

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**ILLINOIS CLAIMED UNALLOWABLE  
FEDERAL REIMBURSEMENT FOR SOME  
MEDICAID PHYSICIAN-ADMINISTERED  
DRUGS**

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# *Office of Inspector General*

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## Report in Brief

Date: June 2019

Report No. A-05-18-00030

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**



### Why OIG Did This Review

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. However, prior OIG reviews found that States did not always invoice and collect all rebates due for drugs administered by physicians.

Our objective was to determine whether Illinois complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

### How OIG Did This Review

Our review covered physician-administered drug claims that were paid by Illinois for the period October 1, 2015, through September 30, 2017.

We used the Centers for Medicare & Medicaid Services (CMS) Medicaid Drug File and CMS's Medicare Part B crosswalk to identify single-source drug and multiple-source drugs. Additionally, we determined whether the National Drug Code (NDC) or Healthcare Common Procedure Coding System codes were published in CMS's top-20 multiple-source drug listing.

## Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs

### What OIG Found

Illinois did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Illinois did not invoice manufacturers for rebates associated with \$4.1 million (Federal share) in physician-administered drugs. Of this amount, \$4.0 million was for single-source drugs, and \$32,620 was for top-20 multiple-source drugs. Because Illinois' internal controls did not always ensure that it invoiced manufacturers to secure rebates, Illinois improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

Further, Illinois did not submit the drug utilization data necessary to secure rebates for other physician-administered drugs, totaling \$258,640 (Federal share), that did not have NDCs or had invalid NDCs.

### What OIG Recommends and Illinois Comments

We recommend that Illinois refund \$4.1 million and work with CMS to determine the proper resolution of the \$258,640 for the other drug claims in question.

We also made procedural recommendations.

In written comments on our draft report, Illinois concurred with our recommendations. Illinois stated that it will continue to work through the outstanding claims to determine those that can be invoiced and will work with CMS to determine the final dollar amount to be returned. Illinois said that it will review and create stronger internal controls to ensure that all eligible physician-administered drugs are invoiced for rebate.

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## INTRODUCTION

### WHY WE DID THIS REVIEW

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. States generally offset their Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, previous Office of Inspector General (OIG) reviews found that States did not always invoice and collect all rebates due for drugs administered by physicians to fee-for-service enrollees. (Appendix B lists previous OIG reports related to the Medicaid drug rebate program.<sup>1</sup>) For this audit, we reviewed the Illinois Department of Healthcare and Family Services' (State agency's) invoicing for rebates for physician-administered drugs for the period October 1, 2015, through September 30, 2017 (audit period).

### OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

### BACKGROUND

#### Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each have specific functions under the program.

Manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price.<sup>2</sup> On the basis of this information, CMS calculates a unit rebate amount for each drug and provides the information to the States quarterly. Covered outpatient drugs reported by participating drug manufacturers are listed in the CMS Medicaid Drug File, which identifies drugs with such fields as National Drug Code (NDC), unit type, package size, and product name.

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for invoicing manufacturers for rebates as described in section 1927

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<sup>1</sup> OIG performed similar reviews for rebates due for drugs administered by physicians to enrollees of Medicaid managed-care organizations. These reviews are included in this appendix.

<sup>2</sup> Section 1927(b) of the Act and section II of the Medicaid rebate agreement.

of the Act. To invoice for rebates, States capture drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers and report the information to the manufacturers (the Act § 1927(b)(2)(A)). The number of units is multiplied by the unit rebate amount to determine the actual rebate amount due from each manufacturer.

States report drug rebate accounts receivable data to CMS on the Medicaid Drug Rebate Schedule. This schedule is part of the Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program report, which contains a summary of actual Medicaid expenditures for each quarter and which CMS uses to reimburse States for the Federal share of Medicaid expenditures.

### **Physician-Administered Drugs**

Drugs administered by a physician are typically invoiced to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.<sup>3</sup> For purposes of the Medicaid drug rebate program, physician-administered drugs are classified as either single-source or multiple-source.<sup>4</sup>

The Deficit Reduction Act of 2005 (DRA) amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source physician-administered drugs and for the top-20 multiple-source physician-administered drugs.<sup>5</sup> Beginning January 1, 2007, CMS was responsible for publishing annually the list of the top-20 multiple-source drugs by HCPCS codes that had the highest dollar volume dispensed. Before the DRA, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. NDCs enable States to identify the drugs and their manufacturers and facilitate the collection of rebates for the drugs.

### **The State Agency's Medicaid Drug Rebate Program**

The State agency is responsible for paying claims, submitting invoices to manufacturers, and collecting Medicaid drug rebates for physician-administered drugs. The State agency also requires physician-administered drug claims to be submitted with the NDC of the product.

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<sup>3</sup> HCPCS codes (sometimes referred to as “J-Codes”) are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

<sup>4</sup> See, e.g., section 1927(a)(7) of the Act. In general terms, multiple-source drugs are covered outpatient drugs for which there are two or more drug products that the U.S. Food & Drug Administration rates as therapeutically equivalent. See, e.g., section 1927(k)(7) of the Act. Single-source drugs do not have therapeutic equivalents.

<sup>5</sup> The term “top-20 multiple-source drugs” is a CMS classification and describes these drugs in terms of highest dollar volume of physician-administered drugs in Medicaid (the Act § 1927(a)(7)(B)(i)).

The State agency used claim utilization data for physician-administered drugs, which it derives from claims submitted by providers, to invoice manufacturers quarterly and to maintain a record of rebate accounts receivable due from the manufacturers. The manufacturers then pay the rebates directly to the State agency.

## **HOW WE CONDUCTED THIS REVIEW**

Our review covered physician-administered drug claims that were paid by the State agency for the period October 1, 2015, through September 30, 2017.

We used the CMS Medicaid Drug File to determine whether each NDC listed on the claims was classified as a single-source drug or multiple-source drug. If the NDC was not listed on the claim, we used CMS's Medicare Part B crosswalk to identify, if possible, the NDC associated with each HCPCS code listed on the claims from providers.<sup>6</sup> Additionally, we determined whether the NDC or HCPCS codes were published in CMS's top-20 multiple-source drug listing.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology.

## **FINDINGS**

The State agency did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. The State agency did not invoice manufacturers for rebates associated with \$7.7 million (\$4.1 million Federal share)<sup>7</sup> in physician-administered drugs. Of this amount, \$7.6 million (\$4.0 million Federal share)<sup>8</sup> was for single-source drugs, and \$63,591 (\$32,620 Federal share) was for top-20 multiple-source drugs. Because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

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<sup>6</sup> CMS publishes the Medicare Part B crosswalk quarterly; it is based on published drug and biological pricing data and information that manufacturers submit to CMS. The crosswalk contains the payment amounts that will be used to pay for Part B-covered drugs as well as the HCPCS codes associated with those drugs. CMS instructed States that they could use the crosswalk as a reference because HCPCS codes and NDCs are standardized codes used across health care programs.

<sup>7</sup> The actual numbers are \$7,668,658 and \$4,065,188, respectively.

<sup>8</sup> The actual numbers are \$7,605,067 and \$4,032,568, respectively.



Further, the State agency did not submit the drug utilization data necessary to secure rebates for other physician-administered drugs. Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, providers submitted claims totaling \$503,950 (\$258,640 Federal share) that did not have NDCs or had invalid NDCs. We were unable to determine whether the State agency was required to invoice for rebates for these other physician-administered drug claims.

## **FEDERAL REQUIREMENTS AND STATE AGENCY GUIDANCE**

The DRA amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. States must capture NDCs for single-source and top-20 multiple-source drugs (the Act § 1927(a)(7)). To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)). Federal regulations prohibit Federal reimbursement for physician-administered drugs for which a State has not required the submission of claims containing the NDCs (42 CFR § 447.520).

In a December 2007 policy update to Illinois Medical providers, the State agency stated that providers must report the NDC in conjunction with the HCPCS codes on all professional claims for physician-administered drugs. If a provider does not report the NDC on a claim, the claim will be rejected.

Appendix C contains Federal requirements and State agency guidance related to physician-administered drugs.

### **THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME SINGLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS**

The State agency improperly claimed Federal reimbursement of \$7.6 million (\$4.0 million Federal share) for single-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Because the State agency did not submit utilization data to the manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these single-source physician-administered drugs.

### **THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME TOP-20 MULTIPLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS**

The State agency improperly claimed Federal reimbursement of \$63,591 (\$32,620 Federal share) for top-20 multiple-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Before 2012, CMS provided the State agency with an annual listing of top-20 multiple-source HCPCS codes and their respective NDCs. However, the State agency did not always submit the utilization data to the drug manufacturers for rebate purposes.

Because the State agency did not submit utilization data to the manufacturers to secure rebates, the State agency improperly claimed Federal reimbursement for these top-20 multiple-source physician-administered drugs.

### **THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON OTHER PHYSICIAN-ADMINISTERED DRUGS**

We were unable to determine whether, in some cases, the State agency was required to invoice for rebates for other physician-administered drug claims.

Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with other physician-administered drug claims, providers submitted claims, totaling \$503,950 (\$258,640 Federal share), that did not have NDCs or had invalid NDCs. We were unable to determine whether the State agency improperly claimed Federal reimbursement for the physician-administered drugs associated with these claims.

### **RECOMMENDATIONS**

We recommend that the State agency:

- refund to the Federal Government \$4,032,568 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$32,620 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;
- work with CMS to determine the unallowable portion of \$258,640 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs or had invalid NDCs and that may have been ineligible for Federal reimbursement and refund that amount;
- work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after September 30, 2017; and
- strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

## STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with our recommendations. The State agency stated that it will continue to work through the outstanding claims to determine those that can be invoiced and will work with CMS to determine the final dollar amount to be returned. The State agency said that it will review and create stronger internal controls to ensure that all eligible physician-administered drugs are invoiced for rebate. The State agency's comments appear in their entirety in Appendix D.

## **APPENDIX A: AUDIT SCOPE AND METHODOLOGY**

### **SCOPE**

Our review covered physician-administered drug claims that were paid by the State agency for the period October 1, 2015, through September 30, 2017.

Our audit objective did not require an understanding or assessment of the complete internal control structure of the State agency. We limited our internal control review to obtaining an understanding of the State agency's processes for reimbursing physician-administered drug claims and its process for claiming and obtaining Medicaid drug rebates for physician-administered drugs.

We performed our fieldwork from April 2018 through December 2018, which included contacting the State agency office in Springfield, Illinois.

### **METHODOLOGY**

To accomplish our objective, we took the following steps:

- We reviewed applicable Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs.
- We reviewed State agency regulations and guidance to providers, including invoicing instructions for physician-administered drugs.
- We reviewed State agency policies and procedures for rebates for physician-administered drugs.
- We interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid invoicing and rebate process for physician-administered drugs.
- We obtained listings of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk, and the CMS Medicaid Drug File for our audit period.
- We obtained claim details from the State agency for all physician-administered drugs for the period October 1, 2015, through September 30, 2017.
- We removed drug claims, totaling \$87,500,589, that either were not eligible for a drug rebate or were invoiced for rebate.

- We reviewed the remaining drug claims to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically:
  - We identified single-source drugs by matching the NDC on the drug claim to the NDC on the CMS Medicaid Drug File. If the NDC was not on the drug claim, we identified single-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify, if possible, the NDC associated with each HCPCS code listed on claims from providers. We used the CMS Medicaid Drug File to determine whether these NDCs were classified as single-source drugs.
  - We identified the top-20 multiple-source drugs by matching the NDC or HCPCS code on the drug claim to the NDC or HCPCS code on CMS's top-20 multiple-source drug listing.
  - We identified the remaining drugs (ones that were not identified as single-source or as top-20 multiple-source drugs) as other outpatient physician-administered drugs.
- We discussed the results of our review with State agency officials on December 12, 2018, and February 14, 2019.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

**APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS**

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-02-16-01012</u></a>	5/09/19
<i>Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-05-17-00038</u></a>	4/05/19
<i>Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-09-16-02031</u></a>	2/16/18
<i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-06-16-00018</u></a>	2/12/18
<i>Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-07-13-06046</u></a>	12/22/17
<i>Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-06-16-00004</u></a>	12/12/17
<i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-05-16-00013</u></a>	11/01/17
<i>Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-09-16-02028</u></a>	9/26/17
<i>Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-09-16-02029</u></a>	9/26/17
<i>Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-09-16-02027</u></a>	9/12/17
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-07-16-06065</u></a>	5/05/17
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-05-16-00014</u></a>	3/23/17

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06050</u></a>	1/05/17
<i>Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-03-15-00202</u></a>	12/30/16
<i>Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-03-15-00201</u></a>	12/22/16
<i>California Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-09-15-02035</u></a>	12/08/16
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-07-15-06060</u></a>	8/18/16
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06057</u></a>	5/26/16
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06063</u></a>	3/31/16
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06059</u></a>	2/09/16
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06062</u></a>	1/14/16
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-15-06058</u></a>	1/13/16
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<a href="#"><u>A-09-14-02038</u></a>	1/07/16
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06056</u></a>	9/18/15

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-14-06049</a>	7/22/15
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-06-12-00060</a>	5/04/15
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-14-06051</a>	4/13/15
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#">A-09-13-02037</a>	3/04/15
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<a href="#">A-06-14-00031</a>	2/10/15
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-03-12-00205</a>	8/21/14
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-13-06040</a>	8/07/14
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-09-12-02079</a>	4/30/14
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<a href="#">A-09-12-02080</a>	4/24/14
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-03-12-00200</a>	11/26/13
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<a href="#">A-06-12-00059</a>	9/19/13
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<a href="#">A-06-10-00011</a>	8/12/11



<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<a href="#">OEI-03-09-00410</a>	6/24/11

## **APPENDIX C: FEDERAL REQUIREMENTS AND STATE AGENCY GUIDANCE RELATED TO PHYSICIAN-ADMINISTERED DRUGS**

### **FEDERAL LAWS**

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). Section 1903(a) of the Act provides for Federal financial participation (Federal share) in State expenditures for these drugs. The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 that added section 1927 to the Act, became effective on January 1, 1991. Manufacturers must enter into a rebate agreement with the Secretary of the U.S. Department of Health and Human Services (HHS) and pay rebates for States to receive Federal funding for the manufacturers' covered outpatient drugs dispensed to Medicaid patients (the Act § 1927(a)). Manufacturers, CMS, and the States share responsibility for the drug rebate program.

Section 6002 of the DRA added section 1927(a)(7) to the Act to require that States capture information necessary to secure rebates from manufacturers for certain covered outpatient drugs administered by a physician. In addition, section 6002 of the DRA amended section 1903(i)(10) of the Act to prohibit Medicaid Federal share for covered outpatient drugs administered by a physician unless the States collect the utilization and coding data described in section 1927(a)(7) of the Act.

Section 1927(a)(7) of the Act requires States to provide for the collection and submission of such utilization data and coding (such as J-codes and NDCs) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug to secure rebates for all single-source physician-administered drugs effective January 1, 2006, and for the top-20 multiple-source drugs effective January 1, 2008. Section 1927(a)(7)(C) of the Act states that, effective January 1, 2007, the utilization data must be submitted using the NDC. To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)).

Section 1927(a)(7)(D) of the Act allowed HHS to delay any of the above requirements to prevent hardship to States that required additional time to implement the physician-administered drug reporting requirements.

### **FEDERAL REGULATIONS**

Federal regulations set conditions for States to obtain a Federal share for covered outpatient drugs administered by a physician and specify that no Federal share is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to invoice a manufacturer for rebates (42 CFR § 447.520).

## STATE AGENCY GUIDANCE

The State agency provider notice, dated December 21, 2007, states:

### **Requirements for Reporting of the National Drug Code (NDC) on Professional Claims**

This notice is an important reminder of the requirements for reporting of the NDC code on all professional claims for physician-administered or dispensed drugs. The NDC reporting requirement will be implemented effective with dates of service on and after January 1, 2008, when billing on the 837P, HFS 2360, HFS 1443 or the HFS 3797. Professional claims that do not meet the NDC reporting requirements will reject beginning with dates of service January 1, 2008. This notice supersedes the previous notices on the NDC requirement issued on October 19, 2007, March 29, 2007, and June 16, 2005. Providers are encouraged to read this notice thoroughly and contact the department with any questions.

As you are aware, the Federal Deficit Reduction Act of 2005 requires all State Medicaid Agencies to collect rebates from drug manufacturers for physician-administered or dispensed drugs. This includes physician-administered or dispensed drugs given in a physician's office or a hospital outpatient department. This requirement also applies to Medicare crossover claims.

The department will continue to reimburse providers based on the HCPCS procedure code and HCPCS procedure code units billed. However, effective with dates of service January 1, 2008, the NDC must be reported in conjunction with the HCPCS. If the NDC is not reported, the claim will reject.

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May 8, 2019

Department of Health and Human Services  
Office of Audit Services, Region V  
Attn: Sheri L. Fulcher, Regional Inspector General for Audit Services  
223 North Michigan Avenue, Suite 1360  
Chicago, IL 60601

Re: Draft Audit Report A-05-18-0030

Dear Ms. Fulcher:

Thank you for providing the opportunity to comment on your draft audit report entitled "Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs".

The Department concurs with the recommendations noted in the draft audit report. In regard to recommendations 1 and 2, the Department continues to work through the outstanding claims to determine those that can be invoiced with information captured in the claim. We will continue to invoice the claims in the findings and once we have invoiced all claims possible, we would then like to work with CMS to determine a final dollar amount to be returned.

In regard to recommendations 3 through 5, we will work with CMS to determine the unallowable portion for the drugs that had either no NDC, or invalid NDCs and provide the appropriate Federal reimbursement. We will also continue to work with CMS to determine the amount of CMS reimbursement for drugs that were not invoiced for rebates after September 30, 2017. Finally, we will review and create stronger internal controls to ensure that all eligible physician administered drugs are invoiced.

We appreciate the work completed by your audit team and the open lines of communication with HFS staff throughout this audit. If you have any questions or comments about our response to the audit, please contact Amy Lyons, External Audit Liaison, and (217) 558-4347 or through email at [amy.lyons@illinois.gov](mailto:amy.lyons@illinois.gov).

Sincerely,

/Doug Elwell/

Doug Elwell  
Medicaid Administrator

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