

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**TEXAS DID NOT BILL
MANUFACTURERS FOR SOME
REBATES FOR PHYSICIAN-
ADMINISTERED DRUGS
DISPENSED TO ENROLLEES OF
MEDICAID MANAGED-CARE
ORGANIZATIONS**

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Office of Inspector General

<https://oig.hhs.gov>

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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: August 2019

Report No. A-06-17-04001

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



Why OIG Did This Review

For a covered outpatient drug to be eligible for Federal Medicaid reimbursement, the manufacturer must enter into a rebate agreement administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Previous OIG reviews found that States did not always bill and collect all rebates due for drugs administered by physicians to enrollees of Medicaid managed-care organizations (MCOs).

Our objective was to determine whether Texas complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees.

How OIG Did This Review

We reviewed physician-administered drug claims that were paid by the MCOs between January 1, 2013, through December 31, 2014 (audit period). We identified drugs that had not been billed by Texas and worked with Texas to calculate the amount of rebates that Texas would have collected from manufacturers had it billed them for the drugs.

Texas Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations

What OIG Found

Texas properly billed manufacturers for some rebates for physician-administered drugs. However, Texas did not bill for and collect from manufacturers rebates of \$4.4 million (\$2.6 million Federal share) for physician-administered drugs. For drugs that were eligible for rebates, Texas did not bill for rebates of \$2.2 million (Federal Share) for single-source and top-20 multiple-source physician-administered drugs. For drugs that may have been eligible for rebates, Texas did not bill for rebates of \$366,578 (Federal share) for other physician-administered drugs. In addition, Texas did not bill for rebates for 160,579 claim lines for other physician-administered drugs that may have been eligible for rebates. These errors occurred because Texas's internal controls did not always ensure that it billed manufacturers to secure rebates, and Texas did not always collect the utilization data necessary to bill the manufacturers.

What OIG Recommends and Texas Comments

We recommend that Texas (1) bill manufacturers for the \$2.2 million (Federal share) in rebates for single-source and top-20 multiple-source physician-administered drugs, and refund the Federal share of rebates collected; (2) work with CMS to determine whether the non-top-20 multiple-source physician-administered drugs were eligible for rebates and, if so bill manufacturers for the \$366,578 (Federal share) in rebates, and refund the Federal share of rebates collected; (3) work with CMS to determine whether the other physician-administered drugs, associated with 160,579 claim lines, were eligible for rebates and, if so, determine the rebates due and upon receipt of the rebates refund the Federal share of the rebates collected; and (4) strengthen internal controls to ensure that all eligible physician-administered drugs are billed for rebate.

In written comments on our draft report, Texas did not indicate concurrence or nonconcurrence with our recommendations. Texas stated that it had billed the identified drugs for rebate and would refund the Federal share collected. Texas also determined that some of the other physician-administered drug claims lines were potentially rebatable and would process these claims for rebate. In addition, Texas also outlined steps taken and additional action planned to strengthen internal controls.

We maintain that our recommendations are valid.

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INTRODUCTION

WHY WE DID THIS REVIEW

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. States generally offset their Federal share of these rebates against their Medicaid expenditures. States bill the manufacturers for rebates to reduce the cost of drugs to the program. However, prior Office of Inspector General (OIG) reviews found that States did not always bill and collect all rebates due for drugs administered to enrollees of Medicaid managed-care organizations (MCOs). (Appendix B lists previous OIG reviews of the Medicaid drug rebate program.¹) Previous OIG reviews at Texas found that Texas claimed unallowable Federal Medicaid reimbursement for some fee-for-service physician-administered drugs and that Texas did not bill manufacturers for some rebates for MCO pharmacy drugs. For this audit, we reviewed the Texas Health and Human Services Commission's (State agency's) billing for rebates for physician-administered drugs dispensed to MCO enrollees.

OBJECTIVE

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

BACKGROUND

Medicaid Drug Rebate Program

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

Manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price.² 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.

¹ OIG performed similar reviews for rebates due for drugs administered by physicians to fee-for-service and MCO enrollees. These reviews 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 of the Act. To bill for rebates, States capture drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers and report the information to the manufacturers (the Act § 1927(b)(2)(A)). The number of units is multiplied by the unit rebate amount to determine the actual rebate amount due from each manufacturer.

Federal Reimbursement to States for Payments to Medicaid Managed-Care Organizations

States use two primary models to pay for Medicaid services: fee-for-service and managed care. In the managed-care model, States contract with MCOs to provide specific services to enrolled Medicaid beneficiaries, usually in return for a predetermined periodic payment known as a capitation payment. States pay MCOs for each covered individual regardless of whether the enrollee received services during the relevant time period (42 CFR § 438.2). MCOs use the capitation payments to pay provider claims for these services. Physician-administered drugs may be covered by the capitation payment.

To claim Federal reimbursement, States report capitation payments made to MCOs as MCO expenditures on the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (CMS-64 report). These expenditures are not identified by specific type of service (such as physician-administered drugs). When States receive drug rebates from manufacturers, the States must report the rebates as decreasing adjustments on the CMS-64 report. States report drug rebate accounts receivable data on the Medicaid Drug Rebate Schedule (Form CMS-64.9R), which is part of the CMS-64 report. CMS reimburses States for the Federal share of Medicaid expenditures reported on the CMS-64 report.

State's Collection of Rebates for 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 to 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 claims did not contain NDCs. Drugs administered by a physician are typically billed to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.³

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

The DRA amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source 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 covered outpatient drugs that have at least one other drug rated as therapeutically equivalent by the 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.

Effective March 23, 2010, the Affordable Care Act (ACA)⁷ required manufacturers to pay rebates on covered outpatient drugs dispensed to MCO enrollees if the MCOs are responsible for coverage of such drugs. Prior to the enactment of the ACA, drugs dispensed by Medicaid MCOs were excluded from the rebate requirements. States typically require MCOs to submit to the State agency NDCs for covered outpatient drugs dispensed to eligible individuals. MCOs submit to the State agency provider claim information including claim lines for covered outpatient drugs. This information includes drug utilization data which States must include when billing manufacturers for rebates.

The State Agency's Medicaid Drug Rebate Program

The State agency, which is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs, contracts with Xerox State Healthcare, LLC⁸ (the contractor) to manage its drug rebate program. As the rebate administrator, the contractor maintains the Drug Rebate Analysis and Management System to administer the rebate program. The State agency receives claim data from MCOs in its Medicaid Management Information System, which contains a field for NDCs associated with drug utilization. The State agency forwards the drug utilization to the contractor to bill the manufacturers. Manufacturers pay rebates directly to the State agency; the State agency then forwards the payment information to the contractor, which reconciles the payments to the rebates. The contractor maintains accounts receivable information and works with manufacturers to resolve any unpaid rebates.

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.

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.

⁷ P.L. No. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (Mar. 23, 2010).

⁸ On February 15, 2017, Xerox State Healthcare, LLC officially changed their name to Conduent State Healthcare, LLC.

HOW WE CONDUCTED THIS REVIEW

We reviewed physician-administered drug claims that were paid by the MCOs between January 1, 2013, through December 31, 2014 (audit period). We limited our review to HCPCS codes contained on CMS's Medicare Part B Crosswalk.⁹ We used the Crosswalk to identify the NDCs associated with each HCPCS code and used the CMS Medicaid Drug File to determine whether the NDCs were classified as single-source or multiple-source drugs. Additionally, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug listing. We identified drugs that had not been billed by the State agency and worked with the State agency to calculate the amount of rebates that would have been collected from manufacturers had it billed them for the drugs.

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

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

FINDING

During our audit period, the State agency did not fully comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. The State agency properly billed manufacturers for some rebates for physician-administered drugs; however, the State agency did not bill for and collect from manufacturers rebates totaling \$4,415,704 (\$2,569,499 Federal share). In addition, the State agency did not bill for rebates for 160,579 claim lines for other physician-administered drugs that may have been eligible for rebates. These errors occurred because the State agency's internal controls did not always ensure that it billed manufacturers to secure rebates, and the State agency did not always collect the utilization data necessary to bill the manufacturers.

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)(C)). Federal regulations prohibit Federal reimbursement for

⁹ The Medicare Part B Crosswalk is published quarterly by CMS and is based on published drug and biological pricing data and information submitted to CMS by manufacturers. It contains the payment amounts that will be used to pay for Part B covered drugs as well as the HCPCS codes associated with those drugs. CMS instructed States that they could use the crosswalk as a reference because HCPCS codes and NDCs are standardized codes used across health care programs.

physician-administered drugs unless the States require the submission of claims containing NDCs (42 CFR § 447.520).

The ACA amended section 1927 of the Act, effective March 23, 2010, to specifically require manufacturers to pay rebates on covered outpatient drugs dispensed to MCO enrollees if the MCOs are responsible for coverage of such drugs. To bill for rebates, States must include information for drugs dispensed to individuals enrolled in MCOs when billing manufacturers for rebates (the Act §§ 1927(b)(1)(A) and (b)(2)(A)).

The ACA also amended section 1903 of the Act to specifically address the conditions of Federal reimbursement for covered outpatient drugs dispensed to MCO enrollees. Essentially, States must secure rebates for drugs dispensed through MCOs and require MCOs to submit to the State NDCs for drugs dispensed to eligible individuals (the Act § 1903(m)(2)(A)).

Appendix C contains Federal and State requirements related to Medicaid drug rebates.

THE STATE AGENCY DID NOT BILL MANUFACTURERS FOR SOME REBATES FOR DRUGS DISPENSED THROUGH MEDICAID MANAGED-CARE ORGANIZATIONS

The State agency did not bill for and collect from manufacturers some rebates for physician-administered drugs dispensed to MCO enrollees:

- For drugs that were eligible for rebates, the State agency did not bill for and collect rebates of \$3,785,737 (\$2,202,921 Federal share) for single-source and top-20 multiple-source physician-administered drugs. We identified 22,356 claim lines for single-source and top 20 multiple-source physician-administered drugs eligible for rebate that were not billed. The claim lines associated with these drugs contained sufficient drug utilization data to determine the specific drug administered and the amount of rebates due.
- For drugs that may have been eligible for rebates, the State agency did not bill for and collect rebates of \$629,967 (\$366,578 Federal share). We identified 91,252 claim lines for non-top-20 multiple source physician-administered drugs with NDCs. Because these drugs were non-top-20 multiple-source physician-administered drugs with NDCs, the State agency's obligation to bill for rebates is unclear. The State has sufficient information to bill the manufacturers for rebate for these drugs and if the State agency had billed these claims for rebate, the drug manufacturers would have been required to pay the rebates. However, there is no Federal requirement to bill these claims for rebate. Accordingly, we set aside for CMS resolution \$629,967 (\$366,578 Federal share) for these drugs.

In addition, the State agency did not bill for rebates for 160,579 claim lines for other physician-administered drugs that may have been eligible for rebates. We determined that the HCPCS codes for these claim lines were HCPCS codes that corresponded with only single source or

top-20 multiple-source physician-administered drugs. However, the State agency did not provide us sufficient drug utilization data (e.g., no NDCs were available) to determine the specific drug administered and the amount of rebates due. Therefore, we set aside for CMS resolution the claim lines for these physician-administered drugs.

RECOMMENDATIONS

We recommend that the Texas Health and Human Services Commission:

- bill manufacturers for the \$3,785,737 (\$2,202,921 Federal share) in rebates for single-source and top-20 multiple-source physician-administered drugs, and refund the Federal share of rebates collected;
- work with CMS to determine whether the non-top-20 multiple-source physician-administered drugs were eligible for rebates and, if so, bill manufacturers for the \$629,967 (\$366,578 Federal share) in rebates and refund the Federal share of rebates collected;
- work with CMS to determine whether the other physician-administered drugs, associated with 160,579 claim lines, were eligible for rebates and, if so, determine the rebates due and upon receipt of the rebates refund the Federal share of the rebates collected; and
- strengthen internal controls to ensure that all eligible physician-administered drugs are billed for rebate.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency did not indicate concurrence or nonconcurrence with our recommendations.

Regarding our first and second recommendations, the State agency stated that it had billed the drugs for rebate and would refund the Federal share collected via the CMS-64 report. Regarding our third recommendation, the State agency determined that some of the claims were potentially rebatable and would process these claims for rebate, invoice the manufacturers accordingly, and refund the Federal share via the CMS-64 report. Regarding our fourth recommendation, the State agency outlined steps taken and additional action planned to strengthen internal controls. The State agency's comments appear in their entirety in Appendix D.

OFFICE OF INSPECTOR GENERAL RESPONSE

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

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed drug utilization data for physician-administered drug claims that were paid by the MCOs between January 1, 2013, and December 31, 2014.

We identified drug utilization data for physician-administered drugs that were not billed for rebates and determined which drugs were eligible or may have been eligible for rebates. For claims not billed that required rebate, we determined the amount that the State agency would have collected from manufacturers had it billed them for the drugs.

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

METHODOLOGY

To accomplish our objective, we:

- reviewed Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs;
- reviewed State agency policies and procedures for rebates for physician-administered drugs and the State agency managed-care contract;
- interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid rebate billing process for physician-administered drugs;
- reviewed the State agency's Form CMS-64 to identify MCO expenditures;
- obtained listings of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalks, and the CMS Medicaid Drug Files for our audit period;
- identified and removed physician-administered drug claims not eligible for rebate as part of the drug rebate program;
- identified MCO drug utilization data for physician-administered drugs not billed for rebates and identified the drugs that were eligible or may have been eligible for rebates by:
 - identifying single-source and top-20 multiple-source physician-administered drugs that were eligible for rebates;

- identifying non-top-20 multiple-source physician-administered drugs that may have been eligible for rebates, and
 - identifying 160,579 claim lines for other physician-administered drugs that may have been eligible for rebates;
- followed up with State officials for explanation of eligible claims not billed for rebate;
- determined the amount of rebates not collected; and
- discussed the results of our review 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.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-05-18-00030	6/18/19
<i>New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-02-16-01012	5/09/19
<i>Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-05-17-00038	4/05/19
<i>Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-16-02031	2/16/18
<i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-06-16-00018	2/12/18
<i>Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-07-13-06046	12/22/17
<i>Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations</i>	A-06-16-00004	12/12/17
<i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-05-16-00013	11/1/17
<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	9/26/17
<i>Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-16-02029	9/26/17
<i>Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-16-02027	9/12/17
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	A-07-16-06065	5/5/17
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-05-16-00014	3/23/17
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06050	1/5/17
<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	12/30/16
<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	12/22/16

Report Title	Report Number	Date Issued
<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	12/8/16
<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	8/18/16
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06057	5/26/16
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician- Administered Drugs</i>	A-07-15-06063	3/31/16
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician- Administered Drugs</i>	A-07-15-06059	2/09/16
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-15-06062	1/14/16
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician- Administered Drugs</i>	A-07-15-06058	1/13/16
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	A-09-14-02038	1/07/16
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-14-06056	9/18/15
<i>States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations Has Improved</i>	OEI-05-14-00431	9/16/15
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06049	7/22/15
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-06-12-00060	5/04/15
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06051	4/13/15
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-13-02037	3/04/15
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	A-06-14-00031	2/10/15
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-03-12-00205	8/21/14

Report Title	Report Number	Date Issued
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician- Administered Drugs</i>	<u>A-07-13-06040</u>	8/07/14
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-12-02079</u>	4/30/14
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-12-02080</u>	4/24/14
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician- Administered Drugs</i>	<u>A-03-12-00200</u>	11/26/13
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-12-00059</u>	9/19/13
<i>States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations</i>	<u>OEI-03-11-00480</u>	9/07/12
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	5/06/11

APPENDIX C: FEDERAL REQUIREMENTS 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 the 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. A manufacturer must enter into a rebate agreement with the Secretary of Health and Human Services and pay rebates for States to receive Federal funding for the manufacturer's covered outpatient drugs dispensed to Medicaid patients (the Act § 1927(a)). Responsibility for the drug rebate program is shared among the drug manufacturers, CMS, and the States.

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

Section 1927(a)(7) of the Act requires that States shall provide for the collection and submission of such utilization data and coding (such as J-codes and NDCs) 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, 2008.¹⁰ 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 2501 of the ACA amended section 1927(b)(1)(A) of the Act to require that manufacturers pay rebates for covered outpatient drugs dispensed to individuals enrolled in an MCO if the MCO is responsible for coverage of such drugs. Section 2501 of the ACA also amended section 1927(b)(2)(A) to require that States submit information necessary to secure rebates from manufacturers for covered outpatient drugs dispensed through MCOs. In addition, section 2501 amended section 1903(m)(2)(A) to essentially extend the Medicaid rebate obligations to drugs dispensed through MCOs. Under this provision, each MCO contract

¹⁰ In general terms, multiple-source drugs are covered outpatient drugs for which there are two or more drug products that are rated therapeutically equivalent by the FDA. See, e.g., section 1927(k)(7) of the Act. Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents. Further, the term "top-20 multiple-source drugs" is drawn from a CMS classification and describes these drugs in terms of highest dollar volume of physician-administered drugs in Medicaid. The Act section 1927(a)(7)(B)(i).

must require that Medicaid rebates apply to drugs dispensed through the MCO. Section 2501 prohibits payment unless the MCO contracts require MCOs to submit to the State NDC drug utilization data for drugs dispensed to eligible individuals.

APPENDIX D: STATE AGENCY COMMENTS



TEXAS
Health and Human
Services

Texas Health and Human Services Commission

Dr. Courtney N. Phillips
Executive Commissioner

July 3, 2019

Ms. Patricia Wheeler
Regional Inspector General for Audit Services
Office of Inspector General, Office of Audit Services
1100 Commerce, Room 632
Dallas, Texas 75242

Re: Report Number A-06-17-04001

Dear Ms. Wheeler:

The Texas Health and Human Services Commission (HHSC) received a draft audit report entitled "Texas Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations" from the U.S. Department of Health and Human Services Office of Inspector General. The cover letter, dated June 4, 2019, requested that HHSC provide written comments, including the status of actions taken or planned in response to report recommendations.

I appreciate the opportunity to respond. Please find the attached HHSC management response, which (a) includes comments related to the content of the findings and recommendations and (b) details actions HHSC has completed or planned.

Please let me know if you have any questions or need additional information. David M. Griffith, Deputy Inspector General for Audit, HHSC Office of Inspector General, serves as the lead staff on this matter and can be reached by telephone at (512) 491-2806 or by email at David.Griffith@hhsc.state.tx.us.

Sincerely,

A handwritten signature in blue ink, appearing to read "Dr. Courtney N. Phillips".

Dr. Courtney N. Phillips

P.O. Box 13247 • Austin, Texas 78711-3247 • 512-424-6500 • hhs.texas.gov

Texas Health and Human Services Commission
Management Response to the
U.S. Department of Health and Human Services Office of Inspector General Report:
A-06-17-04001

**Texas Did Not Bill Manufacturers for Some Rebates for
Physician-Administered Drugs Dispensed to Enrollees of Medicaid
Managed-Care Organizations**

DHHS - OIG Recommendation: *We recommend that the Texas Health and Human Services Commission bill manufacturers for the \$3,785,737 (\$2,202,921 Federal share) in rebates for single-source and top-20 multiple-source physician-administered drugs, and refund the Federal share of rebates collected.*

HHSC Management Response:

HHSC has billed the \$3,785,737 in rebates for single-source and top-20 multiple-source physician-administered drugs.

Actions Planned:

HHSC will collect the \$3,785,737 in rebates and refund the \$2,202,921 Federal share via the CMS-64 report.

Estimated Completion Date:

Within one year of the date of the final audit report.

Title of Responsible Person:

Deputy Director, Vendor Drug Program

DHHS - OIG Recommendation: *We recommend that the Texas Health and Human Services Commission work with CMS to determine whether the non-top-20 multiple-source physician-administered drugs were eligible for rebates and, if so bill manufacturers for the \$629,967 (\$366,578 Federal share) in rebates, and refund the Federal share of rebates collected.*

HHSC Management Response:

HHSC determined that the non-top-20 multiple-source physician-administered drugs were eligible for rebates, and completed the assessment of claims data, and subsequently billed the \$629,967 in rebates.

Actions Planned:

HHSC will collect the \$629,967 in rebates and refund the \$366,578 Federal share via the CMS-64 report.

Estimated Completion Date:

Within one year of the date of the final audit report.

Title of Responsible Person:

Deputy Director, Vendor Drug Program

DHHS - OIG Recommendation: *We recommend that the Texas Health and Human Services Commission work with CMS to determine whether the other physician-administered drugs, associated with 160,579 claim lines, were eligible for rebates and, if so, determine the rebates due and upon receipt of the rebates refund the Federal share of the rebates collected.*

HHSC Management Response:

Actions Planned:

HHSC determined that approximately 16,000 of the 160,579 claims are potentially rebatable. HHSC prepared a rebate extract to be entered into the rebate system by the Rebate Administrator. The Rebate Administrator will determine the rebate amount due and invoice the manufacturers accordingly by September 30, 2019. HHSC will then refund the Federal share of the rebates collected via the CMS-64 report.

Estimated Completion Date:

Within one year of the date of the final audit report.

Title of Responsible Person:

Deputy Director, Vendor Drug Program

DHHS - OIG Recommendation: *We recommend that the Texas Health and Human Services Commission strengthen internal controls to ensure that all eligible physician-administered drugs are billed for rebate.*

HHSC Management Response:

HHSC has strengthened internal controls by creating processes and tools, communicating expectations to managed care organizations (MCOs), and enforcing requirements to ensure all eligible physician-administered drugs are billed for rebate. Effective April 1, 2018, HHSC began retrieving, sorting, and posting monthly MCO-specific Error Reject Files to TexMed Central to identify Healthcare Common Procedure Coding System/National Drug Code (HCPCS/NDC) inaccuracies. The reports provide MCOs data to identify any issues and implement internal corrective actions to prevent future errors.

HHSC currently provides continuous monitoring and oversight by reviewing the error reports and working with MCOs to address any issues. To support this process, HHSC hosts monthly meetings with each MCO to review a list of anomalies identified in the error reports and provide guidance on a resolution. Since the initiation of this process, the monthly error rate files have decreased from 3,000 errors in May 2018 to 1,600 errors in May 2019. Included in the current Uniform Managed Care Contract is a clause that allows HHSC to pursue liquidated damages for each instance an MCO submits a claim that does not contain a matching HCPCS/NDC combination.

Actions Planned:

Effective September 1, 2019, the current warning edit, which advises the MCO that a missing or mismatched HCPCS/NDC code combination exists, will become a fatal edit rejecting the encounter. No missing or mismatched HCPCS/NDCs will be received into the HHSC rebate administration system after the fatal edit is active.

Estimated Completion Date:

September 1, 2019

Title of Responsible Person:

Deputy Director, Vendor Drug Program