

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

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

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Office of Inspector General

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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: July 2020

Report No. A-09-19-02001

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, previous OIG audits found that States did not always bill and collect all rebates due for drugs administered by physicians.

Our objective was to determine whether Alaska complied with Federal Medicaid requirements for billing manufacturers for rebates for pharmacy and physician-administered drugs.

How OIG Did This Audit

Our audit covered \$222 million (Federal share) in pharmacy and physician-administered drug claims that Alaska paid for 2016 and 2017. After removing claims for drugs that were ineligible for rebates or billed for rebates, we reviewed the claims not billed for rebates. For claims with National Drug Codes (NDCs), we used the Centers for Medicare & Medicaid Services (CMS) Medicaid Drug File to determine whether those NDCs were single-source or multiple-source drugs. We identified the top 20 multiple-source drugs by matching the Healthcare Common Procedure Coding System (HCPCS) code on each claim to the HCPCS code on the top-20 listing. We identified the remaining multiple-source drugs as other physician-administered drugs. For claims without valid NDCs, we identified these as other physician-administered drugs that could have been eligible for rebates.

Alaska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs

What OIG Found

Alaska generally complied with Federal Medicaid requirements for billing manufacturers for rebates for pharmacy drugs. However, it did not comply with requirements for billing manufacturers for rebates for some physician-administered drugs. Specifically, Alaska did not bill for and collect from manufacturers rebates associated with about \$1 million (Federal share) in claims for physician-administered drugs. Of this amount, \$939,361 was for single-source drugs, and \$73,892 was for top-20 multiple-source drugs. Because Alaska's internal controls did not always ensure that it billed manufacturers to secure rebates, Alaska improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

In addition, Alaska did not submit the drug utilization data necessary to secure rebates for other physician-administered drugs that did not have valid NDCs, totaling \$3,615 (Federal share). Furthermore, claims totaling \$185,066 (Federal share), which contained NDCs, could have been eligible for rebates. Accordingly, we set aside these amounts for CMS resolution.

What OIG Recommends and Alaska Comments

We recommend that Alaska: (1) refund to the Federal Government \$939,361 (Federal share) for claims for single-source physician-administered drugs; (2) refund to the Federal Government \$73,892 (Federal share) for claims for top-20 multiple-source drugs; (3) work with CMS to determine the unallowable portion of \$188,681 (Federal share) for claims for other physician-administered drugs that did not have valid NDCs or could have been eligible for rebates, and make the appropriate refunds; (4) work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not billed for rebates after December 31, 2017; and (5) strengthen its internal controls to ensure that it bills manufacturers for rebates for all physician-administered drugs that are eligible for rebates.

Alaska concurred with the finding related to our first recommendation and partially concurred with the findings related to our second and third recommendations. Alaska provided information on actions it planned to take that would address our last two recommendations. Regarding our second finding, we maintain that Alaska should have billed manufacturers for rebates for top-20 multiple-source drugs. Regarding our third finding, we continue to recommend that Alaska work with CMS to resolve the Federal share amount.

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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 their Federal share of these rebates against their Medicaid expenditures. States bill the manufacturers for rebates to reduce the cost of drugs to the program. However, previous Office of Inspector General (OIG) audits found that States did not always bill 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.¹) For this audit, we reviewed the Alaska Department of Health and Social Services' (State agency's) billing of rebates for both pharmacy and physician-administered drugs for calendar years 2016 and 2017.

OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for billing manufacturers for rebates for pharmacy and 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 administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Manufacturer rebates are essentially shared between the States and the Federal Government to offset the cost of prescription drugs. 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.² On the basis of this information, CMS calculates a unit rebate amount for each drug and provides these amounts 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.

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

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

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for billing manufacturers for rebates as described in section 1927(a)(7) of the Act. To bill for rebates, States must use drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers. The States must capture these drug utilization data 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.

Pharmacy and Physician-Administered Drugs

Drugs may be provided to a beneficiary through a pharmacy or administered by a physician in an office or a hospital. Pharmacy drugs are typically billed to Medicaid using NDCs. A valid NDC is a unique identifier that represents a drug's specific manufacturer, product, and package size. Physician-administered drugs are typically billed to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.³ Each HCPCS code may have more than one NDC.

States' Collection of Rebates for Pharmacy and Physician-Administered Drugs

To collect rebates for drugs, States submit to the manufacturers the drug utilization data containing NDCs for the drugs. NDCs enable States to identify the drugs and their manufacturers and facilitate the collection of rebates for the drugs. Before the Deficit Reduction Act of 2005 (DRA), many States did not collect rebates on physician-administered drugs if the drug claim did not contain NDCs. NDCs were more readily available for pharmacy drug claims because providers used NDCs to bill for pharmacy drugs.

The DRA amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source drugs and the top 20 multiple-source drugs.⁴ For purposes of the Medicaid drug rebate program, single-source drugs are those covered outpatient drugs produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA).⁵ Multiple-source drugs are defined, in part, as those

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

⁴ 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)).

⁵ Section 1927(k)(7) of the Act. Single-source drugs are commonly referred to as "brand-name" drugs.

covered outpatient drugs that have at least one other drug rated as therapeutically equivalent by FDA.⁶ 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.

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for billing and collecting Medicaid drug rebates for both pharmacy and physician-administered drugs. The State agency also requires claims for physician-administered drugs to list the NDCs of the drugs.

The State agency contracted with Conduent, LLC⁷ (the contractor) to manage its Medicaid Management Information System (MMIS) and its drug rebate program during our audit period. The claims data were transferred from the MMIS to the contractor's rebate-processing system. Using these data, the contractor billed manufacturers for rebates quarterly. Also, the contractor maintained accounts receivable information and worked with manufacturers to resolve any unpaid rebates.

HOW WE CONDUCTED THIS AUDIT

Our audit covered pharmacy and physician-administered drug claims that were paid by the State agency from January 1, 2016, through December 31, 2017 (audit period).

We obtained drug claim details from the State agency for all pharmacy and physician-administered drugs for our audit period. We removed claims for drugs that either were not eligible for rebates or were billed for rebates. We reviewed the remaining claims that were not billed for rebates. For claims submitted with NDCs, we used the CMS Medicaid Drug File to determine whether the NDCs listed on the claims were classified as single-source or multiple-source drugs. We identified the top 20 multiple-source drugs by matching the HCPCS code on each drug claim to the HCPCS code on the top-20 listing. We identified the remaining multiple-source drugs (those not identified as single-source drugs or top-20 multiple-source drugs) as other physician-administered drugs. For claims submitted without valid NDCs, we identified these claims as other physician-administered drugs that could have been eligible for rebates.

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

⁶ Section 1927(k)(7) of the Act. According to the definition of "therapeutic equivalence" in the FDA glossary of terms, a therapeutically equivalent drug product can be substituted with another product to achieve the same clinical effect as the prescribed drug. Available online at <http://www.fda.gov/drugs/informationondrugs/ucm079436.htm>. Accessed on January 16, 2020.

⁷ On December 1, 2017, the State agency signed a new contract for the drug rebate process directly with Magellan Medicaid Administration, Inc., which had been working as a subcontractor for Conduent from October 1, 2013, through November 30, 2017.

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 generally complied with Federal Medicaid requirements for billing manufacturers for rebates for pharmacy drugs. However, it did not comply with Federal Medicaid requirements for billing manufacturers for rebates for some physician-administered drugs. Specifically, the State agency did not bill for and collect from manufacturers rebates associated with \$1,657,015 (\$1,013,253 Federal share) in claims for physician-administered drugs. Of this amount, \$1,541,303 (\$939,361 Federal share) was for single-source drugs, and \$115,712 (\$73,892 Federal share) was for top-20 multiple-source drugs. The State agency's internal controls did not always ensure that it billed manufacturers to secure rebates. Specifically, the MMIS data that were transferred to the contractor's rebate-processing system did not contain all of the necessary claims data for rebate-eligible claims to bill manufacturers for rebates. As a result, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

In addition, 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 utilization data necessary to bill manufacturers for rebates associated with the claims for these drugs, providers submitted claims totaling \$7,229 (\$3,615 Federal share) that did not have valid NDCs. We were unable to determine whether the State agency was required to bill for rebates for the drug claims that did not have valid NDCs in the utilization data. Furthermore, under the Medicaid drug rebate program, claims totaling \$300,266 (\$185,066 Federal share), which contained NDCs, could have been eligible for rebates. Accordingly, we set aside the \$7,229 and \$300,266 for CMS resolution.

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).

The State agency publishes notices to clarify and explain new and existing programs and policies for providers and other interested parties. On April 14, 2008, the "Notice of Changes to Billing Requirements for Drugs Administered in Outpatient Clinical Settings" informed providers of the following: "Effective April 1, 2008, Alaska Medical Assistance claims must include NDC . . .

information for drugs administered by health care providers in outpatient clinical settings.”⁸ The notice informed providers that claims for drugs must include both the NDC number and the units of measurement and stated that providers that do not comply with these billing requirements “will not be reimbursed.”

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

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

The State agency improperly claimed Federal reimbursement of \$1,541,303 (\$939,361 Federal share) for single-source physician-administered drugs for which it did not bill manufacturers for rebates. Because the State agency did not bill for rebates for all single-source physician-administered drugs, these claims were not eligible for Federal reimbursement.

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

The State agency improperly claimed Federal reimbursement of \$115,712 (\$73,892 Federal share) for top-20 multiple-source physician-administered drugs for which it did not bill 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, for rebate purposes, the State agency did not submit to manufacturers the drug utilization data for all of these drugs. Because the State agency did not bill for rebates for all top-20 multiple-source physician-administered drugs, the claims for drugs that were not billed for rebates were not eligible for Federal reimbursement.

THE STATE AGENCY DID NOT BILL MANUFACTURERS FOR REBATES ON OTHER PHYSICIAN-ADMINISTERED DRUGS

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

Although the State agency generally collected the drug utilization data necessary to bill the manufacturers for rebates associated with the claims for other physician-administered drugs, providers submitted some claims, totaling \$7,229 (\$3,615 Federal share), that did not have valid NDCs (e.g., NDCs that were not the standard 11-digit length). Without valid NDCs for those claims, we were unable to determine whether the State agency was required to bill these drugs for rebates. Furthermore, under the Medicaid drug rebate program, claims totaling \$300,266 (\$185,066 Federal share), which contained NDCs, could have been eligible for rebates. Accordingly, we set aside the \$7,229 and \$300,266 for CMS resolution.

⁸ This notice was published following the rule changes made in the DRA.

RECOMMENDATIONS

We recommend that the Alaska Department of Health and Social Services:

- refund to the Federal Government \$1,541,303 (\$939,361 Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$115,712 (\$73,892 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 \$7,229 (\$3,615 Federal share) for claims for other physician-administered drugs that were submitted with invalid NDCs and that may have been ineligible for Federal reimbursement and refund that amount and
 - determine whether the remaining \$300,266 (\$185,066 Federal share) for claims for other physician-administered drugs could have been billed 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;
- work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not billed for rebates after December 31, 2017; and
- strengthen its internal controls to ensure that it bills manufacturers for rebates for all physician-administered drugs that are eligible for rebates.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency concurred with our first finding, regarding not billing manufacturers for rebates on some top-20 multiple-source drugs. The State agency partially concurred with our second and third findings, regarding not billing manufacturers for rebates on some top-20 multiple-source physician-administered drugs and for other physician-administered drugs, respectively. Although the State agency did not explicitly mention our recommendations, it provided information on actions that it planned to take that would address our last two recommendations. The State agency's comments are included in their entirety as Appendix D.

After reviewing the State agency's comments, we maintain that our findings and recommendations are valid.

STATE AGENCY COMMENTS

The State agency had the following comments on our findings:

- Regarding our first finding, the State agency commented that it had identified a system failure in late 2016 that resulted in some of the physician-administered drug claims in our audit period not being sent from the fiscal agent to the rebate contractor.⁹ It stated that, as a result, these claims were not included in the required quarterly rebate invoicing. The State agency provided information on a corrective action plan that it said it had put in place to resolve this issue.
- Regarding our second finding, the State agency commented that it did not evaluate which specific drugs and claims were cited under this finding, because CMS no longer publishes a listing of the top 20 multiple-source physician-administered drugs. The State agency said, however, that its policy was to adhere to the definition of a covered outpatient drug in Federal regulations (42 CFR § 447.502) and to bill manufacturers for rebates on physician-administered drugs that met this definition. The State agency acknowledged that a portion of these physician-administered drugs were not billed for rebates because of the 2016 system failure and stated that a corrective action plan was in progress to resolve these issues when our audit began.
- Regarding our third finding, the State agency commented that some providers may submit drug claims that contain what appear to be NDCs but that the HCPCS code and service may not be recognized as a drug product. The State agency noted that these drug claims may reflect other covered services, such as medical supplies, that do not have Federal rebate obligations. The State agency commented, however, that it welcomes the opportunity to work with CMS on resolution of the Federal share amounts for these claims for other physician-administered drugs.

The State agency commented that it will work with CMS to determine if there is any unallowable portion of Federal reimbursement for physician-administered drugs paid after December 31, 2017. The State agency also commented that internal controls incorporated as part of the corrective action plan will be continually reviewed and revised to ensure that manufacturers are billed for rebates on all rebate-eligible physician-administered drugs.

OFFICE OF INSPECTOR GENERAL RESPONSE

Regarding our second finding, we agree that CMS no longer publishes a listing of the top 20 multiple-source physician-administered drugs. However, we maintain that the State agency should have billed manufacturers for rebates for these top-20 multiple-source physician-administered drugs because these drugs are covered outpatient drugs as defined in Federal

⁹ The State agency refers to Conduent, LLC, as “the fiscal agent” and Magellan Medicaid Administration, Inc., as “the rebate contractor” in its comments on our draft report.

statute (the Act §§ 1927(k)(2) and (3)) and regulations (42 CFR § 447.502). This is also in line with the State agency's policy. In addition, the State agency also acknowledged that a portion of these physician-administered drugs were not billed for rebates because of the system failure that was identified in 2016. Therefore, we maintain that our finding and the related second recommendation (to refund to the Federal Government \$115,712 (\$73,892 Federal share) for these top-20 multiple-source physician-administered drugs) are valid.

Regarding our third finding, as noted in the report, we were unable to determine whether, in some cases, the State agency was required to bill for rebates for claims for other physician-administered drugs. Therefore, in line with the State agency's comment that it welcomes the opportunity to do so, we continue to recommend that the State agency work with CMS on resolution of the Federal share amounts for these claims.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered pharmacy and physician-administered drug claims that were paid by the State agency from January 1, 2016, through December 31, 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 providers for claims for pharmacy and physician-administered drugs and its process for billing and collecting Medicaid drug rebates for pharmacy and physician-administered drugs.

We conducted our audit from February 2019 to March 2020, which included contacting the State agency in Anchorage, Alaska.

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 for both pharmacy and physician-administered drugs.
- We interviewed CMS officials about Federal laws, regulations, and guidance governing pharmacy and physician-administered drugs under the Medicaid drug rebate program.
- We reviewed State agency guidance to providers, including billing instructions for pharmacy and physician-administered drugs.
- We reviewed State agency policies and procedures for rebates for pharmacy and physician-administered drugs.
- We interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid billing and rebate process for pharmacy and physician-administered drugs.
- We obtained a listing of the CMS top-20 multiple-source physician-administered drugs and the CMS Medicaid Drug File for our audit period.
- We obtained drug claim details from the State agency for all pharmacy and physician-administered drugs, totaling \$310,021,207 (\$221,783,610 Federal share) for our audit period.

- We removed claims for drugs that either were not eligible for rebates (including the drug claims submitted by 340B entities¹⁰) or were billed for rebates, totaling \$308,056,697 (\$220,581,676 Federal share).
- We reviewed the remaining claims for physician-administered drugs that were not billed for rebates, totaling \$1,964,510 (\$1,201,934 Federal share). For these claims, we did the following:
 - For claims submitted with NDCs, we used the CMS Medicaid Drug File to determine whether the NDCs listed on the claims were classified as single-source or multiple-source drugs. We identified the top 20 multiple-source drugs by matching the HCPCS code on each drug claim to the HCPCS code on the top-20 listing. We identified the remaining multiple-source drugs (those not identified as single-source drugs or top-20 multiple-source drugs) as other physician-administered drugs.
 - For claims submitted without valid NDCs, we identified these claims as other physician-administered drugs that could have been eligible for rebates.
- We discussed the results of our audit with State agency officials.

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.

¹⁰ 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 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

Report Title	Report Number	Date Issued
<i>New York Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-02-18-01016	4/07/2020
<i>New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-02-18-01011	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-02-16-01011	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-06-17-04001	8/21/2019
<i>Connecticut Claimed Unallowable Federal Reimbursement for Medicaid Physician-Administered Drugs That Were Not Invoiced to Manufacturers for Rebates</i>	A-07-18-06078	8/16/2019
<i>Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-05-18-00030	6/18/2019
<i>New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-02-16-01012	5/9/2019
<i>Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-05-17-00038	4/5/2019
<i>Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-16-02031	2/16/2018
<i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-06-16-00018	2/7/2018
<i>Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-07-13-06046	12/12/2017
<i>Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations</i>	A-06-16-00004	12/12/2017
<i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-05-16-00013	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-09-16-02028	9/26/2017
<i>Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-16-02029	9/26/2017

Report Title	Report Number	Date Issued
<i>Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-16-02027	9/12/2017
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	A-07-16-06065	5/5/2017
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-05-16-00014	3/23/2017
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06050	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-03-15-00202	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-03-15-00201	12/22/2016
<i>California Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations</i>	A-09-15-02035	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-07-15-06060	8/18/2016
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06057	3/31/2016
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-15-06063	2/9/2016
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-15-06059	2/9/2016
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-15-06062	1/14/2016
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-15-06058	1/13/2016
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	A-09-14-02038	1/7/2016
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-14-06056	9/18/2015
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06049	7/22/2015

Report Title	Report Number	Date Issued
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-06-12-00060	5/4/2015
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06051	4/13/2015
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-13-02037	3/4/2015
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	A-06-14-00031	2/10/2015
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-03-12-00205	8/21/2014
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-13-06040	8/7/2014
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	A-09-12-02079	4/30/2014
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	A-09-12-02080	4/24/2014
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-03-12-00200	11/26/2013
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	A-06-12-00059	9/19/2013
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	A-06-10-00011	8/12/2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	OEI-03-09-00410	6/24/2011

APPENDIX C: FEDERAL REQUIREMENTS AND STATE AGENCY GUIDANCE RELATED TO PHARMACY AND 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 (which 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 (the Secretary) 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 States to provide for the collection and submission of such utilization data and coding (such as HCPCS 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 the Department of Health and Human Services to delay any of the above requirements to prevent hardship to States that required additional time to implement the reporting requirements for physician-administered drugs.

FEDERAL REGULATIONS

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).

STATE AGENCY GUIDANCE

The State agency publishes notices to clarify and explain new and existing programs and policies for providers and other interested parties. On April 14, 2008, the “Notice of Changes to Billing Requirements for Drugs Administered in Outpatient Clinical Settings” informed providers of the following: “Effective April 1, 2008, Alaska Medical Assistance claims must include NDC (National Drug Code) information for drugs administered by health care providers in outpatient clinical settings.” The notice informed providers that claims must include both the NDC number and the units of measurement and stated that providers that do not comply with these billing requirements “will not be reimbursed.”

APPENDIX D: STATE AGENCY COMMENTS



THE STATE
of **ALASKA**
GOVERNOR MIKE DUNLEAVY

Department of Health and Social Services

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June 11, 2020

Ms. Lori A. Ahlstrand
Regional Inspector General for Audit Services
Office of Audit Services, Region IX
Office of Inspector General
Department of Health and Human Services
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

Dear Ms. Ahlstrand:

RE: Response to OIG confidential draft report number #A-09-19-02001 received April 21, 2020 titled *Alaska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs*.

Thank you for the opportunity to review and respond to the draft report by the Office of the Inspector General (OIG) regarding the Alaska's Department of Health and Social Service's (AKDHSS) Medicaid drug rebate program. Additionally, I would also like to extend my sincere appreciation of the high level of professional courtesy extended to our program staff throughout the audit process and for granting the state additional time in providing its response.

AKDHSS is in general agreement with the report as shared and has the following responses to the three findings below.

Finding #1: The state agency did not bill manufacturers for rebates on some single-source physician-administered drugs.

AKDHSS concurs with the finding. It is the policy of the program to require National Drug Codes (NDC) to be included on claims submitted with recognized physician-administered drug procedure codes and to send these claims to the rebate contractor for rebate invoice processing. However, the program identified a system failure in late 2016 which resulted in some of the physician-administered drug claims during the CY2016 audit period to not be sent from the fiscal agent to the rebate contractor. As a result, these claims were not included in the required quarterly rebate invoicing. The program engaged the Medicaid Management Information System (MMIS) contractor and fiscal agent to resolve the issue upon identification. To facilitate resolution, a corrective action plan was employed to:

- Resolve the invoicing omissions;
- Initiate recoupment proceedings for improperly billed claims;
- Educate providers on correct billing practices; and

- Set in place additional internal programmatic controls, including prospective claims adjudication enhancements to promote proper interrogation of the submitted Healthcare Common Procedure Coding System (HCPCS) code and quantity against the submitted NDC and quantity.

After a significant amount of work with the MMIS contractor on the corrective action plan and required changes to the MMIS to provide for enhanced editing on physician-administered drug claims, the State engaged with the Centers for Medicare and Medicaid Services (CMS) for technical assistance on an "Enhanced Physician-administered Drug Editing" (PADE) Implementation Advanced Planning Document (IAPD) in February 2019, prior to initiation of this audit. The IAPD was formally submitted in April and subsequently approved by CMS May 2019. These changes, deployed on April 26, 2020, implemented updates to the following areas:

- Database changes to store the procedure code and NDC cross reference table;
- New interface to load the cross reference table from Conduent's subcontractor;
- New error messages for interface load processing;
- Internal User Interface (UI) screens to display the cross references;
- New business rules (BR) to evaluate the cross reference table during claims processing;
- New exceptions codes to communicate errors found during claims processing;
- Claims resolution text to accommodate the enhanced editing;
- Claims response text to accommodate the enhanced editing.

Finding #2: The state agency did not bill manufacturers for rebates on some top-20 multiple-source physician-administered drugs.

AKDHSS partially concurs with the finding. CMS ceased publishing a listing of top-20 multiple-source physician administered drugs in 2012. CMS cited the "impact on states in removing the top 20 listing was minimal, because virtually all states do not limit NDC numbers on claims for only these drugs, but require NDC submission for all physician-administered drugs." Because CMS no longer publishes a listing of the top-20 multiple-source physician administered drugs, the State did not evaluate which specific drugs and claims are cited under this specific finding. However, the program's policy is to adhere to the definition of a covered outpatient drug (COD) as defined in 42 CFR §447.502 and invoice for rebate physician-administered drugs that meet the COD definition. Due to the systems failure outlined in the previous finding, a portion of those physician-administered drugs the program would normally have invoiced for rebate were not. The corrective action plan work was in progress to resolve these issues when this audit commenced.

<https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/index.html>

Finding #3: The state agency did not bill manufacturers for rebates on other physician-administered drugs.

AKDHSS partially concurs with the finding. Physician-administered drugs fall into the category of Covered Outpatient Drugs as defined in 42 CFR §447.502.

Some claims may be submitted by billing providers that contain what appear to be NDCs but the HCPCS code and service may not be recognized as a drug product. Such claims may reflect other covered services, such as medical supplies, that do not have federal rebate obligations.

June 11, 2020
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The State appreciates and welcomes the opportunity to work with the Centers for Medicare and Medicaid Services (CMS) on resolution of these remaining federal share amounts (\$3,615 and \$185,066).

The State will also work with CMS to determine if there is any unallowable portion of Federal reimbursement for physician-administered drugs paid after December 31, 2017, as a result of a potential gap in rebate invoicing. Internal programmatic controls incorporated as part of the corrective action plan will be continually reviewed and revised as part of the program's quality improvement processes to ensure manufacturers are invoiced for rebates for all rebate-eligible physician-administered drugs.

The State wishes again to express our appreciation for the professionalism of your staff throughout the audit process. We look forward to the additional opportunities to reconcile the remaining topics outlined.

Please contact Erin Narus, PharmD, RPh, State Pharmacist at 907-334-2425 or Linnea Osborne, Accountant V at 907-465-6333 if you have any questions or require additional information.

Sincerely,



Adam Crum
Commissioner

- Cc: Albert E. Wall, Deputy Commissioner
Sana P. Efirid, Assistant Commissioner
Renee Gayhart, Director of Healthcare Services
Erin Narus, PharmD, RPh, Lead Pharmacist, Healthcare Services
Charles Semling, PharmD, RPh, Pharmacist, Healthcare Services
Linnea Osborne, Accountant V