

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**STATES' COLLECTION OF  
MEDICAID REBATES FOR  
PHYSICIAN-ADMINISTERED  
DRUGS**



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Inspector General

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## OBJECTIVES

1. To determine the number of States that met Federal requirements for the collection of rebates for certain physician-administered drugs by June 30, 2009.
2. To estimate the dollar amount of rebates that States requested and collected from manufacturers for all physician-administered drugs in the first and second quarters of 2009.
3. To identify issues that prevented States from collecting rebates for all physician-administered drugs that were requested from and/or owed by manufacturers in the first and second quarters of 2009.

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## BACKGROUND

In general, drug manufacturers are required to pay rebates to States for drugs covered under their Medicaid programs. However, a prior Office of Inspector General report found that only 17 States collected rebates from manufacturers for physician-administered drugs in 2001. At that time, many States did not have a system to determine the manufacturer responsible for paying the rebate for these drugs and therefore did not collect the rebates owed. Subsequently, the Deficit Reduction Act of 2005 (DRA), P.L. 109-171, specifically required that States collect rebates on all claims for certain physician-administered drugs for Federal matching funds to be available to the States. To assist in meeting this requirement, the DRA also mandated that claims for certain physician-administered drugs include national drug codes (NDC), a type of drug code that identifies a drug's manufacturer, thereby enabling States to invoice manufacturers responsible for paying rebates. Since the passage of the DRA, the Centers for Medicare & Medicaid Services (CMS) has taken numerous steps aimed at ensuring that States meet the new rebate requirements for physician-administered drugs.

To each of the 50 States participating in the Medicaid drug rebate program, we sent a request for first- and second-quarter 2009 reimbursement and rebate data on physician-administered drugs. We also requested that each State complete a survey about the State's policies, procedures, and controls used to process physician-administered drug rebates. Forty-eight States responded to the data request and 49 States completed the survey. Using data and survey responses, we determined the extent of DRA compliance among the

States and identified common issues preventing States from collecting all the rebates for physician-administered drugs that manufacturers owe. We also calculated the dollar amount States paid and the amount of rebates States requested and collected for physician-administered drugs in the first and second quarters of 2009.

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## FINDINGS

**By June 2009, 73 percent of responding States reported meeting or exceeding the DRA's requirement to collect rebates for certain physician-administered drugs.** As of June 30, 2009, 36 of 49 responding States reported collecting rebates on all single-source, physician-administered drugs and the 20 multiple-source, physician-administered drugs with the highest dollar volume, as required by the DRA. An additional 12 States reported collecting rebates on a subset of physician-administered drugs, but were not in full compliance with the DRA's rebate requirements. Only one State reported that it did not collect rebates on any physician-administered drugs.

Additionally, as of June 2009, 42 of 49 responding States (86 percent) reported meeting the DRA's requirement to collect NDCs on claims for certain physician-administered drugs. States may have collected NDCs for physician-administered drugs and still not have met the DRA's rebate collection requirements.

**We could not determine the financial impact of collecting rebates for physician-administered drugs because of incomplete and potentially inaccurate data provided by States.** For the first and second quarters of 2009, the 26 States that provided complete rebate data reported recouping between 3 and 96 percent of the amount paid for physician-administered drugs by collecting rebates. States also varied widely in the amount they reported spending on physician-administered drugs and the percentage of rebates they reported requesting. Although some variation among States' rebate figures would be expected, this degree of variation calls into question the reliability and accuracy of the data provided. For these reasons, we were unable to calculate the total rebate dollars all States collected and therefore could not determine the financial impact rebate collections had on reducing prescription drug expenditures.

The 26 States that provided complete data reported paying \$577 million for physician-administered drugs, requesting \$148 million in rebates,

and collecting \$112 million in rebates during the first and second quarters of 2009. An additional 19 States, which reported paying approximately \$355 million for physician-administered drugs in the first and second quarters of 2009, either could not provide data on the amount of rebates collected for physician-administered drugs or reported accuracy issues with the collections data that they provided. Three additional States did not provide rebate data because they had not invoiced manufacturers for the first half of 2009 rebates for physician-administered drugs.

**Twenty-nine States reported difficulties with nonpayment of the requested rebates for physician-administered drugs.** In total, 29 States reported difficulties with manufacturer nonpayment of the rebates requested for physician-administered drugs. These difficulties were attributed mainly to providers that entered incorrect NDC information (particularly the number of units billed) on claims for these drugs. Manufacturers also questioned the validity of the NDCs or the number of units listed on the rebate invoices and requested additional information before making the rebate payments. Seven States mentioned data issues with the CMS crosswalk file; several of these emphasized the need for a comprehensive, universal, and accurate crosswalk file for all States to use, specific only to rebateable physician-administered drugs.

Eighteen States reported that Medicare crossover claims (i.e., claims for beneficiaries who are eligible for both Medicare and Medicaid and for which Medicaid receives rebates even if it paid only a small portion of the claim) for physician-administered drugs do not typically include NDCs. Without an NDC, a State would not be able to identify the appropriate manufacturer to bill for rebates and would not be able to collect rebates for these claims.

Twelve States reported that certain manufacturers refused to pay rebates or consistently disputed requested payments. For example, one State described a few manufacturers that have not responded to any rebate invoices.

**Thirty-one States had not implemented certain steps necessary for collecting rebates on all eligible physician-administered drugs purchased by 340B entities.** States may collect rebates for physician-administered drugs when the 340B entity (i.e., an entity with statutory access to discounted drug prices) purchases the drug at the Medicaid rate (as opposed to the discounted 340B rate). However, 31 States did

not have an edit to identify physician-administered drug claims submitted by 340B entities and/or did not require NDCs on 340B claims for physician-administered drugs eligible for rebates. Without edits to identify the claim itself or an NDC to identify the correct manufacturer to invoice, it would have been very difficult, if not impossible, for States to collect the rebates.

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## RECOMMENDATIONS

The DRA mandated that States collect rebates for certain physician-administered drugs for Federal matching funds to be available. According to States' responses, the majority met the DRA's requirements as of June 2009; however, many States reported difficulties that would have prevented them from collecting all rebates owed for these drugs. In a time when many States are experiencing financial difficulties, eliminating delays and inefficiencies with rebate collections could provide States with an additional source of funds in a timelier manner. Although CMS has undertaken numerous steps to ensure that States comply with the DRA's requirements for these drugs, the findings of this report show that substantial issues remain and need to be addressed. To assist in this, we recommend that CMS:

**Take action against States that do not meet the DRA's requirement to collect rebates on physician-administered drugs.**

**Ensure that all State agencies are accurately identifying and collecting physician-administered drug rebates owed by manufacturers.**

**Work with States to develop guidance for implementing edits that increase the efficiency of physician-administered drug claim reviews.**

**Work with States to administer guidance to providers and Medicare contractors about the rebate requirements for physician-administered drugs.**

**Ensure that the crosswalk file is complete, accurate, and identifies rebateable physician-administered drugs.**

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## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our first three recommendations. In concurring, CMS stated that before taking any action against States, it needs to

## E X E C U T I V E   S U M M A R Y

learn more about the systemic problems preventing States from collecting rebates for physician-administered drugs. CMS stated that it will reiterate the DRA rebate requirements in a release to States, as well as provide technical assistance. CMS stated that if a State does not meet these rebate requirements, it may consider withholding Federal matching funds in the future, although the agency anticipates its additional assistance will make such actions unnecessary.

CMS did not concur with our fourth recommendation, that it administer guidance to providers and Medicare contractors about the physician-administered drug rebate requirements. The agency generally considers direct provider communication to be within the States' purview and has therefore left this responsibility to them. CMS maintains that Medicare contractors are aware of these requirements and have established procedures to accept NDCs on crossover claims. We have modified our original recommendation slightly to address CMS's statement that provider communication is the responsibility of the States. However, because States reported that providers and Medicare contractors often did not provide or provided incorrect NDC information, we continue to believe that additional communication and education are warranted.

CMS also did not concur with our fifth recommendation, that it ensure the accuracy and completeness of the crosswalk file, stating that the DRA's NDC requirements render this file unnecessary. However, our findings show that the crosswalk file is still being relied upon by certain States, and we therefore continue to recommend that CMS ensure that States have access to a reliable crosswalk file.

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## BACKGROUND

In general, drug manufacturers are required to pay rebates to States for drugs covered under their Medicaid programs. Although this requirement has always included rebates for physician-administered drugs, a prior Office of Inspector General (OIG) report found that only 17 States collected Medicaid rebates from manufacturers for physician-administered drugs in 2001.<sup>1</sup> At that time, many States did not have a system to identify the manufacturer responsible for paying the rebates for these drugs. In that report, we also found that the savings from rebates in 1 year can exceed the one-time cost of implementing the system changes necessary to collect rebates.

Following the release of that OIG report, the Deficit Reduction Act of 2005 (DRA), P.L. 109-171, was passed. It specifically required States to collect rebates for certain physician-administered drugs for Federal financial participation (FFP)<sup>2</sup> to be available.<sup>3</sup> To assist in meeting this requirement, the DRA also mandated that claims for certain physician-administered drugs include the national drug code (NDC) for each drug. The NDC is an 11-digit numeric code, which is divided into three segments identifying (1) the firm that manufactures, distributes, or repackages the drug; (2) the specific

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<sup>1</sup> OIG, *Medicaid Rebates for Physician-Administered Drugs* (OEI-03-02-00660), April 2004.

<sup>2</sup> FFP refers to matching funds provided to States by the Federal Government for certain social services, including Medicaid.

<sup>3</sup> Section 1927(a)(7) of the Social Security Act (the Act), as added by section 6002 of the DRA.

strength, dosage form, and formulation of the product for a particular firm; and (3) the product's package size. By implementing the DRA's requirement to include the NDC, States could identify and invoice the manufacturers responsible for paying rebates. The Centers for Medicare & Medicaid Services (CMS) estimated that by implementing the DRA rebate provisions, States could potentially reduce prescription drug expenditures by \$179 million between 2007 and 2011.<sup>4</sup> To assist States with the implementation, CMS sent letters to State Medicaid Directors, released news flashes, and followed up with States to offer technical support and encourage readiness.

### **Medicaid Drug Rebate Program**

Currently, all 50 States and the District of Columbia offer prescription drug coverage as part of their Medicaid benefit packages. In 2009, Medicaid expenditures for prescription drugs totaled \$26 billion.<sup>5</sup> Congress created the Medicaid drug rebate program to reduce State and Federal Medicaid expenditures for prescription drugs.<sup>6</sup> For FFP to be available for covered outpatient drugs provided under Medicaid, manufacturers are required to enter into rebate agreements with the Secretary of Health & Human Services (the Secretary) and pay quarterly rebates to State Medicaid agencies.<sup>7</sup> As of April 2010, 49 States and the District of Columbia,<sup>8</sup> and approximately 550 pharmaceutical companies, participated in the rebate program.

### **Medicaid Drug Rebate Process**

Using pricing data submitted by manufacturers each quarter, CMS calculates a unit rebate amount (URA) for NDCs included in the rebate program (see Appendix A for a detailed description of the rebate calculation). After calculating URAs for all NDCs, CMS provides the amounts to State Medicaid agencies. Within 60 days after the end of the quarter, each State Medicaid agency then sends each manufacturer an invoice with information such as the number of units

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<sup>4</sup> 71 Fed. Reg. 77174, 77190 (Dec. 22, 2006).

<sup>5</sup> This was the most recent year for which complete expenditure data were available.

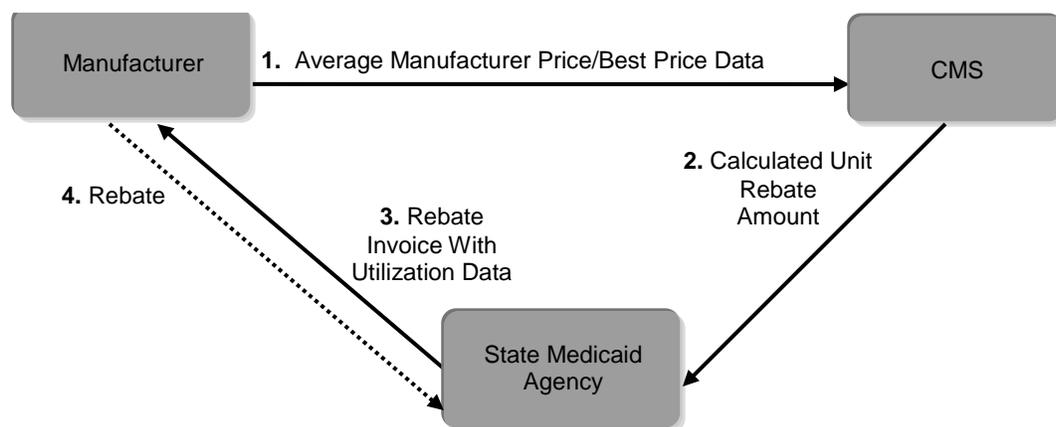
<sup>6</sup> The Omnibus Budget Reconciliation Act of 1990, § 4401, codified at 42 U.S.C. § 1396r-8.

<sup>7</sup> Sections 1927(a)(1) and (b)(1) of the Act.

<sup>8</sup> Hereinafter referred to as States. Arizona currently does not participate in the rebate program, as it was granted a section 1115 waiver that allows it to provide outpatient drugs through managed care organizations that do not meet certain requirements of the Act.

reimbursed for each of its NDCs in the State and these reimbursed NDCs’ URAs. To determine the total rebates due from the manufacturer, URAs are multiplied by the total number of units of each NDC for which the States reimbursed providers during the quarter. The manufacturer processes the invoice and pays the rebate to the State within 37 days of the invoice’s postmark date, after which interest begins to accrue (see Figure 1 for a depiction of the rebate process).<sup>9</sup>

Figure 1: Medicaid Drug Rebate Process



***Rebate exception for 340B entities.*** Section 340B of the Public Health Service Act established the 340B Drug Pricing Program, which requires pharmaceutical manufacturers to enter into an agreement to charge at or below the statutorily defined prices for sales to certain qualified entities.<sup>10</sup> Drug purchases that qualify for discounted 340B rates are not subject to a Medicaid rebate because this would result in duplicate discounts from manufacturers.

<sup>9</sup> A manufacturer may dispute the accuracy of the invoice submitted by the State. To address the problem of unpaid and disputed rebates, CMS implemented the Medicaid Drug Rebate Dispute Resolution program. Through this program, CMS provides mediation and clarification to assist manufacturers and States in identifying and resolving Medicaid drug rebate disputes.

<sup>10</sup> Qualified entities include Ryan White grantees and disproportionate share hospitals, among others. The statutory requirements of the 340B Drug Pricing Program are set forth in 42 U.S.C. § 256b.

However, in some cases, a 340B entity may choose to purchase “off 340B contract” and bill the State at the regular Medicaid rate instead of the discounted rate. The State would then invoice manufacturers for rebates for these drugs.<sup>11</sup>

### **Medicaid Rebates for Physician-Administered Drugs**

Drugs covered under Medicaid are typically self-administered products dispensed by pharmacies. However, physician-administered drugs are also covered under the rebate program.<sup>12</sup> Physician-administered drugs include both injectable and noninjectable drugs and are typically administered by medical professionals in physicians’ offices, clinics, or hospitals. In 2009, Medicaid spent approximately \$4 billion on physician-administered drugs.<sup>13</sup> Single-source drugs (i.e., brand-name drugs) accounted for a substantial majority of this spending (over 90 percent).<sup>14</sup>

*Rebate collections for physician-administered drugs prior to the DRA’s requirements.* Manufacturers with signed rebate agreements are required to pay rebates to States for covered outpatient drugs.<sup>15</sup> Even though this requirement has always included physician-administered drugs, before provisions of the DRA were implemented, many States could not always determine the manufacturer responsible for paying the rebates and therefore had difficulty collecting the rebates that were owed.<sup>16</sup>

At this time, physicians and institutions often submitted claims for drugs to State Medicaid agencies using codes from the Healthcare Common Procedure Coding System (HCPCS) (in contrast to pharmacy claims, which list NDCs).<sup>17, 18</sup> Unlike the NDC, the HCPCS code does not identify the manufacturer responsible for paying a rebate. States

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<sup>11</sup> CMS, *Dispute Resolution – Best Practices Suggestions for Resolving 340B-Related Disputes*. Accessed at <http://www.cms.gov> on August 24, 2010.

<sup>12</sup> Sections 1927(k)(2) and (a)(7) of the Act (as added by the DRA).

<sup>13</sup> CMS, *State Drug Utilization Data*. Accessed at <http://www.cms.gov> on July 26, 2010.

<sup>14</sup> *Ibid.*

<sup>15</sup> Vaccines are exempt from the rebate requirement.

<sup>16</sup> 71 Fed. Reg. 77174, 77188 (Dec. 22, 2006).

<sup>17</sup> OIG, *Medicaid Rebates for Physician-Administered Drugs* (OEI-03-02-00660), April 2004.

<sup>18</sup> A HCPCS code identifies the drug’s name, route of administration, and dosage size, but does not identify the manufacturer or package size.

that were billed using only HCPCS codes for single-source drugs could generally link the codes to NDCs using CMS's crosswalk file because most HCPCS codes for these drugs include only NDCs from one manufacturer.<sup>19</sup> However, if a State was billed with a HCPCS code for a multiple-source drug, identifying the manufacturer was difficult, as a single HCPCS code may represent drugs from more than one manufacturer.<sup>20</sup>

*Rebate collections for physician-administered drugs after the DRA's requirements.* The DRA specifically requires States to provide for the collection of rebates from manufacturers for all single-source and certain multiple-source, physician-administered drugs for Federal matching funds to be available to the States. To that end, effective January 1, 2006, States must provide for the collection and submission of utilization data for all single-source, physician-administered drugs.<sup>21</sup> As of January 1, 2008, States must also provide for the collection and submission of similar data for the 20 multiple-source, physician-administered drugs with the highest Medicaid dollar volume.<sup>22</sup> No later than January 1, 2007, the Secretary was required to publish the list of the 20 highest dollar volume multiple-source, physician-administered drugs and may modify the list yearly as drug volumes change.<sup>23</sup> This list was most recently updated in January 2011 and, for each of the 20 multiple-source drugs, contains the corresponding HCPCS code, the drug's description, the HCPCS dosage, the drug name, any associated NDCs, and the manufacturer name.

To assist in meeting the DRA rebate collection requirements, as of January 1, 2007, claims for all single-source, physician-administered drugs and the 20 multiple-source, physician-administered drugs with the highest dollar volume are required to include NDCs.<sup>24, 25</sup> The new

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<sup>19</sup> CMS creates a quarterly crosswalk file that links drug HCPCS codes to their applicable NDCs.

<sup>20</sup> A drug from one manufacturer can have more than one NDC, but the HCPCS (and therefore all of its associated NDCs) for this drug would only apply to one manufacturer.

<sup>21</sup> Section 1927(a)(7)(A) of the Act.

<sup>22</sup> Sections 1927(a)(7)(B)(i) and (ii) of the Act.

<sup>23</sup> Section 1927(a)(7)(B)(i) of the Act.

<sup>24</sup> Section 1927(a)(7)(C) of the Act.

<sup>25</sup> The Secretary may designate an alternative coding system, although only NDCs have been specified to date.

NDC requirement also applies to claims for dual-eligible beneficiaries (i.e., beneficiaries who qualify for Medicare and Medicaid). Medicare providers billing for dual-eligible beneficiaries are required to enter the NDC and the drug quantity on claims for physician-administered drugs.<sup>26</sup> Medicare providers submit these claims to Medicare contractors, which then transfer the NDC information to Medicaid for the billing of Medicaid rebates (referred to as a crossover claim). By including the NDC information on crossover claims, States can identify manufacturers to bill for Medicaid rebates, where applicable. This enables Medicaid to receive rebates on a crossover claim, even if it paid only a small portion of the claim.

### **CMS Actions To Assist States in Meeting the DRA Rebate Requirements**

Since the passage of the DRA, CMS has completed numerous actions aimed at ensuring that States meet the new rebate requirements for physician-administered drugs. In preparation for implementing the DRA provisions, CMS sent a letter to all State Medicaid Directors on July 11, 2006.<sup>27</sup> This letter introduced States to the new procedures regarding State collection and submission of data for the purpose of collecting Medicaid rebates for physician-administered drugs from manufacturers.

The July 2006 letter also informed States that CMS would be willing to grant extensions if the States needed more time to implement the new requirements regarding the collection and submission of data.<sup>28</sup> Thirty-six States requested and received extensions. Even allowing for these extensions, all States should have been in compliance with the DRA requirements no later than July 1, 2008. Prior to this date, CMS followed up with States through surveys and phone calls to offer technical assistance and support and to encourage readiness among States.<sup>29</sup>

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<sup>26</sup> CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, Transmittal 1401.

<sup>27</sup> CMS, Letter to State Medicaid Directors, *SMDL Number 06-016*. Accessed at <http://www.cms.gov> on January 6, 2011.

<sup>28</sup> To prevent hardship to States, section 1927(a)(7)(D) of the Act allowed the Secretary to delay implementation for the States that needed additional time to meet the DRA requirements.

<sup>29</sup> Before the extensions expired, CMS surveyed States to determine their progress with meeting the DRA requirements. CMS asked questions such as whether the necessary system changes to capture NDCs and bill manufacturers for rebates were completed and whether providers were notified of the NDC requirement.

Furthermore, to address the need for rebates on claims submitted for dual-eligible beneficiaries, CMS developed a method to capture NDCs on crossover claims. CMS informed Medicare providers that they were responsible for submitting NDCs on crossover claims in addition to HCPCS codes. CMS published news flashes to make the involved parties aware of this requirement.<sup>30</sup>

### **Previous OIG Work**

The April 2004 OIG report entitled *Medicaid Rebates for Physician-Administered Drugs* (OEI-03-02-00660) reported that 31 States did not collect any rebates for physician-administered drugs; 14 States collected rebates on only single-source, physician-administered drugs; and 3 States collected rebates on both single-source and multiple-source, physician-administered drugs in 2001.<sup>31</sup> If all States had collected rebates for all single-source and certain multiple-source, physician-administered drugs,<sup>32</sup> Federal and State Medicaid expenditures could have been reduced by \$37 million during that year. OIG recommended that CMS encourage rebate collection for physician-administered drugs among all States and that CMS encourage States to share information that would facilitate rebate collection. CMS concurred with our recommendation; however, the agency disagreed with our estimated savings figure.<sup>33</sup> Subsequent to that report, the DRA imposed the rebate requirements for physician-administered drugs.

A July 2005 OIG report entitled *Multistate Review of Medicaid Drug Rebate Programs* (A-06-03-00048) audited States' accountability and internal controls over their Medicaid drug rebate programs. We found that only four States had no weaknesses in accountability and internal

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<sup>30</sup> For example, see CMS, *MLN Matters Number MM5950*. Accessed at <http://www.cms.gov> on January 6, 2011.

<sup>31</sup> This report collected data from 49 States (the District of Columbia is defined as a State in this report; Arizona and Tennessee did not participate in the rebate program during the time of this review). Forty-eight States provided responses to our questions and most States provided all or some of the requested financial data.

<sup>32</sup> Potential rebates for multiple-source drugs were estimated for only the top 40 multiple-source, physician-administered drugs with the highest Medicaid payments in 2001.

<sup>33</sup> CMS noted that the estimated savings did not take into account States which had improved their rebate collection processes since our surveys were conducted.

controls.<sup>34</sup> Additionally, CMS did not have reliable information to properly monitor the drug rebate program. We recommended that CMS continue to emphasize the requirement that States submit accurate and reliable information and emphasize billing and collection of drug rebates as a high priority. CMS concurred with our recommendations.

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## METHODOLOGY

### Data Collection

In October 2009, we sent data requests and surveys to the 50 States participating in the Medicaid drug rebate program.<sup>35</sup> We received 48 responses to the data request<sup>36</sup> and 49 responses to the survey.<sup>37</sup>

*Data requests.* We requested that State Medicaid agencies provide us with the following data for all physician-administered drugs<sup>38</sup> paid for by the State in the first and second quarters of 2009:

- drug code (e.g., NDC, HCPCS);
- total number of units paid for by the State for each code;
- total dollars paid by the State for each code;
- total rebate amount the State requested (if any) from the manufacturer for each code; and
- total rebate amount the State collected for each code.

Although 48 States responded to our data request, only 26 were able to provide all of the requested data (i.e., the total dollars paid, the total rebate amount requested, and the total rebate amount collected). The

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<sup>34</sup> Specifically, this report documented problems with unreliable information submitted to CMS on the Medicaid Drug Rebate Schedule in 37 States, improper accounting procedures for interest on late rebate payments in 27 States, inadequate rebate collection systems in 17 States, inadequate dispute resolution and collection processes for 15 States, and other significant problems in 13 States (States could be counted in more than 1 category).

<sup>35</sup> In November, we sent second request letters to States that had not responded to the first request. We then followed up with nonresponding States between December 2009 and April 2010.

<sup>36</sup> Hawaii and Pennsylvania reported that they were unable to provide any of the requested data.

<sup>37</sup> We did not receive a survey from Ohio (but the State did provide data).

<sup>38</sup> We provided each State with CMS's definition of a physician-administered drug, consistent with section 1927(k)(2) of the Act.

remaining 22 States provided partial data or did not have any rebate data to report. In such cases, we analyzed the limited data that the States were able to provide. In general, States reported that they could not provide the data because they could not differentiate between rebates collected specifically for physician-administered drugs and rebates collected for other drugs covered under Medicaid. See Table 1 for the overall number of States that provided each type of data.

Table 1: Number of States Included in Rebate Calculations

Data	Number of States That Provided Data	Number of States That Did Not Provide Data
The amount paid for physician-administered drugs	45	3
The amount paid and the amount of rebates requested for physician-administered drugs	37	11*
The amount paid, the amount of rebates requested, and the amount of rebates collected for physician-administered drugs	26	22

Source: OIG analysis of State responses to the data request, 2010.

\* One State was able to provide the amount of rebates requested, but not the amount paid.

Surveys. We requested that States complete electronic surveys about the policies, procedures, and controls used to process rebates for physician-administered drugs. We asked States to answer questions regarding their compliance with the DRA’s requirements for physician-administered drugs as of the end of the second quarter of 2009. For example, we asked State Medicaid agencies to identify the types of drugs for which they collected rebates (e.g., all physician-administered drugs, certain physician-administered drugs, or no physician-administered drugs) and indicate when they required providers to include NDCs on professional and institutional physician-administered drug claims for single-source and multiple-source drugs.<sup>39</sup> For the States that required providers to include NDCs on physician-administered drug claims, we asked what changes (if any) the States made to their claims-processing systems to enable the use of NDCs, what costs they incurred (if any) to

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<sup>39</sup> Claims submitted directly by physicians are referred to as professional claims; claims submitted by institutions (e.g., hospital outpatient centers) are referred to as institutional claims.

implement system updates, and whether the States denied claims without NDCs.

We also asked States to describe any difficulties with collecting physician-administered drug rebates. In addition, we asked States to answer questions about their claims review processes for physician-administered drugs, particularly with crossover claims and claims submitted by 340B entities.

### **Data Analysis**

#### *DRA's requirements for rebate collection of physician-administered drugs.*

We identified the number of States that reported (1) meeting the DRA's rebate collection requirement (i.e., collected rebates on all single-source, physician-administered drugs and the 20 multiple-source, physician-administered drugs with the highest dollar volume); (2) exceeding the DRA's rebate collection requirement (i.e., collected rebates on all physician-administered drugs); or (3) not meeting the DRA's rebate collection requirement (i.e., did not collect rebates or collected rebates for only some of the required drugs).<sup>40</sup> If a State reported that it collected rebates in a manner that met or exceeded the DRA's rebate requirement, but also reported that it did not deny claims for drugs without NDCs (i.e., claims would be paid for a drug without enough information to invoice the manufacturer responsible for the rebate), we considered that State to not meet the DRA's rebate requirement.<sup>41</sup>

Using the dates States reported that they began enforcing the NDC requirement, we calculated the number of States that reported requiring NDCs for single-source and multiple-source, physician-administered drug claims by June 30, 2009. We also calculated the average reported cost to implement system changes to

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<sup>40</sup> Two States reported that they collected rebates in a manner that met or exceeded the DRA's rebate requirement (i.e., reported collecting rebates for all physician-administered drugs and would deny claims without NDCs), but that they had not yet invoiced for rebates pertaining to the first half of 2009. Because both States had collected rebates for physician-administered drugs prior to 2009, we considered them in compliance with the DRA's rebate requirements.

<sup>41</sup> States were required to comply with the DRA's rebate provisions for FFP to be available for physician-administered drugs. Therefore, a State could have technically met the DRA requirements if it did not deny drug claims that failed to include NDC information as long as no FFP was requested. However, because none of the States in question reported not seeking FFP for physician-administered drugs, we concluded that these States did not meet the DRA requirements.

enable NDC collection. We then determined from the surveys what these changes entailed.

*Dollar amount of rebates requested and collected.* Although 48 States responded to our data request, only 26 provided complete information on the amount of rebates requested and collected for physician-administered drugs. For each of the 26 States, we summed the total amount reimbursed, the total amount of rebates requested, and the total amount of rebates collected for all drug codes for the first and second quarters of 2009. We then summed this information from all 26 States to calculate overall figures for the first half of 2009.

Of the remaining 22 States that responded to our data request, 19 were unable to determine the amount of rebates collected. To identify the reasons collections data were not provided, we reviewed information provided by these 19 States and followed up via telephone or email with States when clarification was necessary. Although we were unable to calculate the rebates collected by these 19 States, we summed the data provided by these States for the amount reimbursed (16 States) and rebates requested (12 States).

The remaining 3 of the 22 States reported that they had neither requested nor collected any rebates for the first and second quarters of 2009. We summed the total amount reimbursed by these three States for physician-administered drugs.

*States' difficulties with collecting all physician-administered drug rebates.* We determined the number of States that reported difficulties with nonpayment of all the rebates requested for physician-administered drugs. We also reviewed States' descriptions of any other issues with collecting rebates. To identify common problems that States had, we determined the number of States that provided similar descriptions of issues with manufacturers and providers.

We evaluated States' responses to questions pertaining to the review of 340B claims and Medicare crossover claims for physician-administered drugs and identified circumstances in which the State may not have collected all possible rebates for these claim types. We determined the number of States that did not typically receive NDCs on Medicare crossover claims. We also determined the number of States that had edits to prevent manufacturers from paying duplicate discounts on 340B claims and the number of States with edits to enable rebate collection for eligible physician-administered drug claims submitted by 340B entities.

### **Limitations**

As previously mentioned, we received complete data from only 26 States. The data provided by these States may not be representative of the amount of rebates requested and collected for the States with missing data.

The remaining 24 States were unable to provide any or all of the requested data (19 provided a portion of the requested data, 3 had not invoiced manufacturers for rebates for the first and second quarters of 2009, and 2 responded that they were unable to provide any of the requested data). However, we did receive complete surveys from these 24 States.

The findings presented are based on self-reported data and survey responses provided by State Medicaid agencies. Even though we contacted States to clarify their responses to specific questions, we did not verify the accuracy of all data and survey responses provided by each State.

### **Standards**

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

## ► FINDINGS

### **By June 2009, 73 percent of responding States reported meeting or exceeding the DRA's requirement to collect rebates for certain physician-administered drugs**

As of June 30, 2009, 36 of the 49 responding States (73 percent) reported being in full compliance with the DRA's requirement to collect rebates

for all single-source, physician-administered drugs and the 20 multiple-source, physician-administered drugs with the highest dollar volume. Thirty-one of these States reported exceeding the DRA's requirements by collecting rebates on all physician-administered drugs.<sup>42</sup>

Table 2: State-Reported Compliance With DRA Rebate Requirements as of June 2009

<b>Rebates Collected</b>	<b>Number of States</b>
All physician-administered drugs	31
All single-source and the top 20 multiple-source, physician-administered drugs	5
Some physician-administered drugs, but did not meet the DRA's requirement	12
Did not collect any rebates for physician-administered drugs	1

Source: OIG analysis of State responses to survey question, 2010.

Among the 13 States that reported not collecting rebates in accordance with the DRA's rebate requirements, only the District of Columbia stated that it did not collect any rebates for physician-administered drugs.<sup>43</sup> The remaining 12 States reportedly collected rebates on a subset of physician-administered drugs (e.g., only rebates for professional claims, only rebates for single-source drugs), but were not

<sup>42</sup> However, two States that reported collecting rebates for all physician-administered drugs had not invoiced manufacturers for first- and second-quarter 2009 rebates at the time of our data request. Both States reported that they plan to invoice manufacturers for these rebates at a later time and had collected rebates prior to 2009.

<sup>43</sup> We estimate that the District of Columbia could have reduced its physician-administered drug expenditures by at least 25 percent (estimated minimum savings of \$255,000 during the first and second quarters of 2009) had it collected rebates for all physician-administered drugs in the first half of 2009. Because of limitations in the data submitted by the States, we were unable to calculate potential savings for the remaining 12 States that did not fully meet the DRA's rebate collection requirements.

in full compliance with the DRA requirements.<sup>44</sup> See Table 2 for an overall description and Appendix B for a detailed description of States' collection of rebates for physician-administered drugs as of June 2009.

**As of June 2009, 86 percent of responding States reported meeting the DRA's requirement to collect NDCs on physician-administered drug claims**

To facilitate rebate collection, the DRA also required States to collect NDCs on claims for certain physician-administered drugs. By June 30, 2009, 42 of the 49 responding States (86 percent) reported that they required NDCs on all claims for physician-administered drugs.<sup>45</sup> See Appendix B for a detailed description of States' NDC requirements as of June 2009.

**On average, States reported spending \$540,000 to implement the changes necessary to collect NDCs for physician-administered drugs**

The States' costs to implement the necessary system changes to collect NDC information averaged \$540,000 (costs ranged from \$0 to \$4 million).<sup>46</sup> States reported that these changes included updating States' claim systems to accept NDC codes, creating new edits to deny claims billed without NDCs or with invalid NDCs, educating providers about the NDC requirement, and maintaining a list of HCPCS codes and NDCs (including a crosswalk).

**We could not determine the financial impact of collecting rebates for physician-administered drugs because of incomplete and potentially inaccurate data provided by States**

In total, 26 States provided complete data on the amount of rebates requested and collected for physician-administered drugs in the first and second quarters of 2009. An additional 19 States

were either unable to provide complete rebate collections data or reported accuracy issues with the data provided. Finally, three more States had not invoiced manufacturers for rebates for physician-administered drugs at the time of our request. In many cases, there was substantial variability among the data provided by

<sup>44</sup> According to the States' responses, 3 of the 12 were or planned to be in full compliance with the DRA's rebate requirement by the end of 2009, and an additional 4 of the 12 reported plans to meet the requirements in 2010 or 2011.

<sup>45</sup> Six of the 42 States that required NDCs did not otherwise meet the DRA's rebate collection requirements.

<sup>46</sup> Twenty-nine States were able to calculate and provide cost estimates. One of these States reported that it makes continuous payments of approximately \$1,700 per quarter to update its system to collect NDCs. This State was not included in the average.

responding States, casting doubts about their accuracy and reliability. For these reasons, we were unable to calculate the total rebate dollars all States collected and therefore could not determine the financial impact rebate collections had on reducing prescription drug expenditures.

**States reported recouping between 3 and 96 percent of the amount paid for physician-administered drugs by collecting rebates**

The reimbursement and rebate data reported for physician-administered drugs varied greatly among States. In fact, the 26 States that provided rebate collections data reported recouping between 3 and 96 percent of the amount paid for these drugs in the first half of 2009 by collecting rebates. States also varied widely in the amount that they reported spending on drugs. The 45 States that provided reimbursement data reported paying between \$503,000 and \$162 million for physician-administered drugs in the first and second quarters of 2009. See Appendix C for the total amount reimbursed, rebates requested, and rebates collected, as reported by all responding States.

The percentage of reimbursement that States reported requesting in rebates also varied widely. Seven States reported requesting in rebates more than half of their total payments for physician-administered drugs (one of these States requested almost three times as much as it paid). However, another seven States reported requesting rebates that represented less than 10 percent of total payments.

Although some variation among States' rebate figures would be expected, this degree of variation calls into question the accuracy of the data provided. In particular, variations did not relate to the size of the State or the amount the State reported paying for physician-administered drugs in the first and second quarters of 2009.<sup>47</sup> For example, California requested \$9.5 million in physician-administered drug rebates for this period, even though it reported paying \$162 million for these drugs.<sup>48</sup> Smaller States, such as Tennessee and Wisconsin, paid significantly less for

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<sup>47</sup> The amount of rebates that should be requested by each State is determined by a statutorily defined formula.

<sup>48</sup> This State reported that it did not collect rebates for multiple-source, physician-administered drugs in the first quarter of 2009.

physician-administered drugs, but requested more than double the dollar amount California requested in rebates. In another example, when we requested data for an earlier study, Maryland reported paying \$25 million for physician-administered drugs in 2001. In contrast, as part of our current study, Maryland reported paying \$503,000 for physician-administered drugs in the first half of 2009.<sup>49</sup>

Because it was beyond the scope of this study to verify the data provided by States, we were not able to determine whether these variations are a result of incorrect data or whether the amounts provided are in fact correct.

**Twenty-six States reported collecting \$112 million in physician-administered drug rebates for the first half of 2009**

In total, 26 States provided complete data on the amount paid and the amount of rebates requested and collected in the first and second quarters of 2009. The 26 States reported paying \$577 million for physician-administered drugs and requesting \$148 million in rebates from manufacturers during that period. Based on the data provided, these States collected \$112 million in rebates for physician-administered drugs in the first and second quarters of 2009, resulting in an overall collection rate of 75 percent and representing 19 percent of their total payments for physician-administered drugs. (Refer to Table 3 and Table C-1 in Appendix C for information about overall and individual States' rebate collections, respectively.)

**Nineteen States either could not provide data on the amount of rebates collected for physician-administered drugs or reported accuracy issues with the collections data they provided**

An additional 19 States stated that they were unable to provide complete and/or reliable information about the total rebate dollars collected from drug manufacturers for physician-administered drugs.<sup>50</sup> Among these 19 States, 13 States provided no rebate collections data on physician-administered drugs because they could not differentiate between rebates collected for these drugs and rebates collected for

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<sup>49</sup> See OEI-03-02-00660 for Maryland's reported reimbursement for physician-administered drugs in 2001.

<sup>50</sup> Even though specific rebate figures were not provided, six States provided assumptions for the percentage of rebates collected. These assumptions are provided in Table C-2 of Appendix C.

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other drugs covered under Medicaid,<sup>51</sup> 3 States noted accuracy issues with the data they provided,<sup>52</sup> 1 State reported that it documented only a portion of the rebates collected, 1 State reported that it did not document any of the rebates collected, and 1 State could not readily determine rebates collected.

These 19 States reported paying approximately \$355 million for physician-administered drugs in the first and second quarters of 2009.<sup>53</sup> Even though the amount of rebates received was not provided, 12 of the 19 States could determine the amount of rebates requested for physician-administered drugs. These 12 States requested \$57 million in rebates for physician-administered drugs for that period. Refer to Table 3 and Table C-2 in Appendix C for overall and individual rebate data for these States, respectively.

Table 3: Physician-Administered Drug Data Provided by States for the First and Second Quarters of 2009

Data Provided by States	Amount Reimbursed	Amount of Rebates Requested	Amount of Rebates Collected
States with complete rebate data (n=26)	\$577,174,377	\$148,448,829	\$112,066,822
States with incomplete rebate data (n=19)	\$354,597,303*	\$56,982,977**	Could not determine
States that did not invoice for rebates (n=3)	\$51,957,878	\$0	\$0
<b>Total based on data provided</b>	<b>\$983,729,558*</b>	<b>\$205,431,806**</b>	<b>\$112,066,822</b>

Source: OIG analysis of State data, 2010.

\* Three States were unable to provide the amount reimbursed for physician-administered drugs and therefore were not included in this total.

\*\* Seven States were unable to provide the amount of rebates requested for physician-administered drugs and therefore were not included in this total.

<sup>51</sup> Two additional States, Pennsylvania and Hawaii, were not included in the data portion of the analysis because they did not provide any of the requested data (i.e., the amount reimbursed, the amount of rebates requested, and the amount of rebates received). Both States reported that they did not have the ability to determine any data specifically for physician-administered drugs.

<sup>52</sup> For example, States reported that there were incorrect unit conversions in the amounts invoiced to manufacturers or reported that the data did not account for any adjustments made as a result of manufacturer disputes over the rebate amount invoiced (most likely, from inaccurate unit conversions). A manufacturer that questions the accuracy of the State's rebate invoice may either pay for the disputed units and work with the State to resolve the issue or withhold payment until the issue is resolved.

<sup>53</sup> This amount would be higher, but 3 of the 19 States were unable to provide the amount reimbursed for physician-administered drugs.

**Three States did not provide rebate data because they had not invoiced manufacturers for first half of 2009 rebates for physician-administered drugs**

Two States that reported that they collected rebates for all physician-administered drugs never sent invoices to manufacturers for rebates pertaining to utilization in the first and second quarters of 2009 because of computer issues. These States had therefore not requested or collected rebates for physician-administered drugs at the time of our data request. These two States paid \$51 million for physician-administered drugs for the period under review. Both States reported that they collected rebates for such drugs prior to 2009 and that they plan to invoice for the rebates covered under the first and second quarters of 2009.

Additionally, as previously mentioned, the District of Columbia reported not collecting any rebates for physician-administered drugs and therefore did not have any rebate data to report. In the first and second quarters of 2009, the District of Columbia paid \$999,000 for these drugs. Refer to Table 3 and Table C-3 in Appendix C for overall and individual rebate data for these States, respectively.

**Twenty-nine States reported difficulties with nonpayment of the requested rebates for physician-administered drugs**

In total, 29 of 48 States<sup>54</sup> reported difficulties with manufacturer nonpayment of all of the rebates requested for physician-administered drugs.

Many difficulties involved potentially incorrect or missing NDC information on the claims submitted by providers. This would frequently lead manufacturers to dispute the amounts States requested on rebate invoices, including the amounts requested for crossover claims (claims that Medicare contractors transfer to Medicaid).<sup>55</sup> Other issues, however, involved more general problems with certain manufacturers.

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<sup>54</sup> Although we received surveys from 49 States, the District of Columbia reported not collecting rebates and was therefore exempt from answering the survey questions pertaining to difficulties with rebate collections.

<sup>55</sup> Crossover claims are those for beneficiaries who are eligible for both Medicare and Medicaid and for which Medicaid receives rebates even if it paid only a small portion of the claims.

**Twenty-one States reported provider or manufacturer issues with the accuracy of the NDC information included on physician-administered drug claims**

Traditionally, providers billed for physician-administered drugs using HCPCS codes rather than NDCs. Even though Medicaid payment for a physician-administered drug claim is usually based on the HCPCS code, the NDC is used for rebate processing, and therefore providers typically need to include both codes on the claim for payment and rebate collection. In many cases, the billing unit for an identical quantity (e.g., 1,000 milligrams versus 1 gram) of a drug differs between the two code types.

As a result, 21 States reported issues with the NDC information on the claim, such as providers that inaccurately converted HCPCS code units to NDC units, providers that listed NDCs that did not correspond to the same drug as the HCPCS code, and manufacturers that questioned the validity of the NDC information on the rebate invoice. Two States mentioned that even though they had held training sessions and made one-on-one educational calls, providers continued to incorrectly report NDCs and the corresponding units.<sup>56</sup>

Because States invoice manufacturers for rebates based on the number of units billed, inaccurate conversions may cause States to request substantially more or less than they are actually owed. This could be a factor contributing to the significant variations among the data reported by States. Among the 29 States that reported difficulties with manufacturer nonpayment of rebates, 16 stated that manufacturers questioned the validity of the NDC information, questioned the conversions for the number of NDC units listed on the invoice, or requested additional information to support the utilization invoiced before making the rebate payments. In addition, a few of these States also reported that verifying unit conversions can be extremely time consuming and that this had sometimes delayed the collection of rebates.

Seven States mentioned data issues with the CMS crosswalk file. CMS maintains a file that crosswalks a drug's HCPCS code to the

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<sup>56</sup> Additional States may have offered training to providers; however, we did not specifically ask States to describe these efforts. States were included in this count if they mentioned provider training when asked to generally describe issues with claims reviews and rebate collections.

corresponding NDC. However, a few of these States reported that CMS's currently available crosswalk file and the drug compendia (e.g., First DataBank) that States use to obtain drug information contain inaccuracies and omissions. Several States emphasized the need for a comprehensive, universal, and accurate crosswalk file for all States to use, specific only to rebateable physician-administered drugs.<sup>57</sup> This could improve the efficiency of rebate collections by assisting States in tasks such as claim validation and unit-of-measure conversions.

**Eighteen States reported that Medicare crossover claims for physician-administered drugs do not typically include NDCs**

When submitting crossover claims, Medicare providers are required to enter NDCs and the corresponding quantities on claims for physician-administered drugs. The Medicare contractor then transfers the claim to Medicaid to determine any additional coverage. However, 18 States reported that Medicare contractors do not typically provide them with the NDC information when transferring the claims to the State Medicaid agencies (either because Medicare providers do not include the NDC information on the claims or because the Medicare contractors do not transfer this information to Medicaid). Without an NDC, a State would generally not be able to identify the appropriate manufacturer to bill for rebates and would not be able to collect rebates for these claims.

In addition, four States reported difficulties with manufacturer nonpayment of rebates for crossover claims (three reported an increase in disputes from manufacturers; one stated that manufacturers were unwilling to pay rebates for these types of claims).<sup>58</sup> An additional two States believed that CMS did not require Medicare providers to include NDCs on crossover claims,<sup>59</sup> and one State was unsure if CMS allowed the collection of rebates on crossover claims for physician-administered drugs.

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<sup>57</sup> Numbers relating to crosswalk files may be higher because States were never explicitly asked on our survey about issues with CMS's crosswalk file. States were included in this count if they opted to mention crosswalk issues.

<sup>58</sup> Three of these four States reported that an NDC was typically listed on a crossover claim.

<sup>59</sup> Both States reported that an NDC was typically listed on a crossover claim.

**Twelve States reported that certain manufacturers refused to pay rebates or consistently disputed requested payments**

Twelve States described issues with manufacturers other than inaccurate unit conversions of NDCs and inaccurate reporting of NDC information. Among these, States reported disputes that did not appear to have a legitimate reason. States’ descriptions included manufacturers that refused to pay rebates and manufacturers that requested the same information each quarter to substantiate the amount requested. One State reported that “simply those manufacturers that like to dispute are determining how far they can push things in this area.” This State reported that one manufacturer’s refusal to pay rebates had resulted in a loss of more than \$400,000. Another State reported that a few manufacturers “have just not responded to any invoices and letters.” CMS facilitates the Medicaid Drug Rebate Dispute Resolution Program, which is specifically designed for resolving these types of issues.<sup>60</sup>

**Thirty-one States had not implemented certain steps necessary for collecting rebates on all eligible physician-administered drugs purchased by 340B entities**

Physician-administered drug claims submitted by a 340B entity generally do not qualify for rebates because the drugs are already purchased at a discounted

rate. All but three of the States reported that they have an edit or another mechanism to prevent manufacturers from paying duplicate discounts (this occurs when a manufacturer charges a discounted rate for a 340B drug and also pays a rebate for that discounted drug).<sup>61</sup> For example, States identify claims submitted by 340B entities and exclude these from rebate invoicing.

However, States may collect rebates for physician-administered drugs in cases in which the physician-administered drugs were “carved out” (i.e., the 340B entity maintains a separate inventory of non-340B drugs for the purposes of dispensing to Medicaid patients and billing to States at the regular Medicaid rates). In total, 31 States did not

<sup>60</sup> We did not ask States to describe their knowledge and use of the Medicaid Drug Rebate Dispute Resolution Program.

<sup>61</sup> Section 340B of the Public Health Service Act requires States to establish a mechanism to prevent duplicate discounts. 42 U.S.C. § 256b(a)(5).

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have an edit to identify carved-out claims for physician-administered drugs submitted by 340B entities and/or did not require the 340B entities to put NDCs on carved-out claims. Without edits to identify the claim itself or an NDC to enable States to determine the correct manufacturer to invoice, it would have been very difficult, if not impossible, to collect the rebates.



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An April 2004 OIG report found that many States were not collecting rebates for physician-administered drugs and could have saved millions of dollars had they collected these rebates. Subsequently, the DRA mandated that States collect rebates for all single-source, physician-administered drugs and the 20 multiple-source, physician-administered drugs with the highest dollar volume. The DRA also mandated that States require providers to include NDCs on claims for these drugs. According to States' responses, as of June 2009, the majority met the DRA's requirements. However, many States reported difficulties that would have prevented or delayed them from collecting all rebates owed for these drugs.

In addition, 22 States could not provide complete rebate data for physician-administered drugs. The available data provided by these States and the complete data from the remaining 26 responding States had such variability that we had concerns about the data's accuracy and reliability. In other words, not all States appear to be adequately tracking rebates, which are an additional source of funds for the States. Furthermore, factors such as manufacturer disputes, incorrect NDC reporting by providers, the absence of NDCs on 340B claims and crossover claims, and States' inability to identify 340B claims most likely contributed to States' not collecting all rebates requested and/or not requesting all rebates owed.

Impending changes mandated in the Patient Protection and Affordable Care Act include expanding the Medicaid eligibility guidelines, which will most likely result in an increase in the number of covered beneficiaries. It is therefore imperative that States collect the required physician-administered drug rebates in the most efficient manner as soon as possible. Many States are currently experiencing financial difficulties; eliminating delays and inefficiencies with rebate collections would provide States with an additional source of funds in a timelier manner.

Although CMS has undertaken numerous steps to ensure that States comply with the DRA's requirements for physician-administered drugs, the findings of this report show that substantial issues remain and need to be addressed. Therefore, we recommend that CMS:

**Take action against States that do not meet the DRA's requirement to collect rebates on physician-administered drugs**

As of June 2009, 13 States were not collecting rebates on all single-source, physician-administered drugs and the 20 multiple-source, physician-administered drugs with the highest dollar volume and therefore were not fully meeting the DRA's requirements. As a result, the FFP should not be available on any eligible physician-administered drug claims for which States are not seeking rebates. CMS should instruct these States to begin collecting the required rebates as soon as possible and consider withholding the FFP if States do not comply.

CMS should also emphasize to all State Medicaid agencies the additional savings that could result from collecting rebates for physician-administered drugs billed on applicable crossover claims and carved-out 340B claims. States were not always obtaining the NDC information on crossover or eligible 340B claims. CMS should ensure that the Medicare providers billing crossover claims, the Medicare contractors processing crossover claims, and the 340B entities submitting carved-out claims include the NDC for rebate purposes.

**Ensure that all State agencies are accurately identifying and collecting physician-administered drug rebates owed by manufacturers**

Many States could not determine the amount of rebates collected and some States could not determine the amount of rebates requested for physician-administered drugs. Those States that could provide this information had such variation in their data that it calls into question the accuracy of the data provided. Without accurate and complete records, States cannot identify all of the rebates owed by manufacturers for physician-administered drugs.

Furthermore, many States reported inaccurate NDC information on the claims providers submit and an increase in disputes from manufacturers regarding such claims. Any disputes would most likely delay rebates or even reduce the amount of rebates collected, thereby decreasing the State's collection rate. To alleviate these difficulties, CMS could encourage States to take advantage of the agency's Medicaid Drug Rebate Dispute Resolution Program.

**Work with States to develop guidance for implementing edits that increase the efficiency of physician-administered drug claim reviews**

Implementing additional edits may help to increase the accuracy of physician-administered drug claims and the efficiency of the claims' review, thereby reducing the time and effort States need to verify or obtain accurate NDC information from providers. CMS had followed up with States in 2008 about implementing edits for denying claims without NDCs; however, based on our findings, not all States have followed through with this implementation. CMS should continue to work with States to develop guidance about edits that facilitate efficient rebate collection and should encourage their implementation among all States. These edits could include denying claims without an NDC (including crossover claims); verifying the accuracy of the NDC, the NDC's units, and corresponding HCPCS code; and verifying that the units for the NDC and HCPCS are converted correctly.

Edits, such as denials for claims without an NDC, may help facilitate rebate collection by creating an incentive for providers to report accurate NDC information. In addition, by having an edit(s) that verifies the NDC aspect of the claim, manufacturer disputes about the accuracy of claim information may be lessened. Also, States may further reduce expenditures on physician-administered drugs by having an edit to identify and enable rebate collection for the carved-out physician-administered drug claims.

**Work with the States to administer guidance to providers and Medicare contractors about the rebate requirements for physician-administered drugs**

Although CMS has issued guidance to State Medicaid Directors and providers in the past, our findings demonstrate that many States are not meeting the DRA's rebate requirements. CMS should reiterate the importance of collecting rebates for physician-administered drugs to States and should work with States to convey this information to providers and Medicare contractors that submit claims for dual-eligible beneficiaries. To that end, CMS should assist States in developing guidance that clarifies the NDC requirement for the States to pass on to all providers and Medicare contractors. Having States offer guidance to providers and Medicare contractors about the DRA requirements may eliminate any confusion or alleviate the resistance providers may have to reporting NDCs. In addition, CMS should ensure that States reemphasize to those Medicare contractors that

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process claims for dual-eligible beneficiaries the importance of providing the NDC information when the claims are crossed over to Medicaid.

### **Ensure that the crosswalk file is complete, accurate, and identifies rebateable physician-administered drugs**

Although CMS currently publishes a quarterly crosswalk file, seven States mentioned issues with the data in this file. Certain States expressed concern with the accuracy and completeness of the data in this file, as well as the file's usefulness for identifying and crosswalking rebateable physician-administered drugs. These States mentioned that an official crosswalk that contains accurate and up-to-date information for physician-administered drugs would make rebate collections more efficient and timely. States that described issues with the crosswalk file used the file either to identify the NDC or to validate the NDC information on the claim.

The agency could also add an identifier to the crosswalk that would enable States to easily identify rebateable physician-administered drugs. This crosswalk would include all rebateable NDCs linked to the corresponding HCPCS code, the units of service for each NDC and HCPCS code, and a conversion factor for all available drug codes. All States would have access to this crosswalk. It would be maintained and updated frequently so that States could easily identify terminated physician-administered drugs and physician-administered drugs provided by manufacturers without a rebate agreement.

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

CMS concurred with our first three recommendations, but did not concur with the remaining two. CMS also noted that it has taken many steps to ensure that States are meeting the rebate requirements for physician-administered drugs.

In concurring, CMS stated that before taking any action against States, the agency needs to learn more about the systemic problems that prevent States from collecting rebates for physician-administered drugs and that it will continue to work with States to identify and reduce these barriers. CMS also stated that it will reiterate the rebate requirements in a release to States, as well as provide technical assistance. CMS stated that if States do not meet the requirements, it may consider withholding FFP in the future, although the agency

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anticipates the additional assistance to the States, as described above, will make such actions unnecessary.

CMS did not concur with our fourth recommendation, that it administer guidance to providers and Medicare contractors about the physician-administered drug rebate requirements. The agency generally considers direct provider communication to be within the States' purview and has therefore left this responsibility to them. CMS also maintains that Medicare contractors are aware of the physician-administered drug requirements through *Med Learn Matters* and have established procedures to accept NDCs on crossover claims.

We have modified our original recommendation slightly to address CMS's statement that provider communication is a responsibility of the State. However, because States reported that providers and Medicare contractors often did not provide or provided incorrect NDC information on physician-administered drug claims, we continue to believe that additional communication with and education for providers and Medicare contractors are warranted.

Finally, CMS did not concur with our fifth recommendation, that it ensure that the crosswalk file is complete and accurate. According to CMS, a State that is in full compliance with the DRA's NDC requirements should not need to rely on the crosswalk to properly collect rebates. Although CMS's assertion is accurate, not all States fully met the DRA's NDC requirements and therefore needed to use the crosswalk. Additionally, some DRA-compliant States reported using the crosswalk to perform tasks such as manual claim validations and unit-of-measure conversions. Therefore, we continue to believe that CMS should ensure that States have access to a reliable crosswalk file.

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

Detailed Description of the Medicaid Drug Rebate Calculation

**Manufacturer requirements.** Currently, manufacturers must submit average manufacturer price (AMP) data to the Centers for Medicare & Medicaid Services (CMS) for each of their covered outpatient drugs on monthly and quarterly bases, although only the quarterly data are used for rebate purposes.<sup>62</sup> The AMP is defined as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer, with certain exclusions.<sup>63</sup>

Manufacturers must also provide CMS with the drug category for each of their covered outpatient drugs in conjunction with AMP data.<sup>64</sup> In the Medicaid drug rebate program, drugs are generally categorized as one of three types: single-source, innovator multiple-source, or noninnovator multiple-source. In general terms, a single-source drug would typically be a brand-name product with no available generic versions. An innovator multiple-source drug would typically be a brand-name product that has available generic versions. A noninnovator multiple-source drug would simply be a generic version of any multiple-source product.

Manufacturers of single-source and innovator multiple-source drugs are also required to provide CMS with the best price available for each covered outpatient drug.<sup>65</sup> Best price is defined as the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, with certain exceptions.<sup>66</sup> Manufacturers of noninnovator multiple-source drugs are not required to provide their best price.

**Basic rebate.** CMS uses the manufacturer-reported AMP data and drug type information to calculate a unit rebate amount (URA) for

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<sup>62</sup> Section 1927(b)(3) of the Social Security Act (the Act).

<sup>63</sup> Section 1927(k)(1) of the Act, as amended by section 2503(a)(2) of the Patient Protection and Affordable Care Act (ACA), P.L. 111-148.

<sup>64</sup> Section II of the rebate agreement between the manufacturer and the Secretary of Health & Human Services.

<sup>65</sup> Section 1927(b)(3)(A)(i)(II) of the Act.

<sup>66</sup> Section 1927(c)(1)(C)(i) of the Act.

each covered outpatient drug. The formula used to determine the URA depends on the drug category reported by the manufacturer.<sup>67</sup> From 1996 to 2009, the basic 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, and the basic URA for noninnovator multiple-source drugs was 11 percent of the AMP.<sup>68, 69</sup>

*Additional rebate for innovator drugs.* Manufacturers of single-source and innovator multiple-source drugs are required to pay an additional rebate if the drug's AMP increases faster than inflation.<sup>70, 71, 72</sup> To determine whether manufacturers owe an additional rebate for a drug, its "base date" AMP is updated for the present quarter using the Consumer Price Index published by the Bureau of Labor Statistics.<sup>73</sup> If the resulting figure is greater than or equal to the reported AMP in the quarter, no additional rebate is owed (i.e., the AMP did not increase at a greater rate than inflation). If the resulting figure is less than the reported AMP in the quarter, then the additional URA is equal to the difference between the reported AMP and the inflation-adjusted base date AMP.

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<sup>67</sup> Section 1927(c) of the Act.

<sup>68</sup> Sections 1927(c)(1)(A) and (c)(3)(A) of the Act.

<sup>69</sup> Pursuant to section 2501(a) of the ACA, as of January 1, 2010, the basic URA for single-source and innovator multiple-source drugs was increased to the greater of 23.1 percent of the AMP or the difference between the AMP and best price (with certain exceptions). Pursuant to section 2501(b) of the ACA, the basic URA for noninnovator multiple-source drugs was increased to 13 percent of the AMP.

<sup>70</sup> Section 1927(c)(2) of the Act.

<sup>71</sup> Manufacturers of noninnovator multiple-source drugs are not required to pay an additional rebate.

<sup>72</sup> CMS, *Unit Rebate Amount Calculation*. Accessed at <http://www.cms.hhs.gov> on August 20, 2009.

<sup>73</sup> Base date AMP is the AMP in the first full quarter that a drug is on the open market.

▶ **A P P E N D I X ~ B**

State Responses About the Deficit Reduction Act of 2005 Requirements for Physician-Administered Drugs

Table B-1: Detailed Description of Responses From States That Reported Meeting the Deficit Reduction Act of 2005<sup>1</sup> Rebate Requirements for Physician-Administered Drugs as of June 2009

State	Physician-Administered Drugs for Which States Collected Rebates in the First Half of 2009	Did the State Require National Drug Codes on Physician-Administered Drug Claims as of June 2009?	State's Action When a National Drug Code Was Not Included on a Claim as of June 2009
AK	All physician-administered drugs	Yes	Crosswalks the Healthcare Common Procedure Coding System (HCPCS) codes to national drug codes (NDC) for single-source drugs; denies for multiple-source drugs
AL <sup>2</sup>	All single-source and the 20 highest dollar volume multiple-source, physician-administered drugs	Yes	Crosswalks HCPCS to NDC for single-source drugs; denies for multiple-source drugs
AR	All physician-administered drugs	Yes	Denies the claim
CA <sup>3</sup>	All physician-administered drugs	Yes	Denies the claim
CO	All single-source and the 20 highest dollar volume multiple-source, physician-administered drugs	Yes	Crosswalks HCPCS to NDC for single-source drugs; denies for the required top 20 multiple-source drugs
CT	All physician-administered drugs	Yes	Denies the claim
DE	All physician-administered drugs	Yes	Denies the claim
GA	All physician-administered drugs	Yes	Denies the claim
HI	All physician-administered drugs	Yes	Not applicable (providers bill only with NDC)
IA	All single-source and the 20 highest dollar volume multiple-source, physician-administered drugs	Yes	Denies the line item of claim
ID	All physician-administered drugs	Yes	Denies the claim
IL <sup>4</sup>	All physician-administered drugs	Yes	Denies the claim
IN	All physician-administered drugs	Yes	Denies the claim
KS	All physician-administered drugs	Yes	Denies claim detail
KY	All single-source and the 20 highest dollar volume multiple-source, physician-administered drugs	Yes	Denies the claim

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A P P E N D I X ~ B

Table B-1: Detailed Description of Responses From States That Reported Meeting the DRA's Rebate Requirements for Physician-Administered Drugs as of June 2009 (Continued)

State	Physician-Administered Drugs for Which States Collected Rebates in the First Half of 2009	Did the State Require National Drug Codes on Physician-Administered Drug Claims as of June 2009?	State's Action When a National Drug Code Was Not Included on a Claim as of June 2009
MA	All physician-administered drugs	Yes	Denies the claim
MD	All physician-administered drugs	Yes	Denies the claim
MN	All physician-administered drugs	Yes	Denies the claim
MS	All physician-administered drugs	Yes	Not applicable (providers bill only with NDC)
MT	All physician-administered drugs	Yes	Denies the claim
NC	All single-source and the 20 highest dollar volume multiple-source, physician-administered drugs	Yes	Denies the claim detail
ND	All physician-administered drugs	Yes	Denies the claim
NH	All physician-administered drugs	Yes	Denies the claim
NV	All physician-administered drugs	Yes	Denies the claim
OK	All physician-administered drugs	Yes	Denies the claim
PA	All physician-administered drugs	Yes	Not applicable (providers bill only with NDC)
RI <sup>4</sup>	All physician-administered drugs	Yes	Denies the claim
SC	All physician-administered drugs	Yes	Denies the claim
SD	All physician-administered drugs	Yes	Denies the claim
UT	All physician-administered drugs	Yes	Denies the claim
VA	All physician-administered drugs	Yes	Denies the claim
VT	All physician-administered drugs	Yes	Denies the claim detail
WA	All physician-administered drugs	Yes	Denies the claim
WI	All physician-administered drugs	Yes	Denies the claim
WV	All physician-administered drugs	Yes	Denies the claim
WY	All physician-administered drugs	Yes	Denies the claim

Source: Office of Inspector General (OIG) analysis of State survey responses, 2010.

<sup>1</sup> DRA.

<sup>2</sup> Collected rebates for 29 multiple-source, physician-administered drugs that either are currently or have previously been on the top 20 list.

<sup>3</sup> Collected only single-source rebates in the first quarter of 2009, but collected rebates for all physician-administered drugs in the second quarter of 2009.

<sup>4</sup> These States collected rebates prior to 2009, but at the time of our data request, they had not yet invoiced for first- and second-quarter 2009 rebates.

Table B-2: Detailed Description of Responses From States That Reported Not Meeting the DRA's Rebate Requirements for Physician-Administered Drugs as of June 2009

State	Physician-Administered Drugs for Which States Collected Rebates in the First Half of 2009	Did the State Require National Drug Codes on Physician-Administered Drug Claims as of June 2009?	State's Action When a National Drug Code Was Not Included on a Claim as of June 2009
DC	No rebate collection	No NDC required	No rebate collection
FL	All physician-administered drugs with an NDC and single-source drugs that can be crosswalked to an NDC	No NDC required for institutional claims	Crosswalks the HCPCS to the NDC for single-source drugs; for multiple-source drugs, denies professional claims; pays institutional and 340B claims regardless of NDCs
LA <sup>1</sup>	For professional claims only	No NDC required for institutional claims	Denies professional claims only
ME <sup>2</sup>	All physician-administered drugs for professional claims; only the top 20 multiple-source, physician-administered drugs for institutional claims	No NDC required for institutional claims for single-source drugs	Except for single-source institutional claims, denies the claims
MI <sup>3</sup>	All single-source drug claims and multiple-source outpatient claims	Yes	Denies all single-source drug claims; denies professional claims for multiple-source drugs (but pays institutional claims for multiple-source drugs)
MO	All outpatient physician-administered drugs and the top 20 inpatient drugs	Yes	Crosswalks the HCPCS to the NDC for single-source drugs; in certain cases, pays providers on a HCPCS with no NDC for multiple-source drugs
NE	All physician-administered drugs if an NDC is submitted	Yes	Crosswalks the HCPCS to the NDC for single-source drugs; for multiple-source drugs, attempts to contact provider for the NDC; otherwise, pays the claim and collects no rebate
NJ <sup>4</sup>	All physician-administered drugs if an NDC is submitted	No NDC required for institutional claims	Denies professional claims only
NM <sup>5</sup>	All physician-administered drugs if an NDC is submitted	No NDC required	Crosswalks the HCPCS to the NDC for single-source drugs; for multiple-source drugs, attempts to contact provider for the NDC; otherwise, pays the claim and collects no rebate

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Table B-2: Detailed Description of Responses From States That Reported Not Meeting the DRA’s Rebate Requirements for Physician-Administered Drugs as of June 2009 (Continued)

State	Physician-Administered Drugs for Which States Collected Rebates in the First Half of 2009	Did the State Require National Drug Codes on Physician-Administered Drug Claims as of June 2009?	State’s Action When a National Drug Code Was Not Included on a Claim as of June 2009
NY <sup>6</sup>	All single-source and the 20 highest dollar volume multiple-source drugs if an NDC is submitted	No NDC required	Crosswalks the HCPCS to the NDC for single-source drugs; for multiple-source drugs, pays the claim and collects no rebate
OR <sup>7</sup>	All single-source drugs only	Yes	Crosswalks the HCPCS to the NDC for single-source drugs (no edit that denies physician-administered drug claims)
TN	Physician-administered drugs if an NDC is submitted	Yes	Pays the claim, but does not invoice for a rebate
TX	Outpatient claims only	Yes	Crosswalks to the NDC for single-source drugs; denies claims for multiple-source drugs

Source: OIG analysis of State survey responses, 2010.

<sup>1</sup> For institutional claims, Louisiana reported that it required NDCs and began to deny institutional claims without NDCs on July 6, 2009; the State reported invoicing manufacturers for rebates on institutional claims in the third quarter of 2009.

<sup>2</sup> Maine reported that it had plans to deny institutional claims in April 2010.

<sup>3</sup> Michigan reported that it anticipates having an edit to deny institutional claims in the first quarter of 2010.

<sup>4</sup> New Jersey reported that it required NDCs for institutional claims and began denying those without NDCs on November 1, 2009.

<sup>5</sup> New Mexico reported that it had plans to begin denying claims in September 2010.

<sup>6</sup> New York reported that it required NDCs and began denying claims without NDCs in September 2009.

<sup>7</sup> Oregon reported that it had plans to deny claims beginning in the first quarter of 2011.

▶ A P P E N D I X ~ C

Physician-Administered Drug Data Reported by States for the First Half of 2009

Table C-1: Data Reported by States With Complete First- and Second-Quarter 2009 Rebate Collection Information for Physician-Administered Drugs

State	Amount Reimbursed	Rebates Requested	Rebates Collected
AR	\$4,048,745	\$1,289,196	\$500,913
CA <sup>1</sup>	\$161,713,669	\$9,493,609	\$6,126,611
CO	\$43,629,213	\$2,321,421	\$1,367,797
GA	\$32,903,117	\$14,277,592	\$12,899,334
IA	\$7,066,332	\$1,329,335	\$1,194,332
IN	\$49,896,247	\$16,025,453	\$5,173,816
KS	\$12,671,634	\$3,573,547	\$3,185,071
LA	\$31,769,620	\$3,355,007	\$2,791,403
MA	\$673,636	\$1,894,216	\$649,389
MD	\$502,569	\$216,153	\$75,401
ME <sup>2</sup>	\$2,734,419	\$1,293,708	\$1,129,499
MN	\$11,762,804	\$4,318,050	\$3,470,199
MS	\$8,904,654	\$5,731,922	\$2,857,323
MT	\$4,204,705	\$1,047,235	\$897,013
NC	\$43,420,571	\$14,763,273	\$13,134,910
ND	\$1,948,523	\$1,245,305	\$548,465
NM	\$1,621,813	\$261,676	\$245,420
NY	\$17,228,950	\$7,193,340	\$6,425,807
OH	\$12,761,519	\$1,671,643	\$1,644,731
OR	\$4,031,303	\$4,538,946	\$240,682
TN	\$32,793,117	\$20,500,859	\$19,278,252
UT	\$7,869,410	\$1,434,168	\$1,212,263

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Table C-1: Data Reported by States With Complete First- and Second-Quarter 2009 Rebate Collection Information for Physician-Administered Drugs (Continued)

State	Amount Reimbursed	Rebates Requested	Rebates Collected
WA <sup>3</sup>	\$14,550,089	\$1,192,532	\$706,330
WI	\$59,564,540	\$25,411,782	\$24,820,264
WV	\$8,070,634	\$3,832,915	\$1,275,701
WY	\$832,546	\$235,942	\$215,897
<b>Total<sup>4</sup></b>	<b>\$577,174,377</b>	<b>\$148,448,829</b>	<b>\$112,066,822</b>

Source: Office of Inspector General (OIG) analysis of State rebate data, 2010.

<sup>1</sup> In the first quarter of 2009, California was collecting rebates only for single-source, physician-administered drugs.

<sup>2</sup> At the time of our data collection, Maine was still invoicing for rebates applicable to second-quarter 2009 institutional claims.

<sup>3</sup> At the time of our data request, Washington had not invoiced manufacturers for second-quarter 2009 rebates.

<sup>4</sup> Figures do not add to totals because of rounding.

Note: For certain States, the rebates requested exceed the amounts reimbursed. These States reported that this may occur, for example, when the rebate rate is greater than what they pay in reimbursement or because the reimbursement amount does not include third-party liabilities, copays, etc. The State can invoice for the full rebate amount, which may include these figures.

A P P E N D I X ~ C

Table C-2: Data Reported by States Without Complete First- and Second-Quarter 2009 Rebate Collection Information for Physician-Administered

State	Amount Reimbursed	Rebates Requested	Rebates Collected	Reason for Missing Data
AK	\$23,430,017	\$1,407,365	DK <sup>1</sup>	Could not differentiate between physician-administered and all other Medicaid claims, but provided an estimated rebate collection rate of nearly 100 percent
AL	\$8,973,445	\$2,651,094	DK	Could not differentiate between physician-administered and all other Medicaid claims
CT	DK	\$6,551,347	DK	Could not differentiate between physician-administered and all other Medicaid claims, but provided an estimated rebate collection rate of 67 percent
DE	\$1,683,131	\$216,430	DK	Could not differentiate between physician-administered and all other Medicaid claims
FL	\$46,127,270	\$19,563,323	DK	Documented some of the rebates collected
ID	\$3,837,264	DK	DK	Did not document any rebates requested or collected
KY	\$14,780,463	\$1,272,449	DK	Could not differentiate between physician-administered and all other Medicaid claims, but provided an estimated rebate collection rate of nearly 100 percent
MI	\$30,647,239	\$8,720,352	DK	Could not differentiate between physician-administered and all other Medicaid claims, but provided an estimated rebate collection rate of nearly 98 percent
MO	\$16,881,431	DK	DK	Could not differentiate between physician-administered and all other Medicaid claims
NE <sup>2</sup>	\$3,641,198	DK	DK	Reported unit conversion inaccuracies in the rebate data, but working with manufacturers to make adjustments
NH	\$14,960,227	\$1,205,831	DK	Could not differentiate between physician-administered and all other Medicaid claims, but provided an estimated rebate collection rate of nearly 100 percent
NJ	\$3,514,685	DK	DK	For rebates requested, reported inaccuracies with the data; for rebates collected, could not differentiate between physician-administered and all other Medicaid claims

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Table C-2: Data Reported by States Without Complete First- and Second-Quarter 2009 Rebate Collection Information for Physician-Administered Drugs (Continued)

State	Amount Reimbursed	Rebates Requested	Rebates Collected	Reason for Missing Data
NV	DK	DK	DK	Could not differentiate between physician-administered and all other Medicaid claims for reimbursement and rebates requested; rebates collected amount was an estimate
OK	DK	DK	DK	Could not differentiate between physician-administered and all other Medicaid claims
SC	\$114,155,241	\$6,901,292	DK	Could not differentiate between physician-administered and all other Medicaid claims
SD	\$1,388,505	\$1,052,284	DK	Could not readily determine rebates collected
TX	\$56,645,451	DK	DK	Reported unit conversion inaccuracies in the rebate data
VA	\$12,280,254	\$6,954,167	DK	Could not differentiate between physician-administered and all other Medicaid claims, but provided an estimated rebate collection rate of nearly 100 percent
VT	\$1,651,481	\$487,043	DK	Could not differentiate between physician-administered and all other Medicaid claims
<b>Total</b>	<b>\$354,597,303</b>	<b>\$56,982,977</b>	<b>Could not determine</b>	

Source: OIG analysis of State rebate data, 2010.

<sup>1</sup> DK = State could not determine the data requested.

<sup>2</sup> The amount reimbursed is only for the first quarter of 2009. In addition, Nebraska had yet to receive any rebate payments for the first quarter of 2009 and had not invoiced for second-quarter 2009 rebates at the time of our request.

Table C-3: Data Reported by States That Did Not Invoice for Physician-Administered Drug Rebates During the First and Second Quarters of 2009

State	Amount Reimbursed	Rebates Requested	Rebates Collected	Reason for Missing Data
DC	\$999,379	\$0	\$0	Did not collect rebates
IL	\$47,461,395	\$0	\$0	At the time of this study, this State had not yet billed first- and second-quarter 2009 rebates
RI	\$3,497,104	\$0 <sup>1</sup>	\$0	At the time of this study, this State had not yet billed first- and second-quarter 2009 rebates
<b>Total</b>	<b>\$51,957,878</b>	<b>\$0</b>	<b>\$0</b>	

Source: OIG analysis of State rebate data, 2010.

<sup>1</sup> This State estimated that \$550,000 in rebates for physician-administered drugs will be invoiced for the first and second quarters of 2009.

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

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*Administrator*  
Washington, DC 20201

Centers for Medicare & Medicaid Services

**DATE:** MAR 23 2011

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

**FROM:** Donald M. Berwick, M.D. /S/  
Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: "States' Collection of Medicaid Rebates for Physician-Administered Drugs" (OEI-03-09-00410)

Thank you for the opportunity to review and comment on the subject OIG draft report. The purpose of this report was to determine the compliance of States with the Medicaid drug rebate requirements for physician-administered drugs.

The Deficit Reduction Act of 2005 (DRA) specifically requires that States collect rebates on claims for certain physician-administered drugs for Federal matching funds to be available. The DRA also mandated that claims for physician-administered drugs include national drug codes (NDCs), thereby allowing States to invoice manufacturers that are responsible for paying rebates. Since the passage of the DRA, the Centers for Medicare & Medicaid Services (CMS) has taken many steps to ensure that States are meeting the new rebate requirements for physician-administered drugs.

**OIG Findings**

The OIG found that as of June 2009, 42 of 49 responding States reported meeting the DRA's requirement to collect NDCs on claims for physician-administered drugs. The findings noted that States may have collected NDCs for physician-administered drugs and still not have met the DRA's rebate collection requirements. By June 2009, 73 percent of responding States reported meeting or exceeding the DRA's requirement to collect rebates for certain physician-administered drugs. Specifically, 36 of 49 responding States reported collecting rebates on all single-source physician-administered drugs and the 20 multiple source physician-administered drugs with the highest dollar volume, as required by the DRA. An additional 12 States reported collecting rebates on a subset of physician-administered drugs, but were not in full compliance with the DRA's rebate requirements. Only 1 State reported that it did not collect rebates on any physician-administered drugs.

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The OIG also noted that incomplete and potentially inaccurate data provided by States inhibited the determination of the financial impact of collecting rebates for these drugs. For the first and second quarters of 2009, the 26 States that provided complete rebate data reported recouping between 3 percent and 96 percent of the amount paid for physician-administered drugs in rebates. States also varied widely in the amount they reported spending on physician-administered drugs and the percentage of rebates they reported requesting.

During the first and second quarters of 2009, 26 States that provided complete data reported paying \$577 million for physician-administered drugs, requesting \$148 million in rebates, and collecting \$112 million in rebates for these drugs. An additional 19 States that reported paying approximately \$355 million for physician-administered drugs in the first and second quarters of 2009 either could not provide data on the amount of rebates collected or reported accuracy issues with the collections data that they provided. Three additional States did not provide rebate data, because they had not invoiced manufacturers for the first half of 2009 rebates for physician-administered drugs.

In addition, 29 States reported having difficulties with manufacturers not paying all of the requested rebates for physician-administered drugs. According to 21 States, these difficulties were mainly attributed to providers entering incorrect NDC information. Additionally, manufacturers questioned the validity of the NDC or the number of units listed on the rebate invoice and requested additional information before making the rebate payment to the States. Seven States mentioned data issues with the CMS crosswalk file. Eighteen States reported that Medicare crossover claims for physician-administered drugs do not typically include NDCs. Twelve States described general problems with manufacturers refusing to make rebate payments or consistently disputing requested payments.

It was also found that 31 States did not have an edit to identify physician-administered drug claims submitted by 340B entities and/or did not require NDCs on 340B claims for physician-administered drugs when these drugs were purchased at the Medicaid rate and eligible for rebates. Consequently, these States were not able to adequately collect rebates on eligible physician-administered drugs purchased by 340B entities.

#### **OIG Recommendation**

Take action against States that do not meet the DRA's requirement to collect rebates on physician-administered drugs.

#### **CMS Response**

We concur that we need to learn more about the systematic problems that prevent these rebates from being collected and help States to begin collecting these rebates as soon as possible. To this end, we will continue to work with States to identify and reduce the barriers that impact the collection of manufacturer rebates for these drugs. We will reiterate these requirements in a release to the States, as well as provide technical assistance to the States. We further plan to look

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to those States that have successfully implemented these requirements to get advice to help those that need it. In the future, we may consider possibly withholding Federal financial participation for these claims as necessary; however, we anticipate that our further assistance to the States will result in the collection of rebates from drug manufacturers to which the State and Federal governments are entitled.

**OIG Recommendations**

Ensure that all State agencies are accurately identifying and collecting physician-administered drug rebates owed by manufacturers.

**CMS Response**

We concur and will reiterate these requirements in a release to States as well as provide technical assistance to the States.

**OIG Recommendation**

Work with States to develop guidance for implementing edits that increase the efficiency of physician-administered drug claim reviews.

**CMS Response**

We concur and we will also reiterate this rebate requirement in a State release, as well as provide technical assistance to the States.

**OIG Recommendation**

Administer guidance to providers and Medicare contractors about the rebate requirements for physician-administered drugs.

**CMS Response**

We appreciate the comment; however, we do not concur with this recommendation. CMS has issued guidance to the States regarding rebate requirements for physician-administered drugs through the Notice of Proposed Rule Making and the follow-up comments and responses in the Final Rule published July 17, 2007, implementing the relevant provisions of the DRA. However, we have generally held to the practice that direct provider communication is within the purview of the States, and we have left that responsibility to them. Medicare contractors are aware through *Med Learn Matters* and have established procedures to accept the NDC number information on paper claims, and automatically accept the NDC numbers on electronic claims. We will reiterate this rebate requirement in a State release, as well as provide technical assistance to the States.

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**OIG Recommendation**

Ensure that the crosswalk file is complete and accurate, and contains a way to identify rebateable physician-administered drugs.

**CMS Response**

We appreciate the comment; however, we do not concur with this recommendation. We believe that the crosswalk is not needed to properly collect rebates for these drugs. NDC numbers cannot always be properly identified from the crosswalk, since there may be multiple NDC numbers for each Healthcare Common Procedure Coding System code. However, the Medicaid provider is required to record the NDC number of the product used at the time of drug administration and submit that on the Medicaid claim. If a State has these proper edits in place, it will ensure that a valid Medicaid claim contains the necessary information to obtain rebates. If such edit is in place, a NDC can then be matched to that list of manufacturers participating in the Medicaid drug rebate program. We will reiterate this rebate requirement in a State release, as well as provide technical assistance to the States.

The CMS would again like to thank the OIG for its efforts in reviewing the compliance of States' participation in the Medicaid drug rebate program for physician-administered drugs.



## 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 of the Medicare and Medicaid Prescription Drug Unit.

Stephanie Yeager served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to the report include Kevin McAloon. Central office staff who contributed include Kevin Manley and Arianne Spaccarelli.

# *Office of Inspector General*

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