in the second quarter of 2007 as used in the analysis presented in this report. We conclude that the unit of measure inconsistencies we identified in this report remain.

CMS also stated that it did not believe that broad guidance could resolve unit of measure issues that differ on a case-by-case basis. We agree that broad guidance may not be as useful as more specific guidance, similar to that provided in Manufacturer Release No. 73. As

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

such, we continue to recommend that CMS provide manufacturers more specific guidance regarding the unit type “each.”

CMS also stated that because packaging differs from one drug to the next, it is virtually impossible for CMS to develop a framework or process that would effectively apply to all products. We appreciate the complexity involved with selecting a CMS unit type. However, a framework could be useful to ensure that manufacturers ask themselves the correct questions before choosing a unit type appropriate for the Medicaid rebate program. The framework could be a modified version of the decision tree used by industry when selecting an NCPDP unit type. In addition, for unique products, the decision tree could lead manufacturers to request more case-specific guidance from CMS.

Guidance to States. CMS disagreed with the recommendation that CMS advise States about how they could appropriately use CMS package size data to identify drugs with unit of measure inconsistencies and how to correctly convert these data. Additionally, CMS stated that it has issued guidance to States on an individual basis and on specific drugs that have widespread and significant financial impact on States. We support CMS’s past efforts to provide States with guidance on unit of measure inconsistencies. However, as noted in the report, drugs with unit of measure inconsistencies resulting in smaller financial differences in rebates are less likely to be converted by States. As such, issuing guidance only for drugs that have significant financial impact on States could leave other unit of measure inconsistencies unresolved. In addition, we encourage CMS to be proactive in its guidance to alleviate problems before they cause a significant impact.

CMS also disagreed with the suggestion that it could maintain a master list of drugs with unit of measure inconsistencies on the Dispute Resolution Program Web site. CMS indicated that it alone cannot identify the drugs that have such issues and cannot offer a conversion solution that would apply to all States. We agree that CMS could not alone identify the drugs that have unit of measure issues. Instead, the drugs could be identified by manufacturers and States.

The master list could be a formal process by which manufacturers communicate with States regarding unit of measure inconsistencies. This would provide all States with information about unit of measure inconsistencies identified by other States, manufacturers, or CMS. In the report, we noted how difficult it is to use CMS data to identify and correct for drugs with unit of measure inconsistencies. Further, the list

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

would also be a resource for States opting to use the AMP as part of their reimbursement formulas, enabling them to avoid unit of measure inconsistencies that would lead to inappropriate pharmacy reimbursement.

---

## DETAILED METHODOLOGY

### Data Analysis

*Determining Drugs With Unit of Measure Inconsistencies.* From the list of 28,091 drugs reimbursed by Medicaid during the first two quarters of 2006, we eliminated 1,766 drugs that did not have the National Council of Prescription Drug Program (NCPDP) and/or the Centers for Medicare & Medicaid Services (CMS) unit type.

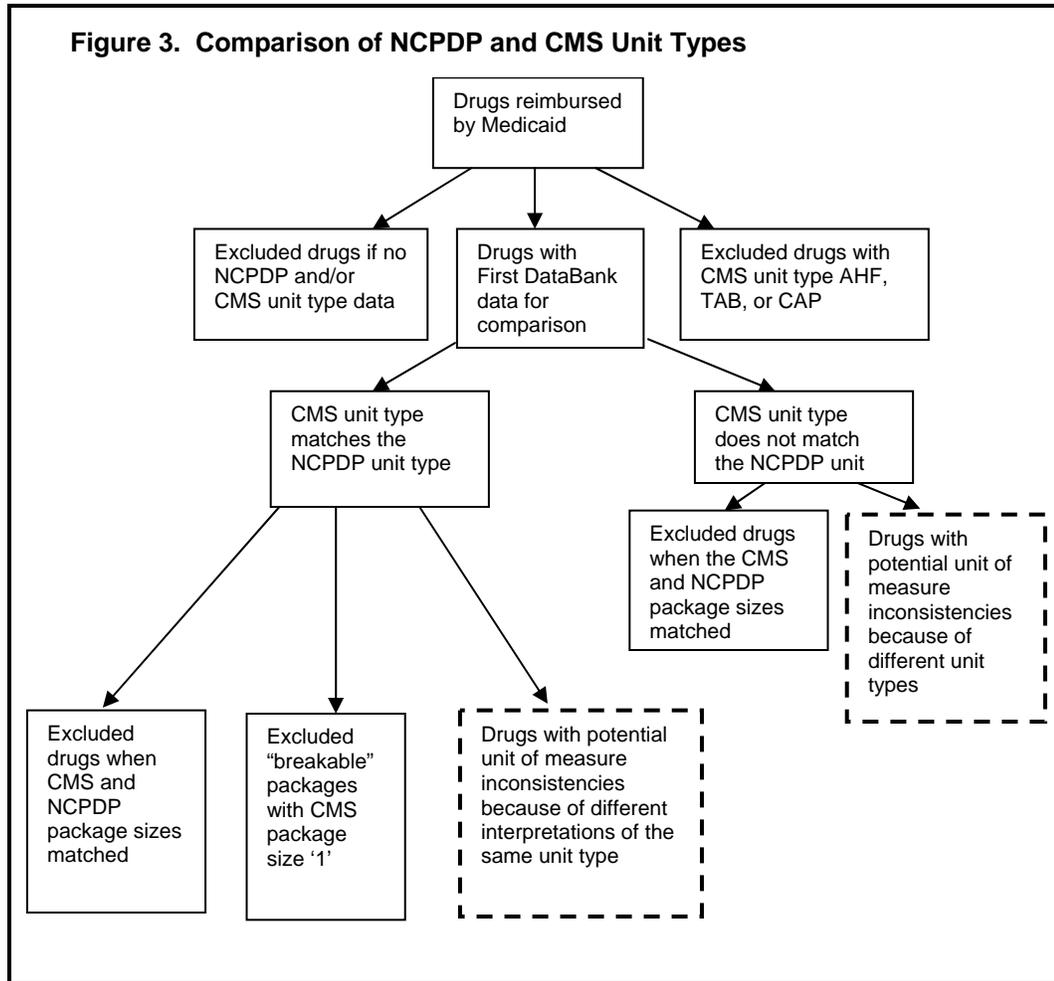
Additionally, we eliminated drugs with a CMS unit type of antihemophilic factor (AHF), tablet (TAB), or capsule (CAP). Because AHF products are made from human plasma and each vial contains a unique amount of product, AHF products are unlikely to have unit of measure inconsistencies. We eliminated TAB and CAP drugs because they did not have unit of measure inconsistencies according to our analysis. Additionally, our interviews with State Medicaid directors indicated that TAB and CAP drugs do not typically have unit of measure inconsistencies. We excluded 17 drugs with a CMS unit type of AHF and 15,397 drugs with a CMS unit type of TAB or CAP.

From the remaining drugs with unit type data for comparison, we divided drugs into two groups: drugs for which the CMS and NCPDP unit type match and drugs for which the CMS and NCPDP unit type do not match.

From the list of drugs for which the CMS and NCPDP unit type match, we eliminated 7,361 drugs for which the package sizes were also the same. In these cases in which the unit type and package size are identical, there are no unit of measure inconsistencies. In addition, we eliminated 2,231 drugs for which the CMS and NCPDP package sizes could not be compared because of different NCPDP and CMS definitions of package size.

From the list of drugs for which the CMS and NCPDP unit types did not match, we eliminated 207 drugs for which the CMS and NCPDP package sizes were the same because these inconsistencies would not have a financial impact on the Medicaid prescription drug program. Unit of measure inconsistencies have a financial impact on the Medicaid drug rebate program if the unit of measure inconsistency leads to inappropriate Medicaid rebate claims. If the NCPDP and CMS package sizes are the same, then regardless of which unit of measure is used, the number of units claimed would be the same.

Figure 3 below, illustrates the process used to identify drugs with unit of measure inconsistencies.



Source: Office of Inspector General, 2007

*Determining State Conversion of Utilization Data.* To determine whether States used the correct unit of measure for rebates, we compared the actual per unit reimbursement to an estimated per unit cost in CMS units and an estimated per unit cost in NCPDP units.

When calculating actual per unit reimbursement, we subtracted dispensing fees paid from the dollars reimbursed reported in the Medicaid utilization data. We obtained State Medicaid prescription drug dispensing fees from CMS’s Web site.

To estimate the per unit cost in CMS units, we divided the average wholesale price (AWP) per drug package by the CMS package size. To estimate the per unit cost in NCPDP units, we used the per unit AWP

from First DataBank. Because the per unit AWP is used in retail transactions, it is based on NCPDP standards.

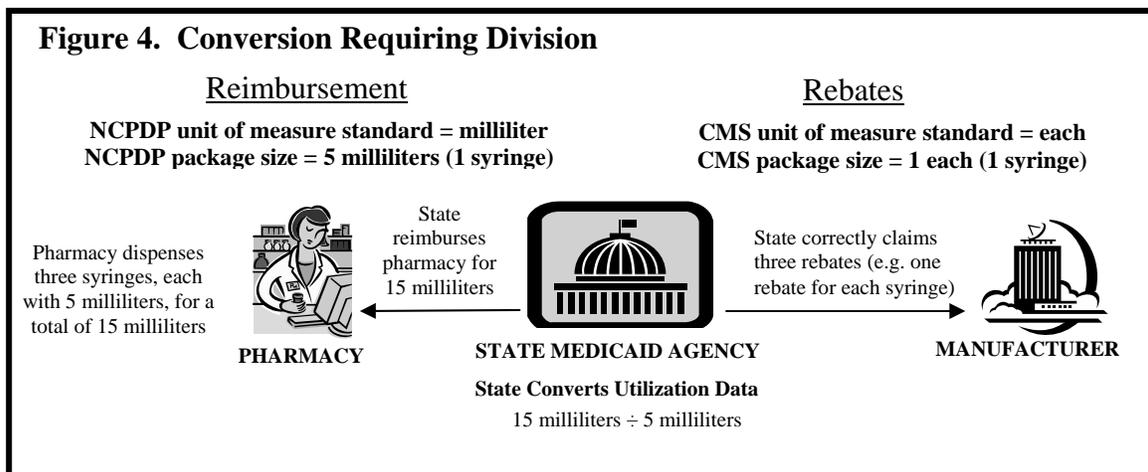
Additionally, to make the actual per unit cost and the estimated per unit costs comparable, we subtracted each State's reimbursement formula discount from the estimated per unit costs. The total reimbursement figures reported in the utilization data reflect the discounts associated with each State's estimated acquisition formula. Therefore, the actual per unit reimbursement also reflects this discount. For example, if a State reimburses pharmacies at the AWP minus 15 percent, then the State's actual per unit cost would be approximately 15 percent below the AWP. In this example, we would have subtracted 15 percent from the estimated per unit costs for this State to make the items comparable. We obtained each State's reimbursement formula from CMS's Web site.

## DETAILED EXAMPLES REGARDING UTILIZATION DATA CONVERSION

CMS guidance does not advise States how to convert utilization data from NCPDP units into CMS units. CMS guidance only instructs States to multiply the number of packages dispensed by CMS package size.<sup>27</sup> In some cases, this simple multiplication does not apply.

### Example 1: The NCPDP package size equals the number of milliliters or grams and the CMS package size equals “1”

The process of converting utilization data to CMS units may not be straightforward when the NCPDP package size equals the number of milliliters or grams and the CMS package size equals “1,” representing an “each.” In this situation, to correctly convert utilization data to CMS units, States must divide their utilization data by the NCPDP package size. We identified 53 drugs with unit of measure inconsistencies for which States would have to divide utilization data by the NCPDP package size to correctly convert utilization data to CMS units. Figure 4 provides a theoretical example of this type of conversion.

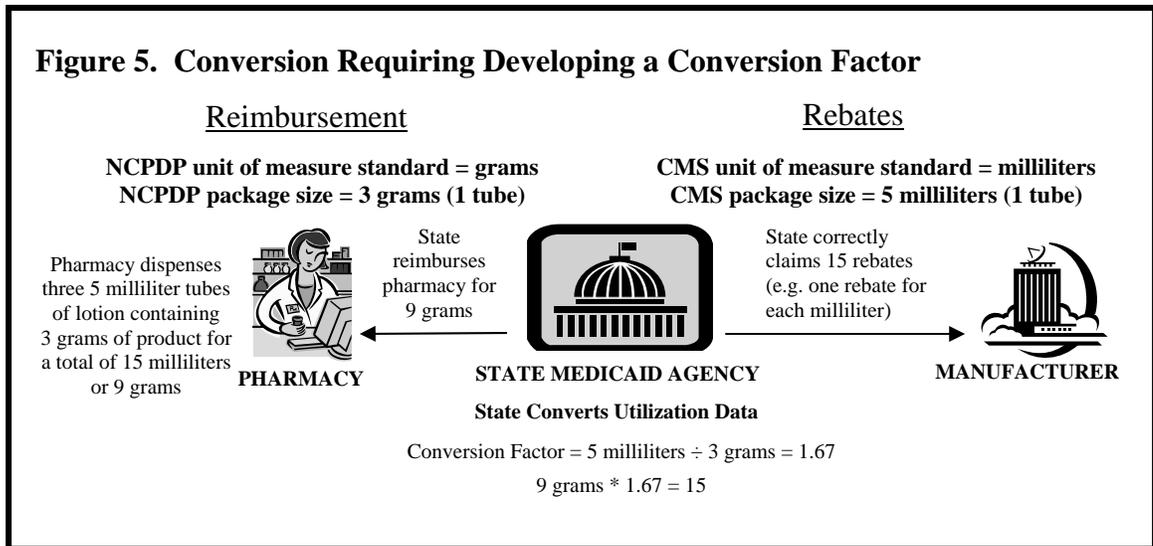


Source: Office of Inspector General, 2007.

<sup>27</sup> "Medicaid Drug Rebate Program Letter to State Medicaid Directors," Release Number 61. Available online at [http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02\\_StateReleases.asp](http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02_StateReleases.asp). Accessed on August 2, 2007.

**Example 2: NCPDP and CMS package sizes equal the number of units but use different units of measure**

Converting utilization data by simply multiplying the number of NCPDP units by the CMS package size would be inappropriate when both the CMS and NCPDP package size represent the number of units but use a different standard. To appropriately convert utilization data to CMS units for these drugs, States must create a conversion factor by dividing the CMS package size by the NCPDP package size. Utilization data must be multiplied by the conversion factor to correctly convert NCPDP units into CMS units. We identified 35 drugs with unit of measure inconsistencies for which States would have to use a conversion factor to appropriately convert utilization data to CMS units. Figure 5 provides a theoretical example of utilization data conversions when States must develop a conversion factor to appropriately convert utilization data.



Source: Office of Inspector General, 2007.

▶ A P P E N D I X ~ C

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW  
Washington, DC 20201

**DATE:** SEP 26 2007

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

**FROM:** Kerry Weems *Kerry Weems*  
Acting Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: "Unit of Measure  
Inconsistencies in the Medicaid Prescription Drug Program,"  
(OEI-05-07-00050)

Thank you for the opportunity to review and comment on the subject OIG Report. The purpose of this report was--(1) to estimate the amount of inappropriate Medicaid rebate claims caused by unit of measure inconsistencies; and (2) to determine how often States convert their Medicaid utilization data to correct for unit of measure inconsistencies.

In response to the individualized characteristics of each National Drug Code (NDC), the Centers for Medicaid and Medicare Services (CMS) issues specific guidance to manufacturers and States on unit of measure conversion issues. When appropriate, CMS issues guidance in program releases to States on certain highly utilized and expensive drugs where unit of measure problems have been discovered. CMS extends the opportunity to manufacturers to put information in regard to their NDCs on the Dispute Resolution Program's (DRP) Web site. Finally, CMS discusses unit of measure issues at DRP meetings and Medicaid Drug Rebate conferences, consistently advising manufacturers of the importance of communicating conversion information on problematic unit of measure NDCs, and reminding States to avail themselves of Federal matching funds for systems enhancements that would help them better detect and convert unit of measure problems.

After reviewing this report, CMS has the following comments in response to the report's recommendations:

**OIG Recommendation**

The CMS should provide more specific guidance to manufacturers regarding the unit type "each."

Page 2- Daniel R. Levinson

**CMS Response**

The CMS agrees that individualized guidance to manufacturers regarding unit of measure issues, including those regarding the unit type “each”, should continue to be provided. However, the OIG’s report suggests that CMS issue broad guidance, implying that such broad guidance could resolve issues that differ on a case-by-case basis. We do not agree with the suggestion that CMS can issue useful guidance that would apply to all unit of measure scenarios. We further do not agree with the OIG opinion that CMS could offer guidance as specific to its unit types as the National Council of Prescription Drug Programs (NCPDP) can offer in relation to their unit types. Given the structure of the rebate program, CMS issues unit guidance at the broad product level, while NCPDP unit standards apply at the specific package level. Therefore, NCPDP is able to be more specific with its reimbursement guidance than CMS can be in regard to rebate standards, as those standards must apply to all package sizes of a product.

In Release 73, CMS issued guidance on the unit type “each.” The OIG’s report seems to indicate that problems remain despite this guidance; however, this release was issued in March 2006, and the OIG studied data from the first two quarters of 2006. Thus, the OIG’s report should not imply that this guidance was not effective, as changes resulting from the guidance may have been fully implemented subsequent to this study’s findings.

Finally, in response to the OIG’s recommendation that CMS could provide manufacturers with a detailed framework or analytical process that would resolve unit of measure discrepancies, CMS disagrees. The Food and Drug Administration approves drugs and their packaging differently from one NDC to the next, making it virtually impossible for CMS to develop a framework or process that would effectively apply to all products. As a result, CMS continues to issue broad guidance regarding unit of measure discrepancies to all manufacturers and States, where appropriate, and more specific guidance on a case-by-case basis.

**OIG Recommendation**

The CMS should improve its guidance to States regarding detecting and converting unit of measure inconsistencies.

**CMS Response**

The OIG recommends that CMS advise States about how they could appropriately use CMS package size data to identify drugs with unit of measure inconsistencies, and how to correctly convert this data. CMS disagrees. This suggestion concerning the rebate data’s ability to be used as a conversion table oversimplifies the issue of unit of measure conversions. CMS has issued guidance to States on an individual basis and issued releases on certain unit of measure problems on specific drugs that have widespread and significant financial impact on States. We concur that such specific guidance may again

Page 3- Daniel R. Levinson

be necessary in the future should a similar widespread need arise.

The CMS informed the OIG during the course of this study that we encourage States to seek Federal matching funds for systems enhancements related to unit of measure issues. Therefore, we agree with the OIG that, as we have done in the past and continue to do, we will remind States to avail themselves of this option.

Finally, we do not agree that CMS can maintain a master list of drugs with unit of measure problems on the DRP Web site because CMS alone cannot identify the drugs that have such issues and cannot offer a conversion solution that would apply to all States based on each State's individualized guidance to its pharmacy providers. However, we agree that the DRP Web site and meetings have been, and will continue to be useful resources to manufacturers that want to have an additional way to communicate information about their drug's specific unit of measure issue to the States.

#### **General Comments**

Overall, the OIG's report oversimplifies the complexities inherent to the issue of unit of measure as applied to the rebate program. CMS implemented a rebate invoicing and payment process that addresses these complexities. The report stops short of measuring the financial impact of unit of measure problems; however, it does acknowledge that these errors account for less than 1 percent of total rebates billed. The ability of States and manufacturers to adjust and dispute rebate invoices so that unit of measure issues could be addressed is not fully acknowledged by the OIG.

The CMS does not believe that unit of measure issues account for significant improper rebate payments, and the report does not refute this assertion. Rather, it stops at the rebate invoicing, and does not contemplate the rebate payment steps of the billing process. Further, the OIG spoke with four State Medicaid Directors during the course of this study and used the result of that small sample as the basis for the report's findings. CMS met with 15 States at the fall DRP meetings, and discussed the unit of measure issue with the State representatives who are directly responsible for unit of measure conversions, rebate invoicing, and dispute resolution. All States concurred that unit of measure errors are not widespread, result in little financial impact, and are easy for the States to detect and correct through the invoice adjustment and dispute resolution processes.

The CMS believes that the appropriate guidance has been issued to States and manufacturers on unit of measure issues. We look forward to continuing to work with our State and manufacturer partners to ensure that future unit of measure discrepancies are resolved as efficiently as possible.



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

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Thomas Komaniecki, Deputy Regional Inspector General.

This study was led by Suzanne Bailey. Other principal Office of Evaluation and Inspections staff from the Chicago regional office who contributed include Melissa Hafner and Mollie Hertel; central office staff who contributed include Cynthia Thomas and David Graf.