

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**NORTH DAKOTA  
CORRECTLY CLAIMED  
FEDERAL REIMBURSEMENT  
FOR MOST MEDICAID  
PHYSICIAN-ADMINISTERED DRUGS**

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# *Office of Inspector General*

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## EXECUTIVE SUMMARY

*North Dakota claimed \$79,000 over 3 years in Federal reimbursement that was unallowable because it did not comply with Federal Medicaid requirements for invoicing manufacturers for rebates for some physician-administered drugs.*

### 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, a prior Office of Inspector General review found that States did not always invoice and collect all rebates due for drugs administered by physicians. For this audit, we reviewed the North Dakota Department of Human Services (State agency), invoicing for rebates for physician-administered drugs for the period January 1, 2011, through December 31, 2013.

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

### BACKGROUND

The Medicaid drug rebate program became effective in 1991 (the Social Security Act § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the 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. The Deficit Reduction Act of 2005 amended section 1927 of the Social Security Act to specifically address the collection of rebates on certain physician-administered drugs. To collect these rebates, States submit to the manufacturers the drug utilization data containing National Drug Codes (NDCs) for all single-source physician-administered drugs and for the top 20 multiple-source physician-administered drugs. Federal reimbursement for covered outpatient drugs administered by a physician is not available to States that do not comply with Federal requirements for capturing NDCs to invoice and collect rebates.

The State agency is responsible for paying claims, submitting invoices to manufacturers, and collecting Medicaid drug rebates for physician-administered drugs. The State agency uses its 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.

### WHAT WE FOUND

Although the State agency generally complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs, it claimed unallowable Federal reimbursement for some of these drugs. The State agency did not invoice manufacturers for rebates associated with \$138,094 (\$78,736 Federal share) in physician-administered drugs. Of

this amount, \$136,738 (\$78,006 Federal share) was for single-source drugs, and \$1,356 (\$730 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.

Further, the State agency did not submit the utilization data necessary to secure rebates for all other physician-administered drugs. The State agency collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, but it did not invoice the manufacturers for rebates for these other physician-administered drugs. Under the Medicaid drug rebate program, claims totaling \$521,406 (\$302,512 Federal share) that were associated with these other physician-administered drugs could have been eligible for rebates. Accordingly, we set aside the \$521,406 (\$302,512 Federal share) and are recommending that the State agency work with CMS to determine whether these claims could have been invoiced to the manufacturers for rebates.

## **WHAT WE RECOMMEND**

We recommend that the State agency:

- refund to the Federal Government \$78,006 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$730 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;
- work with CMS to determine whether \$302,512 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims; 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 all of our recommendations and described actions that it had taken or planned to take.

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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, a prior Office of Inspector General review found that States did not always invoice and collect all rebates due for drugs administered by physicians.<sup>1</sup> (Appendix A lists previous reviews of the Medicaid drug rebate program.) For this audit, we reviewed the North Dakota Department of Human Services (State agency), invoicing for rebates for physician-administered drugs for the period January 1, 2011, through December 31, 2013.

### 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 each quarter. 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, units per 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 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.

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<sup>1</sup> *States' Collection of Medicaid Rebates for Physician-Administered Drugs* (OEI-03-09-00410), issued June 24, 2011.

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

States report drug rebate accounts receivable data to CMS on the Medicaid Drug Rebate Schedule. This schedule is part of the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program report, which contains a summary of actual Medicaid expenditures for each quarter and is used by CMS 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 on 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 all physician-administered drug claims to be submitted with the NDC of the product. The State agency uses its 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**

The State agency claimed \$13,809,613 (\$7,994,327 Federal share) for physician-administered drugs paid between January 1, 2011, and December 31, 2013.

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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 are rated therapeutically equivalent by the FDA. See, e.g., section 1927(k)(7) of the Act. Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents.

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

We used the CMS Medicaid Drug File to determine whether the NDCs listed on the claims were classified as single-source drugs or multi-source drugs.

We used CMS's Medicare Part B crosswalk to identify, if possible, the NDCs associated with each HCPCS code listed on claims from providers. We then used the CMS Medicaid Drug File to determine whether the identified NDCs were classified as single-source drugs or multiple-source drugs.<sup>6</sup> Additionally, we determined whether the 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 B contains the details of our audit scope and methodology.

## FINDINGS

Although the State agency generally complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs, it claimed unallowable Federal reimbursement for some of these drugs. The State agency did not invoice manufacturers for rebates associated with \$138,094 (\$78,736 Federal share) in physician-administered drugs. Of this amount, \$136,738 (\$78,006 Federal share) was for single-source drugs, and \$1,356 (\$730 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.

Further, the State agency did not submit the utilization data necessary to secure rebates for all other physician-administered drugs. The State agency collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, but it did not invoice the manufacturers for rebates for these other physician-administered drugs. Under the Medicaid drug rebate program, claims totaling \$521,406 (\$302,512 Federal share) that were associated with these other physician-administered drugs could have been eligible for rebates. Accordingly, we set aside the \$521,406 (\$302,512 Federal share) and are recommending that the State agency work with CMS to determine whether these claims could have been invoiced to the manufacturers for rebates.

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<sup>6</sup> The Medicare Part B crosswalk is published quarterly by CMS and is based on published drug and biological pricing data and information submitted to CMS by manufacturers. It 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.

## **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).

A North Dakota Department of Human Services *Memorandum*, issued on July 25, 2007, notified providers that “[t]he requirement for NDC collection is a direct result of the rebates being based on NDC’s. The NDC identifies the manufacturer and product and is how rebates are invoiced. The J-code, unfortunately, does not identify the drug to that level.” This memorandum also stated that the requirement for NDC collection “... applies to any provider billing J-codes in an outpatient setting (physicians, clinics, hospitals)... [North Dakota] Medicaid will require these to be submitted electronically with the NDC, as well.” This memorandum specified that the NDC requirement would become effective on December 1, 2007, and added that after that date, claims would be denied if they lack an NDC, the NDC is invalid, or the NDC is not covered by the State agency.

Appendix C contains Federal and State requirements 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 \$136,738 (\$78,006 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 \$1,356 (\$730 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, on a yearly basis, with a 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**

The State agency did not submit the utilization data necessary to secure rebates for all other physician-administered drugs. The State agency collected the drug utilization data (including NDCs) necessary to invoice the manufacturers for rebates associated with these claims, but it did not invoice the manufacturers for rebates for these other physician-administered drugs. Under the Medicaid drug rebate program, claims totaling \$521,406 (\$302,512 Federal share) that were associated with these other physician-administered drugs could have been eligible for rebates. If the State agency would have invoiced these claims for rebate, the drug manufacturers would have been required to pay the rebates.

Accordingly, we set aside the \$521,406 (\$302,512 Federal share) and are recommending that the State agency work with CMS to determine whether these claims could have been invoiced to the manufacturers for rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

### **RECOMMENDATIONS**

We recommend that the State agency:

- refund to the Federal Government \$78,006 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$730 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;
- work with CMS to determine whether \$302,512 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims; 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 all of our recommendations and described corrective actions it had taken or planned to take. The State agency's comments appear in their entirety as Appendix D.

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

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

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<a href="#"><u>A-06-10-00011</u></a>	8/12/11
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<a href="#"><u>OEI-03-09-00410</u></a>	6/24/11

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

### **SCOPE**

The State agency claimed \$13,809,613 (\$7,994,327 Federal share) for physician-administered drugs paid between January 1, 2011, and December 31, 2013.

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 conducted our audit work, which included contacting the State agency in Bismarck, North Dakota, from November 2014 to July 2015.

### **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 interviewed CMS officials about the Federal requirements and guidance governing physician-administered drugs under the Medicaid drug rebate program.
- 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 drug claims, including physician-administered drugs, for the period January 1, 2011, through December 31, 2013.
- We removed drug claims totaling \$13,144,315 (\$7,609,851 Federal share) that either were not eligible for a drug rebate or contained an NDC and were invoiced for rebate.

- We reviewed the remaining drug claims totaling \$665,298 (\$384,476 Federal share) 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 CMS's Medicaid Drug File. For claims in which the claim's NDC did not match to the Drug File, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the drug classification.
  - We identified the top 20 multiple-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's top-20 multiple-source drug listing.
  - We removed drug claims totaling \$521,406 (\$302,512 Federal share) that we identified as multiple source physician-administered drugs that were not required to be rebated.
  - We removed additional drug claims totaling \$5,798 (\$3,228 Federal share) that were not eligible for drug rebates.
  
- We discussed the results of our review with State agency officials on July 8, 2015.

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 C: FEDERAL REQUIREMENTS AND STATE AGENCY REGULATIONS AND 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 Health and Human Services (HHS) and pay rebates for States to receive Federal funding for the manufacturer's covered outpatient drugs dispensed to Medicaid patients (the Act § 1927(a)). Responsibility for the drug rebate program is shared among the drug manufacturers, CMS, and the States.

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 that States shall provide for the collection and submission of such utilization data and coding (such as J-codes and NDC numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order 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 stated 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 REGULATIONS AND GUIDANCE

The *North Dakota Department of Human Services Provider Manual for Pharmacies*, “Manufacturer/Labeler Drug Rebate Agreement Program,” states (page 28): “The Omnibus Budget Reconciliation Act (OBRA) of 1990 requires that pharmaceutical manufacturers have a rebate agreement in effect with CMS for their pharmaceuticals to be reimbursed by Medicaid programs.”

The same section of the *North Dakota Department of Human Services Provider Manual for Pharmacies* states (page 28):

Manufacturer rebate payments to the state are based on prescription claims payment data identified by NDC number. To assure that the appropriate manufacturer is billed for the rebate, accurate records must be maintained by pharmacies. The actual NDC number on the package from which the medication is dispensed must be utilized on all pharmacy claims submitted for payment.

Inaccurate records may result in:

- The Medicaid agency billing the wrong manufacturer
- Disputes between the state and the manufacturer in the amount of rebate due
- An audit of the records of pharmacy providers which may result in false claims charges and reversals of payments.... [Emphasis in original.]

A North Dakota Department of Human Services *Memorandum*, issued on July 25, 2007, notified providers that “[t]he requirement for NDC collection is a direct result of the rebates being based on NDC’s. The NDC identifies the manufacturer and product and is how rebates are invoiced. The J-code, unfortunately, does not identify the drug to that level.” This memorandum also stated that the requirement for NDC collection “... applies to any provider billing J-codes in an outpatient setting (physicians, clinics, hospitals).... [North Dakota] Medicaid will require these to be submitted electronically with the NDC, as well.” This memorandum specified that the NDC requirement would become effective on December 1, 2007, and added that after that date, claims would be denied if they lack an NDC, the NDC is invalid, or the NDC is not covered by the State agency.



Jack Dalrymple, Governor  
 Maggie D. Anderson, Executive Director

December 14, 2015

Patrick J. Cogley  
 Regional Inspector General for Audit Services  
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Report Number: A-07-15-06058

Inspector Cogley,

North Dakota received the draft report entitled *North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs*. We have reviewed the report and please see below for our response regarding each recommendation.

1. **OIG recommends that the State agency refund to the Federal Government \$78,006 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement.** North Dakota concurs with this recommendation. North Dakota has taken steps (even prior to the conclusion of the audit) to change Medicaid Management Information System (MMIS) coding to require the National Drug Code (NDC) to be submitted for the codes that did not previously require the NDC.
2. **OIG recommends that the State agency refund to the Federal Government \$730 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement.** North Dakota concurs with this recommendation. North Dakota has taken steps (even prior to the conclusion of the audit) to change MMIS coding to require the NDC to be submitted for the codes that did not previously require the NDC.
3. **OIG recommends that the State agency work with CMS to determine whether \$302,512 (Federal share) of other physician-administered drug claims could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.** North Dakota concurs with this recommendation. We have confirmed with our drug rebate vendor that they will be able to integrate the claims data into past invoices which

will result in the manufacturers being invoiced for the rebates. We will work with CMS to review the plan and upon successful collection of any rebates for these claims, we will refund the Federal share of the collected manufacturers' rebates through the normal CMS 64 process.

4. **OIG recommends that the State agency strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.** North Dakota concurs with this recommendation. Processes have been revised for addition of HCPCs and CPT codes to the list of codes that require NDC's, and the user interface now displays the requirement for ease of confirmation. Also, the number of individuals allowed to add codes has been decreased to help ensure that any code that is added is reviewed by pharmacy program staff to determine the final status of the NDC requirement for that code.

It was a pleasure to work with your staff on this audit, and feel free to contact us with any questions you may have with regards to our rebate program.

Sincerely,

A handwritten signature in blue ink that reads "Maggie D. Anderson for".

Maggie D. Anderson  
Executive Director