Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

TEXAS CLAIMED UNALLOWABLE FEDERAL REIMBURSEMENT FOR SOME MEDICAID PHYSICIAN-ADMINISTERED DRUGS

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

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Deputy Inspector General
for Audit Services

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A-06-12-00060

Office of Inspector General

http://oig.hhs.gov

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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EXECUTIVE SUMMARY

Texas claimed Federal reimbursement of $3.9 million over 3 months that was unallowable and $300,000 that may have been unallowable because it did not comply with Federal Medicaid requirements for billing manufacturers for rebates for some physician-administered drugs.

WHY WE DID THIS REVIEW

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States. States bill the manufacturers for the rebates to reduce Medicaid's drug costs. However, recent Office of Inspector General reviews found that States did not always bill and collect all rebates due for drugs administered by physicians in an office or hospital outpatient facility.

The objective of this review was to determine whether the Texas Health and Human Services Commission (State agency) complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs.

BACKGROUND

The Medicaid drug rebate program became effective in 1991 (the Social Security Act, § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States.

The Deficit Reduction Act of 2005 amended section 1927 to specifically address the collection of rebates on physician-administered drugs. To collect these rebates, States submit to the manufacturers the National Drug Codes (NDCs) for all single-source and the top 20 multiple-source physician-administered drugs. Federal reimbursement for covered outpatient drugs administered by a physician is not available to States that do not comply with Federal requirements for capturing data to bill and collect rebates.

In Texas, the State agency is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs. The State agency contracts with a contractor to bill for rebates. The contractor uses the State agency's claim data for physician-administered drugs to bill manufacturers quarterly and to maintain a record of rebate accounts receivable due from the manufacturers.

WHAT WE FOUND

The State agency did not always comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs. Of the $28,914,583 in paid claims reviewed for our audit period, July through September 2011, the State agency properly billed for rebates associated with $20,470,078 in paid claims and did not bill for rebates associated with

$1,137,513 in paid claims for which rebates were not required. However, the State agency did not bill for rebates associated with $7,306,992 in paid claims:

- The State agency did not have valid NDCs to submit drug utilization data to bill rebates for some claims, and the State agency did not identify all claims that were eligible for rebate. These claim lines totaled $6,777,929, consisting of $6,105,755 for claim lines for single-source drugs and $672,174 for claim lines for top-20 multiple-source drugs. As a result, the State agency improperly claimed reimbursement for $6,777,929 ($3,946,110 Federal share) for these claim lines.

- We were unable to determine the portion of $529,063 ($308,021 Federal share) for which the State agency may have improperly claimed reimbursement. This amount was for claim lines for drugs for which there was insufficient information to determine whether the drugs were required to be invoiced for rebates.

The State agency did not always bill manufacturers for rebates because the State agency's Medicaid Management Information System did not have an edit to ensure that NDCs were present on drug claims and an edit to validate NDCs if submitted.

WHAT WE RECOMMEND

We recommend that the State agency:

- refund $3,946,110 (Federal share) for claim lines for single-source and top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement,

- work with CMS to determine the portion of the $308,021 (Federal share) for other claim lines for physician-administered drugs that was ineligible for Federal reimbursement and refund that amount,

- determine and refund the unallowable Federal reimbursement for single-source and top-20 multiple-source physician-administered drugs for which the rebates were not invoiced before and after our audit period, and

- establish and implement processes to ensure that all physician-administered drugs eligible for rebates are invoiced for rebates.

STATE AGENCY COMMENTS AND OUR RESPONSE

In written comments on our draft report, the State agency did not state whether it concurred with our recommendations but described some of the corrective actions that it has taken or plans to take to address them. Regarding our first recommendation, State agency officials said that they had reduced the recommended refund amount by nearly $1 million by invoicing questioned claims for rebate and would continue to invoice manufacturers and collect the additional rebates that are due. State agency officials also said that they would analyze and determine the extent of the remaining questioned claims that were ineligible for Federal reimbursement and would work

with CMS to refund the Federal share. Regarding our second recommendation, State agency officials said that they would work with CMS to determine the extent of other claim lines that were ineligible for Federal reimbursement and refund the Federal share. Regarding our third recommendation, State agency officials said that they would work with CMS to determine the extent of claims before and after our audit period that were ineligible for Federal reimbursement and refund the Federal share. Regarding our fourth recommendation, State agency officials said that they had implemented and strengthened acute-care claim processing controls and rebate processes to ensure that manufacturers are billed for physician-administered drugs that are eligible for rebate. The State agency also described actions it plans to take to further strengthen these processes.

We did not audit the State agency's actions because they came after our audit period; therefore, we did not revise the refund amount in our first recommendation.

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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. States bill the manufacturers for the rebates to reduce Medicaid's drug costs. However, recent Office of Inspector General reviews found that States did not always bill and collect all rebates due for drugs administered by physicians in an office or hospital outpatient facility. (Appendix A lists previous reviews of the Medicaid drug rebate program.)

OBJECTIVE

Our objective was to determine whether the Texas Health and Human Services Commission (State agency) complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs.

BACKGROUND

Medicaid Drug Rebate Program

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

Manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price.[1] 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 fields such as National Drug Code (NDC), unit type, units per package size, and product name.

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 (§ 1903(i)(10)).[2,3] To bill for rebates, States must capture drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers and must report the information to the manufacturers (the Act § 1927(b)(2)(A)). The number of units

[1] Section 1927(b) of the Act and section II of the Medicaid rebate agreement.

[2] Section 1927(a)(7) of the Act essentially requires the collection of information necessary to bill for rebates for all single-source and the top-20 multiple-source physician-administered drugs.

[3] Beginning January 1, 2007, CMS was responsible for publishing annually the list of the top-20 multiple-source drugs that had the highest dollar volume dispensed (the Act § 1927(a)(7)(B)(i)).

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 (CMS-64 report), which contains a summary of actual Medicaid expenditures for each quarter and which CMS uses to reimburse States for the Federal share of Medicaid expenditures.

Physician-Administered Drugs

Drugs administered by a physician are typically billed to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes. 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).[4] Multiple-source drugs are defined, in part, as those covered outpatient drugs that have at least one other drug rated as therapeutically equivalent by FDA.[5]

Before the Deficit Reduction Act of 2005, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. The Deficit Reduction Act essentially amended section 1927 of the Act to require States to capture the necessary information, including NDCs, to bill manufacturers for rebates on such drugs. However, section 1927(a)(7) of the Act allowed CMS to delay some collection and submission requirements for States that demonstrated a need for additional time for implementation.

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs. Providers may submit claim forms electronically or in paper form. The State agency contracted with Xerox Corporation (Xerox)[6] to manage its drug rebate program and to process claims for physician-administered drugs. Xerox, the claims processor, sent the claim lines with the NDCs for drug utilization to the rebate system.[7] Using this data, Xerox identified the units eligible for rebate, calculated the rebates due based on CMS's unit rebate amount, and billed the manufacturers by NDC. The manufacturers pay the rebates directly to the State agency. The State agency forwarded copies of the payment information to Xerox, which reconciled the invoiced amount with the paid amount.

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

[5] 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 June 2, 2014.

[6] Texas notified Xerox in May 2014 that it was terminating the contract.

[7] A claim line represented one physician-administered drug service. Claims may include more than one claim line.

Xerox maintained accounts receivable information and worked with manufacturers to resolve any unpaid rebates.

As allowed by section 1927(a)(7) of the Act, the State agency requested a waiver from CMS to meet the requirement of the Deficit Reduction Act related to capturing NDCs for drugs administered by physicians in outpatient hospital settings. Accordingly, CMS granted a 6-month extension through June 30, 2008, for hospital outpatient claims.

HOW WE CONDUCTED THIS REVIEW

Our audit covered $29,802,149 of State agency fee-for-service claims for physician-administered drugs paid between July 1 and September 30, 2011 (audit period). We excluded from our review $887,566 of certain fee-for-service claims, such as claims that are exempt from Medicaid drug rebates (i.e., claims for drugs provided under the 340B Drug Pricing Program) and claims paid during the audit period for services provided on or before June 30, 2008, when the State agency's waiver expired.[8] Therefore, we reviewed $28,914,583 of fee-for-service claims for physician-administered drugs.

We interviewed State personnel and tested a limited number of claims for rebate invoicing. We determined that the rebate-invoicing process had issues and therefore expanded our testing to all paid physician-administered claims for the audit period.

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

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

FINDINGS

The State agency did not always comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs. Of the $28,914,583 in paid claims reviewed for our audit period, the State agency properly billed for rebates associated with $20,470,078 in paid claims and did not bill for rebates associated with $1,137,513 in paid claims for drugs for which we were able to determine that rebates were not required. However, the State agency did not bill for rebates associated with the remaining $7,306,992 in paid claims:

- The State agency did not have valid NDCs to submit drug utilization data to bill rebates for some claims, and the State agency did not identify all claims that were eligible for rebate. These claim lines totaled $6,777,929, consisting of $6,105,755 for claim lines for single-source drugs and $672,174 for claim lines for top-20 multiple-source drugs. As a

[8] Drug manufacturers are not required to pay rebates under the Medicaid drug rebate program for covered outpatient drugs that are subject to discounted pricing under the 340B Drug Pricing Program (42 U.S.C. § 256b(a)(5)).

result, the State agency improperly claimed reimbursement for $6,777,929 ($3,946,110 Federal share) for these claim lines.

- We were unable to determine the portion of $529,063 ($308,021 Federal share) for which the State agency may have improperly claimed reimbursement. This amount was for claim lines for drugs for which there was insufficient information to determine whether the drugs were required to be invoiced for rebates.

The State agency did not always bill manufacturers for rebates because the State agency's Medicaid Management Information System did not have an edit to ensure that NDCs were present on drug claims and an edit to validate NDCs if submitted. Also, the State agency did not bill some claims for rebates because the HCPCS were not included in the State's Drug Rebate Analysis and Management System.

FEDERAL AND STATE REQUIREMENTS AND GUIDANCE

The Deficit Reduction Act 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)(A)). Federal regulations prohibit Federal reimbursement for physician-administered drugs unless the States require the submission of claims containing the NDCs (42 CFR § 447.520). CMS granted temporary waivers to certain States that needed additional time to implement these requirements. CMS granted Texas a waiver through June 30, 2008, for physician-administered drugs on claims generated in an outpatient hospital setting.

The Texas Administrative Code (TAC) states that claims must be complete, accurate, and as specified by the State agency.[9] The *2011 Texas Medicaid Provider Procedures Manual*, section 6, chapter 3.4, states that providers must submit an NDC for physician-administered drug claims.

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

THE STATE AGENCY DID NOT ENSURE THAT MANUFACTURERS WERE BILLED FOR REBATES AS REQUIRED FOR FEDERAL REIMBURSEMENT FOR SOME PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of $6,777,929 ($3,946,110 Federal share) for 96,565 claim lines for which it did not bill manufacturers for rebates. Some claim lines did not include an NDC, or the provided NDC was not valid and therefore could not be invoiced for rebate. Other claim lines had valid NDCs, but the State agency failed to ensure that rebates were billed. The State agency did not always bill manufacturers for rebates because the State agency's Medicaid Management Information System did not have an edit to ensure that NDCs were present on drug claims and an edit to validate NDCs if submitted. Also, the State agency did not bill some claims for rebates because the HCPCS were not included in the State's Drug Rebate Analysis and Management System.

[9] Title 1, part 15, chapter 354, subchapter A, rule 354.1001.

The claim lines that the State agency provided to us identified the drugs by HCPCS codes. We used the HCPCS code and NDC, when available, to classify each claim line as single-source, top-20 multiple-source, all other multiple-source, or could not determine. The State agency paid:

- $6,105,755 ($3,554,771 Federal share) for 45,753 claim lines for single-source drugs administered by physicians and

- $672,174 ($391,339 Federal share) for 50,812 claim lines for top-20 multiple-source drugs administered by physicians.

Because the State agency failed to ensure that rebates were billed on these claims, the claims were not eligible for Federal reimbursement.

THE STATE AGENCY DID NOT ENSURE THAT MANUFACTURERS WERE BILLED FOR REBATES THAT MAY HAVE BEEN REQUIRED FOR FEDERAL REIMBURSEMENT FOR OTHER PHYSICIAN-ADMINISTERED DRUGS

We were unable to determine whether the State agency improperly claimed Federal reimbursement for $529,063 ($308,021 Federal share) for 12,994 claim lines that were not billed for rebates. These claim lines either included HCPCS codes that did not appear on CMS's Medicare Part B crosswalk or included NDCs that did not appear on the CMS Medicaid Drug File.[10] Thus, we were unable to determine whether these claim lines were for single-source drugs or top-20 multiple-source drugs for which the State agency was required to bill for rebates.

Accordingly, we set aside $529,063 ($308,021 Federal share) for CMS's resolution.

RECOMMENDATIONS

We recommend that the State agency:

- refund $3,946,110 (Federal share) for claim lines for single-source and top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement,

- work with CMS to determine the portion of the $308,021 (Federal share) for other claim lines for physician-administered drugs that was ineligible for Federal reimbursement and refund that amount,

- determine and refund the unallowable Federal reimbursement for single-source and top-20 multiple-source physician-administered drugs for which the rebates were not invoiced before and after our audit period, and

- establish and implement processes to ensure that all physician-administered drugs eligible for rebates are invoiced for rebates.

[10] CMS instructed States that they could use the Medicare Part B crosswalk as a reference because HCPCS codes and NDCs are standardized codes.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency did not state whether it concurred with our recommendations but described some of the corrective actions that it has taken or plans to take to address them. Regarding our first recommendation, State agency officials said that they had reduced the recommended refund amount by nearly $1 million by invoicing questioned claims for rebate and would continue to invoice manufacturers and collect the additional rebates that are due. State agency officials also said that they would analyze and determine the extent of the remaining questioned claims that were ineligible for Federal reimbursement and would work with CMS to refund the Federal share. Regarding our second recommendation, State agency officials said that they would work with CMS to determine the extent of other claim lines that were ineligible for Federal reimbursement and refund the Federal share. Regarding our third recommendation, State agency officials said that they would work with CMS to determine the extent of claims before and after our audit period that were ineligible for Federal reimbursement and refund the Federal share. Regarding our fourth recommendation, State agency officials said that they had implemented and strengthened acute-care claim processing controls and rebate processes to ensure that manufacturers are billed for physician-administered drugs that are eligible for rebate. The State agency also described actions it plans to take to further strengthen these processes.

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

We did not audit the State agency's actions because they came after our audit period; therefore, we did not revise the refund amount in our first recommendation.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Missouri Claimed Unallowable Federal Reimbursement For Some Medicaid Physician-Administered Drugs	A-07-14-06051	April 2015
Oregon Did Not Bill Manufacturers For Rebates For Physician-Administered Drugs Dispensed To Enrollees Of Medicaid Managed-Care Organizations	A-09-13-02037	March 2015
Louisiana Complied With The Federal Medicaid Requirements For Billing Manufacturers For Rebates For Physician-Administered Drugs	A-06-14-00031	February 2015
The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00205	August 2014
Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-13-06040	August 2014
Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs	A-09-12-02079	April 2014
Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-12-02080	April 2014
Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00200	November 2013
Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-12-00059	September 2013
Nationwide Rollup Report for Medicaid Drug Rebate Collections	A-06-10-00011	August 2011
States' Collection of Medicaid Rebates for Physician-Administered Drugs	OEI-03-09-00410	June 2011

Report Title	Report Number	Date Issued
Medicaid Rebates for Physician-Administered Drugs	OEI-03-02-00660	April 2004

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $29,802,149 of State agency fee-for-service claims for physician-administered drugs paid between July 1 and September 30, 2011 (audit period). We excluded from our review $887,566 of certain fee-for-service claims, such as claims that are exempt from Medicaid drug rebates (i.e., claims for drugs provided under the 340B Drug Pricing Program) and claims paid during the audit period for services provided on or before June 30, 2008, when the State agency's waiver expired. Therefore, we reviewed $28,914,583 of fee-for-service claims for physician-administered 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 and controls over billing for Medicaid rebates for physician-administered drugs.

We conducted our audit from August 2012 through March 2014 and performed our fieldwork at the State agency in Austin, Texas.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance on the Medicaid drug rebate program and physician-administered drugs;
- reviewed State agency regulations and guidance to providers, including billing instructions for physician-administered drugs;
- reviewed State agency policies and procedures for Medicaid drug rebates;
- interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid drug rebate process for physician-administered drugs;
- obtained the CMS Medicare part B crosswalk, the CMS Medicaid drug file, and the CMS list of top-20 multiple-source drugs;
- created a crosswalk to identify each HCPCS code, based on the associated NDCs, as single-source, top-20 multiple-source, all other multiple-source, or could not determine;
- obtained from the State agency the claims for physician-administered drugs listed on the CMS-64 report for the fourth quarter of calendar year 2011[11] totaling $29,802,149;

[11] There is typically a 1-quarter difference between when claims are paid and when they are reported to CMS (i.e., July through September 2011 paid claims were reported on the October through December quarterly report).

- reviewed all physician-administered drug claims to determine which claims included drugs that were eligible for rebate but were not invoiced for rebate;

- used the CMS Medicaid Drug File to identify single-source drugs for claim lines containing an NDC;

- used the crosswalk that we created to classify the remaining claim lines as single-source, multiple-source, top-20 multiple-source, or could not determine; and

- discussed the results of our review with the State agency.

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 AND STATE REQUIREMENTS AND GUIDANCE RELATED TO PHYSICIAN-ADMINISTERED DRUGS

FEDERAL LAWS

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). Section 1903(a) of the Act provides for Federal financial participation (Federal share) in State expenditures for these drugs. The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 that added section 1927 to the Act, became effective on January 1, 1991. Manufacturers must enter into a rebate agreement with the Secretary of Health and Human Services (HHS) and pay rebates for States to receive Federal funding for the manufacturer's covered outpatient drugs dispensed to Medicaid patients (the Act § 1927(a)). Responsibility for the drug rebate program is shared among the drug manufacturers, CMS, and the States.

Section 6002 of the Deficit Reduction Act of 2005 added to the Act section 1927(a)(7), which requires 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 Deficit Reduction Act 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 submit the utilization and coding data described in section 1927(a)(7) of the Act.

The Act requires that States capture utilization and coding data necessary 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 (§ 1927(a)(7)). In addition, the Act mandated that, effective January 1, 2007, the utilization data must be submitted using the NDC (§ 1927(a)(7)(C)).

The Act allowed the Secretary of HHS to delay any of the above requirements to prevent hardship to States that required additional time to implement the physician-administered drug-reporting requirements (§ 1927(a)(7)(D)).

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).

Federal regulations in effect during most of the audit period defined a brand-name drug as a single-source or innovator multiple-source drug and, in relevant part, a multiple-source drug as a covered outpatient drug for which there is at least one other drug product that is rated as therapeutically equivalent (42 CFR § 447.502).[12]

[12] CMS amended 42 CFR § 447.502 by removing the definition of multiple-source drug. See 75 Fed. Reg. 69591, 69592 (November 15, 2010).

STATE REGULATIONS AND GUIDANCE

TAC, Title 1, part 15, chapter 354, subchapter A, rule 354.1001, states that claims must be complete, accurate, and as specified by the State agency.

The *2011 Texas Medicaid Provider Procedures Manual*, section 6, chapter 3.4, states that providers must submit an NDC for physician-administered drug claims.

APPENDIX D: STATE AGENCY COMMENTS

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

KYLE L. JANEK, M.D.
EXECUTIVE COMMISSIONER

January 26, 2015

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-06-12-00060

Dear Ms. Wheeler:

The Texas Health and Human Services Commission (HHSC) received a draft audit report entitled "Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs" from the Department of Health and Human Services Office of Inspector General. The cover letter, dated November 25, 2014, 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, Director of HHS Risk and Compliance Management. Mr. Griffith may be reached by telephone at (512) 424-6998 or by e-mail at David.Griffith@hhsc.state.tx.us.

Sincerely,

Kyle L. Janek, M.D.

P. O. Box 13247 • Austin, Texas 78711 • 4900 North Lamar, Austin, Texas 78751 • (512) 424-6500

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

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

Summary of Management Response

The Texas Health and Human Services Commission (HHSC) is actively working to strengthen controls and processes to ensure drug manufactures are billed for physician-administered drug rebates. Since passage of the Deficit Reduction Act of 2005 that required states to begin collecting rebates on physician-administered drugs, HHSC has implemented acute care claims processing controls and rebate processes to ensure manufacturers are billed for physician-administered drugs that are eligible for rebate.

Since the audit, HHSC has implemented multiple improvements, primarily focused on increasing the enforcement of the requirement to submit a valid National Drug Code (NDC) on every physician-administered drug claim submitted for fee-for-service and managed care reimbursement.

Detailed responses to address each of the recommendations included in the report follow.

DHHS - OIG Recommendation: *We recommend that the State agency refund $3,946,110 (Federal share) for claim lines for single-source and top-20 multiple source physician-administered drugs that were ineligible for Federal reimbursement.*

HHSC Management Response:

HHSC continues to strengthen processes to capture, enforce, invoice manufacturers, and collect rebates for the physician-administered drug claims questioned by the auditors. Preliminary results of these efforts indicate that the amount questioned by the auditors has been reduced by nearly $1 million with efforts continuing to invoice manufacturers and collect additional rebates that are due.

Actions Planned:

HHSC will continue to invoice and collect rebates on the physician-administered drug claims when a rebatable NDC is identified. HHSC will analyze and determine the extent of the remaining physician-administered drugs that are ineligible for federal reimbursement and will work with CMS to refund the federal share.

Estimated Completion Date:

Within one year from the date of the final audit report

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Title of Responsible Person:

Deputy Director, Vendor Drug Program

DHHS - OIG Recommendation: *We recommend that the State agency work with CMS to determine the portion of the $308,021 (Federal share) for other claim lines for physician-administered drugs that was ineligible for Federal reimbursement and refund that amount.*

HHSC Management Response:

Actions Planned:

HHSC will work with CMS to determine the extent of physician-administered drugs in the other claim lines that are ineligible for federal reimbursement and will refund the federal share.

Estimated Completion Date:

Within one year from the date of the final audit report

Title of Responsible Person:

Deputy Director, Vendor Drug Program

DHHS - OIG Recommendation: *We recommend that the State agency determine and refund the unallowable Federal reimbursement for single-source and top-20 multiple-source physician-administered drugs for which the rebates were not invoiced before and after our audit period.*

HHSC Management Response:

Actions Planned:

HHSC will work with CMS to determine the extent of single and top-20 multiple-source physician-administered drugs for which rebates were not invoiced before and after the audit period and will refund the federal share of any found to be ineligible for reimbursement.

Estimated Completion Date:

Within two years from the date of the final audit report

Title of Responsible Person:

Deputy Director, Vendor Drug Program

DHHS - OIG Recommendation: *We recommend that the State agency establish and implement processes to ensure that all physician-administered drugs eligible for rebates are invoiced for rebates.*

HHSC Management Response:

Since the period subject to the audit, HHSC has implemented and strengthened acute care claims processing controls and rebate processes to ensure manufactures are billed for physician-administered drugs that are eligible for rebate.

Actions Planned:

To further strengthen processes, HHSC will implement acute care claim processing controls and other measures including (a) incorporating the NDC unit of measure and quantity validations (important to accurate rebate billing) with Healthcare Common Procedure Coding System (HCPCS)/NDC code enforcement list for rebatable physician-administered drugs and (b) expanding the enforcement of the HCPCS/NDC code list to include Medicare physician-administered drug cross-over claims for dual eligible beneficiaries and require submission of a corresponding valid NDC with the cross-over claim prior to payment.

Estimated Completion Date:

April 2015	Implement validation of NDC unit of measure and quantity
December 2015	Deny payment for cross-over claims with missing or invalid NDC

Title of Responsible Person:

Deputy Director, Vendor Drug Program