

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MAINE DID NOT ALWAYS  
INVOICE REBATES TO  
MANUFACTURERS FOR PHYSICIAN-  
ADMINISTERED DRUGS**

*Inquiries about this report may be addressed to the Office of Public Affairs at  
[Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov).*



**Amy J. Frontz  
Deputy Inspector General  
for Audit Services**

**September 2020  
A-07-18-06079**

# *Office of Inspector General*

<https://oig.hhs.gov/>

---

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## *Office of Audit Services*

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

## *Office of Evaluation and Inspections*

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

## *Office of Investigations*

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

## *Office of Counsel to the Inspector General*

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

# *Notices*

---

**THIS REPORT IS AVAILABLE TO THE PUBLIC**  
at <https://oig.hhs.gov>

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

## **OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS**

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

## Report in Brief

Date: September 2020  
Report No. A-07-18-06079

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



### Why OIG Did This Audit

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, a prior OIG review found that States did not always invoice and collect all rebates due for drugs administered by physicians.

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

### How OIG Did This Audit

We reviewed claims for physician-administered drugs paid between January 2012 and December 2016.

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

## Maine Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs

### What OIG Found

Maine did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Maine did not invoice for, and collect from manufacturers, rebates associated with \$4.3 million (Federal share) in physician-administered drugs as required. Of this amount, \$4.0 million was for single-source drugs and \$276,000 was for top-20 multiple-source drugs. Further, Maine did not submit the utilization data necessary to secure rebates for all other physician-administered drug claims totaling \$606,000 (Federal share). Finally, Maine could have invoiced manufacturers for rebates totaling \$10.8 million (Federal share) that were associated with physician-administered drugs dispensed at non-Critical Access Hospitals.

### What OIG Recommends and Maine's Comments

We recommend that Maine refund to the Federal Government \$4.0 million (Federal share) for claims for single-source physician-administered drugs and \$276,000 for claims for top-20 multiple-source physician-administered drugs. We also recommend that Maine work with CMS to determine the unallowable portion of \$606,000 (Federal share) for other claims for multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement, refund that amount, and consider invoicing drug manufacturers for rebates for these drugs if CMS determined that the drug claims are allowable. In addition, we recommend that Maine consider invoicing drug manufacturers for rebates totaling \$10.8 million (Federal share) for claims for physician-administered drugs dispensed at non-Critical Access Hospitals, and that Maine strengthen its internal controls.

Maine did not directly agree or disagree with our recommendations but described corrective actions it had taken or planned to take for all but one of them. Maine's comments suggested that it disagreed with our recommendation involving determination of the unallowable portion of \$606,000 (Federal share) for other claims for multiple-source physician-administered drugs. For that recommendation, Maine referred to non-Critical Access Hospitals and said that it was not able to determine the rebates for these drugs. With respect to our recommendation for the \$606,000 (Federal share) for other claims for multiple-source physician-administered drugs, those drugs were not administered at non-Critical Access Hospitals. Therefore, we maintain that our findings and recommendations are valid. We acknowledge the implemented or planned corrective actions that Maine described.

## TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective.....	1
Background.....	1
Medicaid Drug Rebate Program.....	1
Physician-Administered Drugs.....	2
The State Agency’s Medicaid Drug Rebate Program.....	2
How We Conducted This Audit.....	3
FINDINGS.....	4
Federal Requirements.....	5
The State Agency Did Not Invoice Manufacturers for Rebates on Some Single-Source Physician-Administered Drugs.....	5
The State Agency Did Not Invoice Manufacturers for Rebates on Some Top-20 Multiple-Source Physician-Administered Drugs.....	5
The State Agency Did Not Invoice Manufacturers for Rebates on Other Multiple-Source Physician-Administered Drugs.....	6
The State Agency Did Not Invoice Manufacturers for Rebates on Physician-Administered Drugs Dispensed at Non-Critical Access Hospitals.....	6
RECOMMENDATIONS.....	7
STATE AGENCY COMMENTS.....	7
OFFICE OF INSPECTOR GENERAL RESPONSE.....	8
APPENDICES	
A: Audit Scope and Methodology.....	9
B: Related Office of Inspector General Reports.....	11

C: Federal Requirements and Guidance Related to  
Physician-Administered Drugs .....15

D: State Agency Comments .....17

## INTRODUCTION

### WHY WE DID THIS AUDIT

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 the 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 B lists previous audits of the Medicaid drug rebate program.) For this audit, we reviewed the Maine Department of Health and Human Services' (State agency's) invoicing for rebates for physician-administered drugs for the period January 1, 2012, through December 31, 2016.

### 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 with 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(a)(7) 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

---

<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.

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 Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program report (Form CMS-64), 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.

---

<sup>3</sup> HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

<sup>4</sup> See, e.g., the Act § 1927(a)(7). 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 Food and Drug Administration. See, e.g., the Act § 1927(k)(7). 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 § 1927(a)(7)(B)(i).

The State agency awarded the Maine fiscal agent contract to Molina Medicaid Solutions (Molina) in December 2007.<sup>6</sup> As part of this contract, Molina provides drug rebate services for the State agency.

To provide these services with respect to physician-administered drugs, Molina relies on claim utilization data, which it derives from claims submitted by providers, to create invoices that the State agency sends to 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.

During our audit period, certain hospitals in Maine were exempt from the requirement to report rebates. Specifically, the State plan specifies that for outpatient services, these hospitals, which the State agency classifies as Acute Care non-Critical Access Hospitals,<sup>7</sup> are reimbursed at the lower of 83.8 percent of Medicaid's outpatient costs or charges. CMS has endorsed in writing this provision of the State plan.

## **HOW WE CONDUCTED THIS AUDIT**

The State agency claimed \$100,300,774 (\$69,396,568 Federal share) for physician-administered drugs paid between January 1, 2012, and December 31, 2016.

We used the CMS Medicaid Drug File to determine whether the NDCs listed on the claims were classified as single-source drugs or multiple-source drugs. For claims submitted without an NDC, 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.<sup>8</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

---

<sup>6</sup> DXC Technology completed acquisition of Molina in October 2018 (after our audit period).

<sup>7</sup> The term "Critical Access Hospital" is a designation given to eligible rural hospitals by CMS. Critical Access Hospitals are small facilities that give limited inpatient hospital services to people in rural areas and receive cost-based reimbursement. Accordingly, the term "Acute Care non-Critical Access Hospital" refers to a hospital licensed by the State agency as an acute care hospital that is not being reimbursed as a Critical Access Hospital by Medicare.

<sup>8</sup> The Medicare Part B crosswalk is published quarterly by CMS and is based on drug and biological information submitted to CMS by manufacturers. CMS uses this information along with pricing data submitted by manufacturers to calculate a volume-weighted sales price for each HCPCS code, which becomes the basis for the reimbursement rate the State pays to providers for the following quarter. CMS instructed States that they could use the crosswalk as a reference because HCPCS codes and NDCs are standardized codes used across healthcare programs.

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 for, and collect from manufacturers, rebates associated with \$6.8 million (\$4.3 million Federal share) in physician-administered drugs as required. Of this amount, \$6.4 million (\$4.0 million Federal share) was for single-source drugs and \$441,000 (\$276,000 Federal share) was for top-20 multiple-source drugs.<sup>9</sup> 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, we were unable to determine whether, in some cases, the State agency was required to invoice for rebates for other multiple-source physician-administered drug claims. Although the State agency generally collected the drug utilization data necessary to invoice manufacturers for rebates associated with these drugs, the State agency did not invoice the manufacturers for rebates associated with the claims totaling \$963,000 (\$606,000 Federal share) for these multi-source drugs.<sup>10</sup>

Moreover, the State agency did not invoice manufacturers for physician-administered drugs dispensed at non-Critical Access Hospitals. Although not required, the State agency could have invoiced drug manufacturers for rebates totaling \$17.3 million (\$10.8 million Federal share) for these physician-administered drugs.<sup>11</sup>

Accordingly, we set aside the \$963,000 associated with the other multiple-source physician-administered drug claims. If CMS determines that these claims are allowable during the adjudication process, the State agency would have the opportunity to rebate for these drugs as well as those claims associated with physician-administered drugs dispensed at non-Critical Access Hospitals.

With respect to these last two findings, then, we are recommending that the State agency (1) consider invoicing drug manufacturers for rebates totaling \$17.3 million (\$10.8 million Federal share) for physician-administered drugs that were dispensed at non-Critical Access

---

<sup>9</sup> Specifically, \$6,387,953 (\$4,004,984 Federal share) was for single-source drugs and \$441,135 (\$276,229 Federal share) was for top-20 multiple-source drugs.

<sup>10</sup> Specifically, \$962,771 (\$605,768 Federal share) was for other multi-source drugs.

<sup>11</sup> Specifically, \$17,272,850 (\$10,801,067 Federal share) was for physician-administered drug claims at non-Critical Access Hospitals.

Hospitals, and (2) work with CMS to determine the unallowable portion of the \$963,000 (\$606,000 Federal share) of claims and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

## **FEDERAL REQUIREMENTS**

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 NDCs (42 CFR § 447.520).

However, there are exceptions. The Act directs State plans to include a provision that a hospital that dispenses covered outpatient drugs using drug formulary systems, and that bills the Medicaid program no more than the hospital's purchasing costs for covered outpatient drugs, is not subject to the requirements to obtain rebates for physician-administered drugs (the Act § 1927(j)(2)). However, rebates are not prohibited for these claims and can still be obtained if invoiced.

Appendix C contains Federal requirements and 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 \$6.4 million (\$4.0 million Federal share) for single-source physician-administered drugs for which it did not invoice manufacturers for rebates.

Because the State agency did not invoice for rebates for all single-source physician-administered drugs, these claims were not eligible for Federal reimbursement.

### **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 \$441,000 (\$276,000 Federal share) for top-20 multiple-source drugs 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 invoice for rebates for all top-20 multiple-source physician-administered drugs, the claims that were not invoiced for rebates were not eligible for Federal reimbursement.

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

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

Although the State agency generally collected the drug utilization data necessary to invoice manufacturers for rebates associated with these multiple-source physician-administered drugs, the State agency did not invoice the manufacturers for rebates associated with these drugs, which were not identified as top-20 multiple-source drugs. Providers submitted claims totaling \$963,000 (\$606,000 Federal share) that were not used to obtain Medicaid drug rebates.<sup>12</sup> Under the Medicaid drug rebate program, these claims could have been eligible for rebates.

Accordingly, we set aside \$963,000 (\$606,000 Federal share) for the remaining multi-source drug claims and are recommending that the State agency work with CMS to determine the unallowable portion of these claims and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

#### **THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON PHYSICIAN-ADMINISTERED DRUGS DISPENSED AT NON-CRITICAL ACCESS HOSPITALS**

The Act § 1927(j)(2) directs State plans to include a provision that exempts certain hospitals from rebate requirements as long as the hospitals bill Medicaid for covered outpatient drugs at no more than the “hospital’s purchasing costs of covered outpatient drugs (as determined under the State plan).” The Maine State plan specifies that for outpatient services, non-Critical Access Hospitals (footnote 7) are reimbursed at the lower of 83.8 percent of Medicaid outpatient costs or charges.

The State agency did not invoice manufacturers for physician-administered drugs dispensed at non-Critical Access Hospitals. Furthermore, the State agency did not require these hospitals to provide the drug utilization data necessary to invoice manufacturers for rebates associated with these drugs. In this regard, the State agency was not deviating from the provisions of the State plan. However, the Act and the State plan do not prohibit the State agency from obtaining rebates for these physician-administered drugs. The State agency could have invoiced drug manufacturers for rebates totaling \$17.3 million (\$10.8 million Federal share) for these physician-administered drugs. We are therefore recommending that the State agency consider invoicing drug manufacturers for rebates for these physician-administered drugs.

---

<sup>12</sup> None of the providers included in this finding were non-Critical Access Hospitals.

Effective January 1, 2019 (after our audit period), the State agency implemented a policy to obtain Medicaid drug rebates for physician-administered drugs on an outpatient basis at non-Critical Access Hospitals.<sup>13</sup>

## RECOMMENDATIONS

We recommend that the Maine Department of Health and Human Services:

- refund to the Federal Government \$4,004,984 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$276,229 (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 \$605,768 (Federal share) for other claims for multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement, refund that amount, and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable;
- consider invoicing drug manufacturers for rebates totaling \$10.8 million (Federal share) for claims for physician-administered drugs dispensed at non-Critical Access Hospitals; 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 did not directly agree or disagree with our recommendations but described corrective actions it had taken or planned to take for four of them, “to prevent the audit findings identified in this report from recurring.” The State agency’s comments suggested that it disagreed with our third recommendation.

For our first and second recommendations, the State agency said that to the extent possible, it would work with providers to obtain the data needed to invoice drug manufacturers for the claims. The State agency added that it would then work with CMS “on the timing and process of how to repay” the amounts conveyed in those recommendations.

---

<sup>13</sup> The State agency informed all providers on August 1, 2018, that effective January 1, 2019, physician-administered drug claims without an NDC would be denied.

For our third recommendation, the State agency said that it had consulted CMS and received clarification that because the State plan specified that outpatient services in non-Critical Access Hospitals (footnote 7) be reimbursed below cost rates, the State agency was not required to collect NDCs under the DRA for these claims. Therefore, according to the State agency, it was not able to determine the rebates for these drugs.

For our fourth recommendation, the State agency stated that it would consider working with providers to obtain the data needed to invoice drug manufacturers for claims that are within record retention scope.

For our fifth recommendation, the State agency said that internal controls have been strengthened in recent years. The State agency added that effective January 1, 2019 (after our audit period), it implemented policy that requires NDCs for all physician-administered drug claims. The State agency also stated that it would continue to ensure compliance through system edits in the Medicaid Management Information System.

The State agency's comments are included in their entirety as Appendix D.

#### **OFFICE OF INSPECTOR GENERAL RESPONSE**

After reviewing the State agency's comments, we maintain that all our findings and recommendations are valid. We acknowledge the implemented or planned corrective actions that the State agency described in its comments on our first, second, fourth, and fifth recommendations. We note that the drugs covered under our fourth recommendation were administered at non-Critical Access Hospitals and were not required to be invoiced. We also note, as the State agency did, that the implementation date of the strengthened controls that the State agency described in its comments on our fifth recommendation was after our audit period.

Regarding our third recommendation, we agree with the State agency that it was not required to invoice for drug claims associated with non-Critical Access Hospitals. But those drug claims were associated with our fourth recommendation, not with our third. Our third recommendation dealt with other multiple-source physician-administered drug claims, which were not identified as top-20 multiple-source drugs and which could have been eligible for rebates. Furthermore, the drugs covered under our third recommendation were not administered at non-Critical Access Hospitals, a fact that we clarified for this final report by adding footnote 12 to the relevant finding. Accordingly, we continue to recommend that the State agency work with CMS to address these claims that may have been ineligible for Federal reimbursement.

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

### **SCOPE**

The State agency claimed \$110,300,774 (\$69,396,568 Federal share) for physician-administered drugs paid between January 1, 2012, and December 31, 2016.

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 processes for claiming and obtaining Medicaid drug rebates for physician-administered drugs.

We conducted our audit work, which included contacting the State agency, in Des Moines, Iowa, from February 2018 to April 2020.

### **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, including a memorandum issued by CMS regarding provisions of the State plan regarding claims submitted by non-Critical Access Hospitals.
- 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 January 1, 2012, through December 31, 2016.

- We obtained the listing of 340B entities from the State agency.<sup>14</sup>
- We removed drug claims totaling \$85,043,142 (\$53,501,745 Federal share) that either were not eligible for a drug rebate (including the drug claims submitted by 340B entities) or were invoiced for rebate.
- We reviewed the remaining drug claims totaling \$25,257,632 (\$15,894,823 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 the non-Critical Access Hospital drugs that would have been eligible for a drug rebate and worked with the State agency to determine the rebates associated with these drugs. For the remaining drugs, we took the following steps:
  - We identified single-source drugs based on the classification of the drugs in the CMS Medicaid Drug File. If necessary, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the NDCs associated with each HCPCS code listed on claims from providers.
  - 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 identified the remaining drugs as other outpatient physician-administered drugs. These drugs were not identified as single-source or as top-20 multiple-source drugs.
- We discussed the results of our audit with State agency officials on March 10, 2020.

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.

---

<sup>14</sup> Under the 340B drug pricing program (set forth in 42 U.S.C. § 256b), a 340B entity may purchase reduced-price covered outpatient drugs from manufacturers; examples of 340B entities are disproportionate share hospitals, which generally serve large numbers of low-income and/or uninsured patients, and State AIDS drug assistance programs. Drugs subject to discounts under the 340B drug pricing program are not subject to rebates under the Medicaid drug rebate program. Section 1927(j) of the Act and 42 U.S.C. § 256(a)(5)(A).

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

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Michigan Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-05-17-00017</u></a>	8/25/2020
<i>Alaska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-09-19-02001</u></a>	7/21/2020
<i>New York Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-02-18-01016</u></a>	4/7/2020
<i>New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-02-18-01011</u></a>	2/19/2020
<i>New Jersey Did Not Bill Manufacturers for Tens of Millions of Dollars in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-02-16-01011</u></a>	8/30/2019
<i>Texas Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#"><u>A-06-17-04001</u></a>	8/21/2019
<i>Connecticut Claimed Unallowable Federal Reimbursement for Medicaid Physician-Administered Drugs That Were Not Invoiced to Manufacturers for Rebates</i>	<a href="#"><u>A-07-18-06078</u></a>	8/16/2019
<i>Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-05-18-00030</u></a>	6/18/2019
<i>New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-02-16-01012</u></a>	5/9/2019
<i>Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-05-17-00038</u></a>	4/5/2019
<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>	2/16/2018

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-06-16-00018</u></a>	2/12/2018
<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>	12/22/2017
<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>	12/12/2017
<i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-05-16-00013</u></a>	11/1/2017
<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>	9/26/2017
<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>	9/26/2017
<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>	9/12/2017
<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>	5/5/2017
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-05-16-00014</u></a>	3/23/2017
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-14-06050</u></a>	1/5/2017
<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>	12/30/2016
<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>	12/22/2016

<b>Report Number</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>California Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations</i>	<a href="#">A-09-15-02035</a>	12/8/2016
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<a href="#">A-07-15-06060</a>	8/18/2016
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-14-06057</a>	5/26/2016
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-15-06063</a>	3/31/2016
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-15-06059</a>	2/9/2016
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-15-06062</a>	1/14/2016
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-15-06058</a>	1/13/2016
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<a href="#">A-09-14-02038</a>	1/7/2016
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-14-06056</a>	9/18/2015
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-14-06049</a>	7/22/2015
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-06-12-00060</a>	5/4/2015
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#">A-07-14-06051</a>	4/13/2015

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<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>	3/4/2015
<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>	2/10/2015
<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>	8/21/2014
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-07-13-06040</u></a>	8/7/2014
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-09-12-02079</u></a>	4/30/2014
<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>	4/24/2014
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<a href="#"><u>A-03-12-00200</u></a>	11/26/2013
<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>	9/19/2013
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<a href="#"><u>A-06-10-00011</u></a>	8/12/2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<a href="#"><u>OEI-03-09-00410</u></a>	6/24/2011

## **APPENDIX C: FEDERAL REQUIREMENTS 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 a 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 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.

Section 1927(j)(2) of the Act states that the State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and that bills the Medicaid program no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan), shall not be subject to the requirements of this section.

## **FEDERAL REGULATIONS AND GUIDANCE**

Federal regulations set conditions for States to obtain a Federal share for covered outpatient drugs administered by a physician and specifically state 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 bill a manufacturer for rebates (42 CFR § 447.520).

On September 21, 2010, CMS issued a memorandum to the State agency in response to queries from the latter about reporting requirements for non-Critical Access Hospitals:

Because the Maine State plan specifies that for outpatient care services, non-Critical Access Hospitals are reimbursed at the lower of 83.8 percent of [the State Medicaid program's] outpatient cost or charges, we believe that the 1927(j)(2) exemption applies to non-Critical Access Hospitals in Maine. Therefore, these hospitals are not required to report NDCs for the purpose of DRA Section 6002.

## APPENDIX D: STATE AGENCY COMMENTS

Janet T. Mills  
Governor

Jeanne M. Lambrew, Ph.D.  
Commissioner



Maine Department of Health and Human Services  
Commissioner's Office  
11 State House Station  
109 Capitol Street  
Augusta, Maine 04333-0011  
Tel: (207) 287-3707; Fax: (207) 287-3005  
TTY: Dial 711 (Maine Relay)

July 23, 2020

Report Number: A-07-18-06079

Patrick J. Cogley  
Regional Inspector General for Audit Services  
Department of Health and Human Services  
Office of Inspector General  
Office of Audit Services, Region VII  
601 East 12<sup>th</sup> Street, Room 0429  
Kansas City, MO 64106

Dear Mr. Patrick J. Cogley:

The Maine Department of Health and Human Services is in receipt of your draft report dated May 11, 2020. The Department thanks the U.S. Department of Health and Human Services, Office of Inspector General for all the work performed in connection with this review and appreciates the opportunity to comment on the draft report.

The Maine Department of Health and Human Services has reviewed the draft audit report and provided responses to all five (5) recommendations. The Department notes that the time period associated with this audit was from 2012 to 2016, which was during a different Administration in Maine, and the State has implemented subsequent policy changes to prevent the audit findings identified in this report from recurring.

**Recommendation 1:** Maine Department of Health and Human Services refund to the Federal Government \$4,004,984 (Federal share) for claims for single source physician-administered drugs that were ineligible for Federal reimbursement.

**Response from DHHS:** The Department will work with providers to obtain the data needed to invoice drug manufacturers for the claims, to the extent possible. The Department will then work with CMS on the timing and process of how to repay the outstanding balance. Please note that effective January 1, 2019, the State agency implemented policy to require and obtain National Drug Codes (NDCs) for all physician-administered drug claims and furthermore, to obtain rebates for these physician-administered drugs.

**Recommendation 2:** Refund to the Federal Government \$276,229 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement.

**Response from DHHS:** The Department will work with providers to obtain the data needed to invoice drug manufacturers for the claims to the extent possible. The Department will then work with CMS on the timing and the process of how to repay the outstanding balance. The state agency is aware section 1927 of the Act specifically addresses the collection of rebates on physician-administered drugs and CMS published the top-20 multiple-source physician-administered drugs eligible for rebate. Effective January 1, 2019 (after the audit period), the State agency now captures NDCs all top-20 multiple source drugs (the Act § 1927(a)(7)).

**Recommendation 3:** Work with CMS to determine the unallowable portion of \$605,768 (Federal share) for other claims for multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement, refund that amount, and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable.

**Response from DHHS:** The Department worked with CMS and on September 2010, DHHS sought and received clarification of NDC reporting requirements for hospitals (letter provided in audit). It was clarified that since the Maine State plan specified that outpatient services in non-Critical Access Hospitals were reimbursed below cost rates, therefore DHHS was not required to collect NDCs under the DRA for these claims, therefore we cannot determine the rebates for these drugs. We ask that this recommendation be closed.

**Recommendation 4:** Consider invoicing drug manufacturers for rebates totaling \$10.8 million (Federal share) for claims for physician-administered drugs dispensed at non-Critical Access Hospitals.

**Response from DHHS:** Prior to January 1, 2019, the State agency did not require or capture NDC codes for physician-administered drugs dispensed at non-Critical Access Hospitals. The Department will consider working with providers to obtain the data needed to invoice drug manufacturers for the claims that are within record retention scope.

**Recommendation 5:** Strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

**Response from DHHS:** As previously discussed above and during the course of this audit, internal controls have been strengthened in recent years. Effective January 1, 2019 (after the audit period), the State agency implemented policy that requires NDCs for all physician-administered drug claims. DHHS will continue to ensure compliance by its implementation of system edits in the Medicaid Management Information System (MMIS). We ask that this recommendation be closed.

If you have any questions or concerns, please contact Anthony Madden, Deputy Director, Division of Audit, at 207-287-2834 or [Anthony.Madden@Maine.gov](mailto:Anthony.Madden@Maine.gov).

Sincerely,

Benjamin Mann

Benjamin Mann  
Deputy Commissioner of Finance  
Department of Health and Human Services