

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**TEXAS DID NOT BILL
MANUFACTURERS FOR SOME REBATES
FOR PHARMACY DRUGS OF MEDICAID
MANAGED-CARE ORGANIZATIONS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



Gloria L. Jarmon
Deputy Inspector General
for Audit Services

December 2017
A-06-16-00004

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 assessments 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: December 2017

Report No. A-06-16-00004

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



Why OIG Did This Review

Manufacturers must pay Medicaid drug rebates to the States in order for a covered outpatient drug to be eligible for Federal reimbursement. States bill manufacturers for rebates to reduce the cost of the drugs to the Medicaid program. The Affordable Care Act extended the requirement for rebates to include drugs dispensed to enrollees of Medicaid managed-care organizations (MCOs). Previous OIG reviews found that States did not always bill and collect all rebates due for drugs administered to enrollees of MCOs.

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

How OIG Did This Review

We selected a judgmental sample of National Drug Codes (NDCs) representing drugs with high usage from April 2012 through December 2014. We tested claim lines related to these NDCs to determine whether they were properly invoiced and found that in two quarters, some claims were bypassed in the Drug Rebate Analysis and Management System (DRAMS) and were not processed for rebate. We expanded our testing specifically for bypassed claims for these two quarters.

Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations

What OIG Found

We found that Texas did not fully comply with Federal Medicaid requirements for billing manufacturers for some rebates for pharmacy drugs dispensed to MCO enrollees. We found that Texas properly processed claims for rebates in most instances, however, some claims were bypassed in the DRAMS and were not processed for rebate. The bypassed claims occurred during the rebate billing for the second quarters of 2012 and 2014. These claims were bypassed because they were loaded during the rebate invoicing process and Texas did not perform the required invoice recalculation to ensure they were applied to the current quarter. The bypassed claims resulted in 220,336 claim lines that were not invoiced for rebate. The rebates associated with these claims total \$7.8 million (\$4.4 million Federal share).

What OIG Recommends and Texas Comments

We recommend that Texas (1) invoice manufacturers for the \$7.8 million (\$4.4 million Federal share) in rebates and refund the Federal share of rebates collected, and (2) strengthen internal controls to ensure that the invoice recalculation step is performed when needed so that all managed-care pharmacy drugs eligible for rebate are invoiced.

Texas did not indicate concurrence or nonconcurrence with our recommendations. However, Texas stated it has invoiced the rebates of \$7.8 million and refunded the \$4.4 million Federal share, and strengthened internal controls to ensure that the invoice recalculation step is performed.

TABLE OF CONTENTS

INTRODUCTION	1
Why We Did This Review	1
Objective.....	1
Background.....	1
Medicaid Drug Rebate Program	1
Federal Reimbursement to States for Payments to Medicaid Managed-Care Organizations.....	2
Drugs Administered or Dispensed to Enrollees of Medicaid Managed-Care Organizations.....	2
The State Agency’s Medicaid Drug Rebate Program.....	3
How We Conducted This Review.....	3
FINDING	4
Federal Requirements	4
The State Agency Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations.....	5
RECOMMENDATIONS	5
STATE AGENCY COMMENTS.....	5
APPENDICES	
A: Related Office of Inspector General Reports	6
B: Audit Scope and Methodology.....	8
C: Federal Requirements Related to Pharmacy Drugs	10
D: State Agency Comments	11

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. States bill the manufacturers for the rebates to reduce the cost of the drugs to the program. However, previous 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 A lists previous OIG reviews of the Medicaid drug rebate program.¹ In one of those reviews, which focused on fee-for-service claims, we found that the State of Texas claimed unallowable Federal Medicaid reimbursement for some physician-administered drugs. Texas began covering drugs in its Medicaid managed-care programs in 2012. For this audit, we reviewed the Texas Health and Human Services Commission's (State agency's) invoicing for rebates for pharmacy drugs dispensed to enrollees of MCOs for the period April 1, 2012 through December 31, 2014.²

OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for billing manufacturers for rebates for pharmacy 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 administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Manufacturer rebates 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.³ On the basis

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 The OIG is also performing a review of Texas' invoicing for rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations.

³ Section 1927(b) of the Act and section II of the Medicaid rebate agreement.

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 product data file, which identifies drugs with such fields as National Drug Code (NDC), unit type, units per package size, and product name.

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 this 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.

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 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. Capitation payments may cover outpatient drugs, which can include both drugs dispensed to patients at pharmacies (pharmacy drugs) and drugs dispensed by a physician (physician-administered drugs).

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 (Form CMS-64). These expenditures are not identified by specific type of service. CMS reimburses States for the Federal financial participation (Federal share)⁴ of Medicaid expenditures reported on the Form CMS-64.

Drugs Administered or Dispensed to Enrollees of Medicaid Managed-Care Organizations

Effective March 23, 2010, the Affordable Care Act (ACA)⁵ required manufacturers to pay rebates on covered outpatient drugs dispensed to MCO enrollees if the MCOs are responsible for coverage of such drugs. This requirement applies to both pharmacy drugs and physician-administered 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

⁴ § 1903(a) of the Act

⁵ The Patient Protection and Affordable Care Act, 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. 30, 2010), is known as the Affordable Care Act.

drugs. This information includes drug utilization data, which States must include when billing manufacturers for rebates.

States must report adjustments to drug expenditures and drug rebates on the Form CMS-64. States report drug rebate accounts receivable data on the Medicaid Drug Rebate Schedule (Form CMS-64.9R), which is part of the Form CMS-64. The expenditures, adjustments, and rebates do not distinguish between amounts related to pharmacy drugs and amounts related to physician-administered drugs.

The State Agency's Medicaid Drug Rebate Program

Texas began covering pharmacy drugs in its Medicaid managed-care programs on March 1, 2012. Prior to that date, MCOs were not financially responsible for covering pharmacy drugs. The State agency, which is responsible for billing and collecting Medicaid drug rebates for pharmacy drugs, contracts with Xerox State Healthcare, LLC⁶ (the contractor) to manage its drug rebate program. As the rebate administrator, the contractor maintains the Drug Rebate Analysis and Management System (DRAMS) to administer the rebate program. The State agency receives claim data from MCOs in its Medicaid Management Information System (MMIS), 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 rebate invoices. The contractor maintains accounts receivable information and works with manufacturers to resolve any unpaid rebates.

DRAMS calculates a quarterly rebate invoice by NDC from claim data loaded on a weekly basis. DRAMS allows claims to continue to be loaded during the rebate invoicing process until the quarterly invoices are frozen⁷. However, if claims are loaded after the initiation of the invoicing cycle, then an additional step of "invoice recalculation" is required prior to the invoices being frozen to ensure that claims are included in the rebate invoicing process and are not bypassed.

HOW WE CONDUCTED THIS REVIEW

We reviewed the Form CMS-64 and determined that the State agency paid MCOs \$39.8 billion (\$23.6 billion Federal share) from April 2012 through December 2014. This total included expenditures for pharmacy drugs. Our audit covered the State agency's MCO drug utilization data for pharmacy drugs for our audit period.

⁶ On February 15, 2017, Xerox State Healthcare, LLC officially changed their name to Conduent State Healthcare, LLC.

⁷ After invoices have been calculated and reviews have been performed, invoices are frozen. This process in DRAMS locks in the information included for each invoice for the current quarter.

We selected a judgmental sample of NDCs with high utilization to test for proper handling in the drug rebate process. We obtained 230,313 claim lines associated with these NDCs from the State agency. Every quarter of our audit period was represented by these claim lines. We received an extract of these claim lines from Texas's MMIS system and compared to claim lines in DRAMS to determine if claims were properly invoiced. We found an immaterial number of errors, about three-hundredths of a percent, for the tested claim lines. However, we also found that many of the errors were for claim lines which were bypassed during the rebate invoice processing during two quarters. Further analysis showed that other claims were bypassed in these two quarters, so we expanded our testing specifically for bypassed claims during these two quarters. This led to the identification and analysis of an additional 223,428 claim lines. In total, our testing covered 453,741 claim lines.

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

FINDING

The State agency did not fully comply with Federal Medicaid requirements for billing manufacturers for some rebates for pharmacy drugs dispensed to MCO enrollees. We found that the State agency properly processed claims for rebates in most instances, however, some claims were bypassed in DRAMS and were not processed for rebate. These claims were bypassed because they were loaded during the rebate invoicing process and the State Agency did not perform the required invoice recalculation. The bypassed claims resulted in 220,336 claim lines that were not invoiced for rebate. The rebates associated with these claims total \$7,768,891 (\$4,438,368 Federal share).

FEDERAL REQUIREMENTS

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)).

THE STATE AGENCY DID NOT BILL MANUFACTURERS FOR SOME REBATES FOR PHARMACY DRUGS DISPENSED TO ENROLLEES OF MEDICAID MANAGED-CARE ORGANIZATIONS

We identified 220,336 MCO pharmacy drug claim lines totaling \$13,591,472 which were not invoiced for Medicaid drug rebates in accordance with Federal regulations. This occurred due to a weakness in the rebate invoicing process. The DRAMS allowed claims to be loaded during the invoice cycle. However, any claims loaded during this cycle should proceed through an invoice recalculation to ensure that they are applied to the current quarter, and DRAMS did not always provide a warning to recalculate invoices. Claims were loaded into DRAMS for two quarters during the invoice cycle and prior to the invoices being frozen without the invoice recalculation step being performed. Therefore, these claim lines were bypassed and not invoiced.

Some claims were bypassed in the second quarter 2012 billing, when Texas began invoicing managed-care pharmacy claims for the first time. Claims were also bypassed in the second quarter of 2014, specific to one MCO. Because the claims were bypassed, the State did not obtain rebates for these drugs. The rebates associated with these claims total \$7,768,891 (\$4,438,368 Federal share).

RECOMMENDATIONS

We recommend that the State agency:

- invoice manufacturers for the \$7,768,891 (\$4,438,368 Federal share) in rebates, and refund the Federal share of rebates collected; and
- strengthen internal controls to ensure the invoice recalculation step is performed when needed so that all managed-care pharmacy drugs eligible for rebate are invoiced.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency did not indicate concurrence or nonconcurrence with our recommendations. However, the State agency described steps it has taken to address our recommendations.

Regarding our first recommendation, the State agency stated that it has invoiced the \$7,768,891 in rebates, and refunded the \$4,438,368 Federal share via the quarter one 2017 Form CMS 64.

Regarding our second recommendation, the State agency stated that in November 2016, it strengthened internal controls to ensure that the invoice recalculation step is performed when needed so that all managed care pharmacy drugs eligible for rebate are invoiced.

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

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<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
<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	5/5/17
<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
<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

Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations (A-06-16-00004)

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

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed the Form CMS-64 and determined that the State agency paid MCOs \$39.8 billion (\$23.6 billion Federal share) from April 2012 through December 2014. This total included expenditures for pharmacy drugs. Our audit covered the State agency's MCO drug utilization data for pharmacy drugs for our audit period.

We tested 453,741 claim lines. We originally tested 230,313 claim lines associated with a judgmental sample of NDCs with high utilization. Every quarter of our audit period was represented by these claim lines. The results of this testing showed that claims had been bypassed in DRAMS during the rebate invoicing process for two quarters. Further analysis showed that other claims were bypassed in these two quarters, so we expanded our testing specifically for bypassed claims for these two quarters. We identified an additional 223,428 claim lines to test.

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 pharmacy drugs.

We conducted our audit from December 2015 through June 2017, and we performed fieldwork at the State agency office in Austin, Texas.

METHODOLOGY

To accomplish our objective, we:

- reviewed Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and pharmacy drugs;
- reviewed State agency policies and procedures for rebates for pharmacy 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 pharmacy drugs;
- reviewed the State agency's Form CMS-64 to identify MCO expenditures;
- tested the billing of rebates by:
 - obtaining from the State agency the MMIS extract for our sample of NDCs,

- obtaining from the State agency the DRAMS extract for our sampled NDCs, and
- comparing the MMIS extract of claims to the DRAMS extract to determine if all eligible claims were invoiced for rebate;
- followed up with State officials for explanation of eligible claims not invoiced for rebate;
- identified two quarters where claim lines were bypassed and not invoiced for rebates;
- obtained from the State agency the list of claims bypassed by DRAMS and not processed for rebates;
- 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 C: FEDERAL REQUIREMENTS RELATED TO PHARMACY 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 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 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 Commission

Charles Smith
Executive Commissioner

October 27, 2017

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

Reference Report Number A-06-16-00004

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 Pharmacy Drugs of Medicaid Managed Care Organizations" from the U.S. Department of Health and Human Services Office of Inspector General. The cover letter, dated September 27, 2017, 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.

If you have any questions or require additional information, please contact David M. Griffith, Deputy IG for Audit, HHSC Inspector General. Mr. Griffith may be reached by telephone at (512) 491-2806 or by e-mail at David.Griffith@hhsc.state.tx.us.

Sincerely,

A handwritten signature in blue ink that reads "Charles Smith". The signature is written in a cursive style.

Charles Smith

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:
**Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of
Medicaid Managed Care**

DHHS - OIG Recommendation: *We recommend that the State agency invoice manufacturers for the \$7,768,891 (\$4,438,368 Federal share) in rebates and refund the Federal share of rebates collected.*

HHSC Management Response:

Actions Completed: HHSC has invoiced the \$7,768,891 in rebates, and refunded the \$4,438,368 Federal share via the quarter one 2017 Form CMS-64.

Completion Date: January 2017

Title of Responsible Person: Deputy Director, Vendor Drug Program

DHHS - OIG Recommendation: *We recommend that the State agency strengthen internal controls to ensure that the invoice recalculation step is performed when needed so that all managed-care pharmacy drugs eligible for rebate are invoiced.*

HHSC Management Response:

In November 2016, HHSC strengthened internal controls to ensure that the invoice recalculation step is performed when needed so that all managed care pharmacy drugs eligible for rebate are invoiced.

Actions Planned: HHSC will document policies and procedures to reflect the control improvements that have been implemented.

Estimated Completion Date: December 31, 2017

Title of Responsible Person: Deputy Director, Vendor Drug Program