

An Audit Report on

# The Health and Human Services Commission's Prescription Drug Rebate Program

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Office**

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# The Health and Human Services Commission's Prescription Drug Rebate Program

## Overall Conclusion

The Health and Human Services Commission (Commission) has not properly accounted for all the outstanding prescription drug rebate revenue owed to the State. Poor controls and inconsistent procedures have resulted in inaccurate data in the Pharmacy Rebate Information Management System (PRIMS), which is the system of record for the Commission's Prescription Drug Rebate Program (Program). As a result, the Commission does not know the total amount of uncollected drug rebates that drug labelers owe to the State. While PRIMS data for outstanding balances are unreliable, there are indications that a significant amount of rebate revenue could remain outstanding. Although the Program received \$264 million in state and federal revenue in fiscal year 2001, the Commission lacks adequate assurance that drug labelers pay all rebates they owe to the State.

The Commission's lack of basic controls has resulted in significant rebate data integrity problems and leaves the Program susceptible to fraud and abuse. We were able to re-create the outstanding rebate balance owed to the State for only one of the six years from 1996 to 2001. Although we were able to identify specific estimates of uncollected rebate revenue for certain time periods, the generally poor condition of the Commission's rebate data and its inconsistent procedures for processing rebate payments and credits prevented us from calculating the total amount of unpaid rebates.

### The Prescription Drug Rebate Program

The Commission's Prescription Drug Rebate Program (Program) collects rebates on covered outpatient drugs from drug labelers participating in the following programs:

- Medicaid (This portion of the Program operates under Title XIX, Section 1927, of the U.S. Social Security Act, and the State must share Medicaid drug rebate revenue with the federal government.)
- Kidney Health Program
- Children With Special Healthcare Needs Program
- Children's Health Insurance Program (CHIP)

The Department of Health administered the Program until September 1, 2001, when the Program and other state Medicaid functions were transferred to the Health and Human Services Commission. Appendix 2 of this report contains additional background information on the Program.

## Key Points

### The Commission lacks accurate information on outstanding rebate balances.

PRIMS contains unreliable data regarding the amount of unpaid or disputed rebates. As a result, we were able to re-create the Commission's outstanding rebate balance for only one of the six years from 1996 to 2001. As of May 2002, \$20.7 million in rebates remained uncollected from calendar year 2001. In addition, the Commission's data indicates that an estimated \$9.1 million in rebate billings disputed by drug labelers for periods prior to 1995 remains unaccounted for. Furthermore, at least \$4.3 million in interest drug labelers have owed to the State since June 1995 remains uncollected.



**A variety of issues has led to the Commission's inability to determine with certainty the amount of rebate revenue drug labelers owe to the State.**

The following examples illustrate why the Commission has not determined the amount of rebates drug labelers owe:

- Data entry errors in 11,356 rebate transactions in PRIMS create uncertainty about the amount of rebates paid to the State. Our attempts to reconcile payment data associated with these transactions resulted in payment amounts that ranged from \$16.2 million to \$2.69 billion.
- Rebate staff have made at least \$13.6 million in reductions to rebate amounts without properly verifying that the numbers of drug units involved in these transactions were correct.
- Rebate staff have recorded \$373 million in rebate payments and \$30.2 million in rebate credits in PRIMS without using the appropriate types of transactions.
- There is a lack of proper supervision of staff who grant rebate credits to drug labelers. Staff have adjusted drug utilization data without proper supervisory review and lack objective criteria for making adjustments to drug labelers' rebate invoices.
- Inadequate segregation of duties among rebate staff creates the risk of unauthorized rebate adjustments, fraud, or misuse of state funds.

**Rebate collection and dispute resolution processes are not efficient and result in delays, backlogs, and rework.**

The Program has not successfully integrated PRIMS, which it brought online in 1996, with its daily work processes for rebate dispute resolution and collection activities. In addition, the Commission has not created an operational environment with adequate control measures to guard against the potential fraud and misuse of state revenue.

**The Commission has not established performance metrics or standardized methods for assessing the performance of the Program.**

Not evaluating the efficiency and effectiveness of the Program hinders the Commission's ability to make sound business decisions. As a result, the Commission has made decisions materially affecting the Program's ability to collect rebates without evaluating the effects of these decisions. For example, the Commission terminated the Program's participation in a federally sponsored program that assisted in the collection of disputed or delinquent rebates.

***Summary of Management's Response***

The Commission is in general agreement with the audit recommendations.

## ***Summary of Information Technology Review***

This audit addressed the overall effectiveness of processes, control environments, and resulting integrity of data in information systems used in the Program. We identified and reviewed activities and related information system inputs and outputs in the rebate collection and dispute resolution processes, including transactions in PRIMS, a system of organized spreadsheets known as the CashTrac, and various electronic and hard copies of spreadsheets created by rebate staff or drug labelers.

PRIMS is the Commission's primary repository of rebate data and is recognized as the system of record for data collected since June 1995. Prior to June 1995, the Program relied on spreadsheets to track rebate billings, collections, and disputes. The Program continues to use these spreadsheets to process retroactive drug pricing adjustments and to resolve outstanding disputes from this period.

Testing we performed on information systems included verifying the completeness of coding mechanisms, evaluating audit trails, and reconciling data elements. While the report discusses information system controls and data integrity, the purpose of our technology review was to assess the functional utilization of data systems and to quantify the effect of observed weaknesses; we did not perform a comprehensive review of any specific systems.

## ***Summary of Objective, Scope, and Methodology***

The primary objective of this audit was to assess the efficiency, accuracy, and timeliness of the Program's collection process in connection with the Commission's Business Improvement Plan (which was required by Rider 18, page II-53, the General Appropriations Act, 77th Legislature).

Our scope included core business processes and related inputs and outputs in the Program. Because of the retroactive nature of drug labeler adjustments to pricing data and corresponding adjustments to balances owed to the State, we reviewed adjustments to rebate data collected since the inception of the Program in 1991.

Our methodology consisted of performing walk-throughs and mapping core business processes according to standard, activity-based management principles. We used these maps and information gathered through interviews to determine significant risks, inefficiencies, and control weaknesses as the basis for additional review, analysis, and testing.

## Table of Results and Recommendations

The Commission lacks accurate information on outstanding rebate balances. (Page 1)

The Commission should:

- Reconcile outstanding balances for the Program prior to generating reports that it uses to evaluate the Program's performance.
- Identify and track the cause of any discrepancies in the outstanding rebate revenue balance in order to verify the effectiveness of controls and resulting integrity of rebate data.
- Obtain training for staff on how to properly query PRIMS to obtain outstanding balance and collection rate reports.
- Regularly report on the effectiveness of rebate collection activity by reporting quarterly, annual, and cumulative outstanding balances.
- For records and transactions affecting periods prior to June 1995:
  - Quantify the total outstanding rebate revenue owed to the State for the time period before June 1995 by re-creating invoices and reconciling them with payments and credits.
  - Use PRIMS as the system of record and repository of all rebate data and activity for the time period before June 1995.
  - Correct errors caused by the lack of data regarding rebates that are invoiced, paid, and outstanding.
  - Consider contracting with a third party or hiring temporary staff to implement the above recommendations.

The Commission does not reconcile the payments drug labelers make with outstanding rebate amounts in PRIMS. (Page 6)

The Commission should:

- Identify and correct erroneous PRIMS payment transactions in which the unit quantity and rebate amount do not reconcile with the total amount of the rebate payment.
- Develop automated output controls in PRIMS that reconcile the unit quantity, rebate amount, and rebate payment amount during the data entry and AutoPost processes.
- Calculate the Program's unit collection rate after data errors have been resolved to determine the impact of these corrections on the outstanding balance of rebate revenue.

A lack of consistent procedures to adjust drug pricing and utilization data has led to inappropriate adjustments of rebate amounts that drug labelers owe. (Page 8)

The Commission should:

- Develop a standard process and criteria for drug utilization adjustments and retroactive drug pricing adjustments. Utilization adjustment procedures should comply with criteria outlined in federal law and with recommended guidelines issued by the U.S. Centers for Medicare and Medicaid Services (CMS). In addition, the Commission should follow federally recommended procedures for developing drug utilization estimates for cases in which rebate information is required but not available.
- Reconcile drug utilization data for all relevant periods before processing prior-period adjustments.
- Review adjustment records for standardization and compliance with relevant criteria.

The inappropriate use of credit and payment transactions in PRIMS has compromised the integrity of rebate data. (Page 10)

The Commission should:

- Develop criteria and application controls to ensure that staff record all credit activity using credit vouchers.
- Review drug utilization data associated with payment transactions recorded in credit vouchers and determine the possible impact on outstanding rebate revenue balance amounts recorded in PRIMS.
- Periodically review past transactions to identify and correct other non-standard methods of recording credits or using credit vouchers.

Inadequate supervision of rebate adjustments and credits increases the risk of inappropriate and unauthorized adjustments. (Page 12)

The Commission should:

- Perform a complete and effective review of rebate adjustments and ensure that staff follow federal guidelines when resolving rebate disputes.
- Develop and standardize staff review criteria for the resolution of disputed and outstanding rebate revenue.

## Table of Results and Recommendations

The Commission has not collected or accounted for all outstanding interest on rebates owed to the State. (Page 14)

The Commission should:

- Use federal guidelines to accurately calculate and track interest owed to the State on rebates.
- Actively pursue and collect outstanding interest on rebates.
- Determine the accuracy of past interest payments and whether these payments encompass all outstanding interest owed to the State.

Rebate collection and dispute resolution processes are not efficient. (Page 17)

The Commission should:

- Critically assess the rebate collection and dispute resolution processes to maximize the capabilities of PRIMS.
- Re-engineer rebate collection and dispute resolution activities that are not timely, efficient, or accurate. Develop performance measures to monitor the efficiency and effectiveness of the program's billing, collection, and dispute resolution activities.
- Require rebate staff to work exclusively from data in PRIMS.
- Create reports and automated procedures for common tasks performed using rebate data in order to improve the efficiency and accuracy of the rebate collection and dispute resolution process (including adjustment transactions, credit transactions, and a supervisory review of transactions).
- Consolidate and reconcile all mission-critical rebate data that is necessary for current processes (including hard copies of invoices from periods prior to June 1995, staff's spreadsheets and notebooks, CashTrac, and slow pay logs) into PRIMS.
- Follow federally recommended procedures for developing drug utilization estimates for cases in which rebate information is required but is not available.
- Use the amount of time an unpaid balance is outstanding as a factor to prioritize collection activity.

The Commission does not track rebate staff's performance. (Page 22)

The Commission should:

- Develop standard performance measures to evaluate the productivity and effectiveness of individual staff members. Performance measures should clearly define outputs and outcomes for collection and dispute resolution activities.
- Use the performance data it collects to evaluate the Program's appropriateness of staffing levels in relation to workloads.

Inadequate segregation of duties among rebate staff working in PRIMS could subject rebate revenue to loss and misuse. (Page 24)

The Commission should:

- Segregate duties related to rebate billing, payment, and adjustment.
- Limit access to billing, payment, and adjustment transactions in PRIMS.
- Periodically review PRIMS transactions for deleted records and staff compliance with their assigned duties.

The Commission's informal and ineffective coding of rebate data in PRIMS limits its ability to ensure the accuracy of rebate payments and adjustments. (Page 25)

The Commission should:

- Develop a method for recording appropriate audit trails for credit vouchers.
- Discontinue use of manual coding of the audit trail for rebate transactions.
- Integrate its prescribed coding process and associated controls into PRIMS to allow staff to perform accurate calculation and quantification of audit trail codes.

Delays in depositing rebate checks result in lost interest. (Page 27)

The Commission should:

- Maximize interest earned by requiring staff to deposit rebate checks within the statutory three-day requirement.
- Ensure that staff record rebate check receipt and deposit dates in PRIMS so that management can regularly review the timeliness of check deposits.

**Table of Results and Recommendations**

The Commission does not adequately track or report the Program's performance. (Page 29)

The Commission should:

- Establish performance measures for the timeliness, efficiency, and accuracy of the Program's dispute resolution and collections functions that include an average age of receivables, a unit-based collections rate, and quantification and stratification of all adjustments to invoices for drug labelers.
- Import, consolidate, and reconcile rebate data prior to 1995 with automated Program data in PRIMS.
- Ensure that future federal reports correctly account for invoiced, paid, and outstanding rebate revenues.

**Prior SAO Work**

Number	Product Name	Release Date
94-143	An Audit Report on the Medicaid Vendor Drug Rebate Program	August 1994

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# Detailed Results

Chapter 1

## **The Commission Has Not Properly Accounted for All Outstanding Rebate Revenue Owed to the State**

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The Health and Human Services Commission (Commission) has not properly accounted for all outstanding rebate revenue owed to the State because it:

- Lacks accurate information in the Pharmacy Rebate Information Management System (PRIMS) on outstanding rebate balances.<sup>1</sup>
- Does not reconcile the payments drug labelers make with outstanding rebate balances in its automated system.
- Lacks consistent procedures to adjust drug pricing and utilization data, which has led to inappropriate adjustments of rebate amounts that drug labelers owe.
- Inappropriately uses credit and payment transactions in its automated system, which has compromised the integrity of rebate data.
- Does not adequately supervise rebate adjustments and credits, which has hindered the Commission's accountability for outstanding rebate balances.
- Has not collected or accounted for all outstanding interest on rebates that drug labelers owe to the State.

Chapter 1-A

### **The Commission Lacks Accurate Information on Outstanding Rebate Balances**

The Commission's accounting for and reporting of outstanding rebate balances drug labelers owe are unreliable, and this may leave significant amounts of rebate revenue uncollected. Although the rebate billing process is automated and the Program received \$264 million in fiscal year 2001, weaknesses in controls, procedures, and data associated with uncollected and disputed invoices are so extensive that the Commission does not have accurate data on outstanding balance amounts.

#### **We Could Re-create the Outstanding Rebate Balance for Only One Year**

Our attempts to re-create the Commission's outstanding balances in PRIMS were successful for only one of six years. The Program cannot be effectively or efficiently managed without critical baseline information such as the outstanding balance amounts. It is important to note that most of the issues discussed in this report were also cited in a 1994 State Auditor's Office audit, when the program was administered at the Department of Health (see Appendix 3 for more details on *An Audit Report on*

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<sup>1</sup> Throughout this report, outstanding balance amounts cited do not include any applicable interest due to the State.

*the Medicaid Vendor Drug Rebate Program*, SAO Report No. 94-143, April 1994). The Program was transferred from the Department of Health (along with other Medicaid functions) to the Commission in September 2001.

We were able to re-create an outstanding rebate balance for only calendar year 2001. As of May 2002, there was still \$20.7 million outstanding for that year. We were not able to re-create the outstanding balances for 1996 through 2000 within a 5 percent margin of error. The differences between the outstanding balances in PRIMS for 1996 through 2000 and our calculations of outstanding balances for those years ranged from 7 percent to 563 percent. The discrepancies in outstanding balance amounts are attributable to the issues outlined throughout Chapter 1 of this report: failure to reconcile payments to amounts owed, data entry errors, a lack of standard criteria for adjusting pricing and utilization data, inappropriate recording of credits and payments, and a lack of supervisory review.

### **Outstanding Balances Are Not Reported to Commission Management, and the Commission Is Unable to Support the Rebate Collection Rate It Has Reported**

The amount of outstanding balances has not been reported to Commission management since the Program was transferred to the Commission from the Department of Health in 2001. Although \$261 million in Medicaid drug rebate revenue was included in the Commission's method of finance in the General Appropriations Act (77th Legislature) for the 2002–2003 biennium, collected amounts and outstanding balance amounts are not reported to Commission management. In addition, the outstanding balance amount is not recorded as a receivable in the Commission's annual financial report. Our discussions with Program management indicate that Program staff do not know how to properly query PRIMS to extract outstanding balance information or calculate an overall rebate collection rate.

In addition to the lack of accurate outstanding balance data, the Commission is not able to support its collection rate of at least 99 percent that it reported to the Legislature in March 2001. The Commission was unable to provide either documentation or a methodology to support a collection rate of 99 percent. Data in PRIMS for the period from 1996 through 2001 contradicts the Commission's reported 99 percent collection rate. A collection rate of 99 percent would yield an outstanding balance of \$12.2 million for that period, but PRIMS shows an outstanding balance of \$18.6 million. Furthermore, because the Program's manual records for the period prior to June 1995 were never input into PRIMS, the Commission lacks any basis to assert an overall collection rate for 1991 through June 1995.

### **Significant Amounts of Rebate Revenue Could Remain Outstanding**

While PRIMS data for outstanding balances is unreliable, there are indications that a significant amount of rebate revenue could remain outstanding. The \$20.7 million in outstanding rebates for calendar year 2001 (the only year for which we were able to re-create an outstanding balance) translates into a collection rate of 94 percent five months after the last quarter of that year. While there are delays between billing and receipt of payments, both this 94 percent collection rate and the \$20.7 million amount that remained outstanding almost five months after the last quarter in 2001 are indications that significant additional rebate amounts could remain outstanding.

Additional rebate amounts also could remain outstanding for the period prior to June 1995. Our 1994 audit identified \$15.4 million in rebates that drug manufacturers had disputed. The Commission's records for payments received against the disputed \$15.4 million, however, indicate that \$9.1 million associated with those disputes remains unresolved. In addition, while we identified \$15.4 million in disputes from 1991 through June 1993, this amount does not include any amounts that were simply unpaid but not formally disputed. There is no readily available information on the status of total unpaid or total disputed rebates from June 1993 through June 1995. Invoices from 1991 through June 1995 are available only in hard copy form.

Our ability to re-create the amount of outstanding balances was constrained by the labor-intensive nature of this objective. Calculating the outstanding rebate balance for the twelve years since the Program's 1991 inception entails the analysis of more than a million records. As mentioned previously, records for the Program prior to June 1995 are still in hard copy form, and Program management indicated to the federal government in 1998 that it would take approximately one year just to enter those records into PRIMS.

## Recommendations

The Commission should:

- Reconcile outstanding balances for the Program prior to generating reports that it uses to evaluate the Program's performance.
- Identify and track the cause of any discrepancies in the outstanding rebate revenue balance in order to verify the effectiveness of controls and resulting integrity of rebate data.
- Obtain training for staff on how to properly query PRIMS to obtain outstanding balance and collection rate reports.
- Regularly report on the effectiveness of rebate collection activity by reporting quarterly, annual, and cumulative outstanding balances.
- For records and transactions affecting periods prior to June 1995:
  - ♦ Quantify the total outstanding rebate revenue owed to the State for the time period before June 1995 by re-creating invoices and reconciling them with payments and credits.
  - ♦ Use PRIMS as the system of record and repository of all rebate data and activity for the time period before June 1995.
  - ♦ Correct errors caused by the lack of data regarding rebates that are invoiced, paid, and outstanding.
  - ♦ Consider contracting with a third party or hiring temporary staff to implement the above recommendations.

## **Management's Response**

**SAO Recommendation:** *The Commission should reconcile outstanding balances for the program prior to generating reports that it uses to evaluate the Program's performance.*

**Management Response:** *Agree. In March 2003, subsequent to the completion of SAO's field work, HHSC obtained an electronic copy of the data originally submitted to CMS from Market Measures Inc., a company in business to collect and report on drug utilization in all states. This data was loaded into PRIMS and created the beginning balance records for the pre-PRIMS periods.*

**Action Planned:** *Pharmacy Audit Resolutions, Rebates and Contracts (PARC) plans to undertake a payment posting project to enter the remainder of the pre-PRIMS data (payments and adjustments) into PRIMS. As part of the project, PARC will also develop a methodology to reconcile payments and adjustments with invoices. The Oversight Committee will identify for HHSC senior management the appropriate staffing resources needed to complete the payment posting project.*

*In addition, PARC, with Committee oversight, will identify the root causes that have resulted in inaccurate or unsupported data in PRIMS. Once those causes are identified, improvements to automated and manual controls and updates to policies and procedures will be developed to address and correct the causes. PARC will also correct any existing errors in PRIMS data. Many of the actions planned in these areas are addressed in subsequent management responses. The planned result of this effort is for PRIMS to include accurate and properly supported data that can be used, in addition to its other functions, to correctly calculate outstanding balances.*

**Estimated Completion Date:** *Committee staffing recommendations: May 1, 2003; Planning: June 1, 2003; A timeline will be created for the completion of the payment posting project once staffing resources are identified.*

**Title of Responsible Person:** *Rebates Billing and Collection Oversight Committee*

**SAO Recommendation:** *The Commission should identify and track the cause of any discrepancies in the outstanding rebate revenue balance in order to verify the effectiveness of controls and resulting integrity of rebate data.*

**Management Response:** *Agree. Prior to February 2003, PRIMS was not recalculating the outstanding balance on all items on a regular basis. IRM has corrected the problem and PRIMS now recalculates outstanding balances when a payment is reconciled or when new quarterly invoices are generated. This has corrected a majority of the problems that existed.*

**Action Planned:** *PARC will continue to run data integrity reports to identify and track additional causes of errors and will continue to proactively resolve issues as they are identified.*

**Estimated Completion Date:** *August 1, 2003.*

**Title of Responsible Person:** *PARC Manager*

**SAO Recommendation:** *The Commission should obtain training for staff on how to properly query PRIMS to obtain outstanding balance and collection rate reports.*

**Management Response:** *Agree.*

**Action Planned:** *PARC will work with IRM to develop aging reports, collection rate reports, and other reports to facilitate management of collections. Staff will be trained on the new reporting procedures.*

**Estimated Completion Date:** *October 1, 2003*

**Title of Responsible Person:** *PARC Manager*

**SAO Recommendation:** *The Commission should regularly report on the effectiveness of rebate collection activity by reporting quarterly, annual, and cumulative outstanding balances.*

**Management Response:** *Agree.*

**Action Completed:** *Currently, quarterly and annual Rebate Collection Reports based on original billed amounts and total collected amounts for that period of time are created for distribution. These reports were previously distributed to management on a sporadic basis, however they will now be shared quarterly and annually, as will new outstanding balance and collection rate reports.*

**SAO Recommendation:** *The Commission should, for records and transactions affecting periods prior to June 1995:*

- *Quantify the total outstanding rebate revenue owed to the State for the time period before June 1995 by re-creating invoices and reconciling them with payments and credits.*
- *Use PRIMS as the system of record and repository of all rebate and activity for the time period before June 1995.*
- *Correct errors caused by the lack of data regarding rebates that are invoiced, paid, and outstanding.*
- *Consider contracting with a third party or hiring temporary staff to implement the above recommendations.*

**Management Response:** *Agree. As mentioned in an earlier management response, an electronic copy of the original pre-PRIMS invoice data was obtained earlier this year and loaded into PRIMS on March 7, 2003.*

**Action Planned:** *Once the payment posting project (which includes entering pre-PRIMS payment and invoice data, reconciling payments and adjustments with invoices, and correcting errors when identified) is completed, PRIMS will be the repository of all rebate activity and will calculate all outstanding balances.*

**Estimated Completion Date:** *One month after completion of the payment posting project.*

**Title of Responsible Person:** *PARC Manager*

## **The Commission Does Not Reconcile the Payments Drug Labelers Make with Outstanding Rebate Amounts in PRIMS**

Rebate payment transactions in PRIMS contain errors that prevent the Commission from knowing the correct rebate amounts that drug labelers have paid. We identified 11,356 PRIMS transactions that had data entry errors in the drug unit quantity, rebate per unit amount, or total rebate payment amount. We multiplied the number of drug units on the erroneous transactions by the rebate amounts per unit on these transactions, and the result showed that drug labelers associated with these records have paid rebates on units worth \$2.69 billion. However, total rebate amount fields on these same transactions—fields for which staff manually calculate dollar amounts and then enter by hand—indicate that drug labelers associated with these records have paid rebates on units worth only \$16.2 million. There could be errors in both of these dollar amounts, and the actual amount of rebates associated with the erroneous rebate transactions is unknown. The large variance between \$2.69 billion and \$16.2 million demonstrates the degree of error within the rebate payment data recorded in PRIMS.

Included in the 11,356 erroneous transactions we identified were 1,341 transactions (dating back to January 1996) that indicated that drug labelers paid zero dollars in rebates even though they had sold 25,839,091 drug units for which the State reimbursed pharmacy providers. The Commission asserts that these errors occurred because of the improper use of PRIMS's AutoPost procedure, which automatically creates multiple payment transactions in PRIMS. It also asserts that these errors occurred because staff did not perform manual reconciliations. AutoPost calculations are not always accurate because a given drug labeler's payment may not include some past-due balances.

Ultimately, the types of errors we identified impede the collection of rebates because they affect the accuracy of drug labelers' outstanding rebate balances. Additional details regarding these and other specific control and data integrity issues in PRIMS are presented in Appendix 4 of this report.

### **Recommendations**

The Commission should:

- Identify and correct erroneous PRIMS payment transactions in which the unit quantity and rebate amount do not reconcile with the total amount of the rebate payment.
- Develop automated output controls in PRIMS that reconcile the unit quantity, rebate amount, and rebate payment amount during the data entry and AutoPost processes.
- Calculate the Program's unit collection rate after data errors have been resolved to determine the impact of these corrections on the outstanding balance of rebate revenue.

## **Management's Response**

**SAO Recommendation:** *The Commission should identify and correct erroneous PRIMS payments transactions in which unit quantity and unit rebate amount (URA) do not reconcile with the total amount of the rebate payment.*

**Management Response:** *Agree. The primary reasons the total amount of the unit quantity times the rebate amount do not reconcile with the total amount of the rebate payment data are because of data entry errors either on PARC staff's part or on the part of the labeler, and rounding differences.*

**Action Planned:** *Errors on PARC staff's part will be corrected by performing numerous data integrity queries to determine the possible problems. Original payments will then be compared with the payments posted in PRIMS for accuracy. If it is determined that a payment was posted incorrectly, corrections will be made per the Reconciliation Of State Invoice (ROSI).*

*Errors on the part of the labeler will be evaluated for significance. If the amount of the error is significant, the manufacturer will be notified and will be required to correct and submit a prior quarter adjustment (PQA) sheet. Insignificant errors will be noted in the comment field and resolved during the dispute resolution process.*

*Rounding errors will be addressed as part of the review of the PQA posting process.*

**Estimated Completion Date:** *August 31, 2003*

**Title of Responsible Person:** *PARC Manager*

**SAO Recommendation:** *The Commission should develop automated output controls in PRIMS that reconcile the unit quantity, URA, and rebate payment amount during the data entry and AutoPost processes.*

**Management Response:** *Agree.*

**Action Planned:** *PARC will study the feasibility and potential cost-effectiveness of developing automated output controls and how it currently posts prior quarter adjustments. Results of the study will be presented to the Oversight Committee and Division management will approve an action plan as indicated.*

**Estimated Completion Date:** *August 31, 2003*

**Title of Responsible Person:** *PARC Manager*

**SAO Recommendation:** *The Commission should calculate the Program's unit collections rate after data errors have been resolved to determine the impact of these corrections on the outstanding balances of rebate revenue.*

**Management Response:** *Agree.*

**Action Planned:** *Errors will be identified and corrected. PARC will calculate a unit collections rate to determine the impact of the corrections on the outstanding balance amount. PARC will also study how best to apply and track a unit collection rate on*

*an ongoing basis. Results of the study will be presented to the Oversight Committee and Division management will approve an action plan.*

**Estimated Completion Date:** *Errors will be identified and corrected by August 31, 2003. Within two months of the completion of the posting project, PARC will present the Oversight Committee with information related to the unit collections rate.*

**Title of Responsible Person:** *PARC Manager*

Chapter 1-C

## **A Lack of Consistent Procedures to Adjust Drug Pricing and Utilization Data Has Led to Inappropriate Adjustments of Rebate Amounts that Drug Labelers Owe**

The Commission cannot verify the accuracy of the rebate adjustments staff have granted drug labelers (including \$13.6 million in rebate reductions given to 12 drug manufacturers) because it lacks standardized procedures and criteria for adjusting drug pricing and utilization data. The Commission does not consistently verify the accuracy of retroactive drug pricing adjustments that drug labelers make. It also does not use standard procedures or criteria when adjusting rebates for changes to drug utilization data that drug labelers submit. Making such adjustments affects the amount of rebates that drug labelers owe.

### **Drug Rebate Amounts May Be Adjusted in Two Ways**

Federal law allows states to adjust the Medicaid drug utilization data used to calculate the total rebate amount due to the State if they find that actual drug utilization differed from what was originally reported by pharmacies.

In addition, federal law allows drug labelers to retroactively adjust pricing data if they find that actual pricing data differs from amounts originally reported to the federal government.

The Commission processes prior-period drug pricing adjustments that drug labelers submit without verifying whether the rebate reduction a drug labeler seeks is consistent with the number of units of the drug that the State reimbursed to pharmacy providers. As a result, the Commission risks improperly adjusting rebate amounts. Unaudited data the Commission reported to the federal government shows that from the third quarter of calendar year 1995 to the fourth quarter of calendar year 2001, the Commission reduced by \$13.6 million the rebates owed by the 12 drug manufacturers that made the highest dollar amount of drug price adjustments. The Commission assumes drug labelers' utilization data is accurate and complete.

In addition, the Commission has not standardized the process or criteria staff use to review claims that are the basis for adjusting drug utilization data. Rebate staff indicated they may arbitrarily adjust amounts that drug labelers owe on disputed rebates because of what they perceive as unmanageable workloads. Both Commission management and staff acknowledge that the subjective nature of the adjustment process could result in staff resolving the same types of disputed rebates differently. For example, one staff member reduced a drug labeler's disputed units by 50 percent because the claims under review were "confusing." Arbitrary resolution of disputes in this manner violates federal law (United States Code, Title

42, Section 1396r-8), which limits rebate adjustments only to instances supported by utilization data. The arbitrary nature of dispute resolution also compromises the Commission's ability to account for drug utilization information that supports adjustments.

## Recommendations

The Commission should:

- Develop a standard process and criteria for drug utilization adjustments and retroactive drug pricing adjustments. Utilization adjustment procedures should comply with criteria outlined in federal law and with recommended guidelines issued by the U.S. Centers for Medicare and Medicaid Services (CMS). In addition, the Commission should follow federally recommended procedures for developing drug utilization estimates for cases in which rebate information is required but not available.
- Reconcile drug utilization data for all relevant periods before processing prior-period adjustments.
- Review adjustment records for standardization and compliance with relevant criteria.

## Management's Response

**SAO Recommendation:** *The Commission should develop a standard process and criteria for drug utilization and retroactive drug pricing adjustments. Utilization adjustment procedures should comply with criteria outlined in federal law and with recommended guidelines issued by the U.S. Centers for Medicare and Medicaid Services (CMS). In addition, federally recommended procedures for developing drug utilization estimates for cases in which rebate information is required but is not available should also be followed.*

**Management Response:** *Agree.*

**Action Planned:** *The policies and procedures for Rebate Specialists to make adjustments to units during the dispute resolution process are being reviewed and revised to ensure federal compliance. The new DRP Procedures Manual will identify the processes for reviewing the claims for dispute resolution and will include specific guidelines and criteria governing under what circumstances it would be appropriate to adjust units during dispute resolution, and when supervisory approval for these adjustments will be required. PARC will work with the Oversight Committee to revise current methodology used to post drug pricing adjustments, including verification of the units involved.*

**Estimated Completion Date:** *All Rebate Specialists will begin dispute resolution based on the new DRP Procedures Manual no later than July 31, 2003.*

**Title of Responsible Person:** *PARC Manager*

**SAO Recommendation:** *The Commission should reconcile drug utilization data for all relevant periods before processing prior-period adjustments.*

**Management Response:** *Agree. This procedure has been in place throughout the post-PRIMS period, but must be addressed for pre-PRIMS data.*

**Action Planned:** *Payment posting project will reconcile the drug utilization and payment data for the pre-PRIMS periods, in the order the payments were received.*

**Estimated Completion Date:** *Per the recommended timeline developed by the Oversight Committee.*

**Title of Responsible Person:** *PARC Manager*

**SAO Recommendation:** *The Commission should review adjustment records for standardization and compliance with relevant criteria.*

**Management Response:** *Agree.*

**Action Planned:** *HHSC will develop a review methodology that will define specifically what should be reviewed, will include dollar thresholds above which review is required, and include an approach for reviewing the balance of staff work on a sample basis. The methodology will be included in the new DRP Procedures Manual. PARC Manager may conduct a retroactive review of past adjustments to help formalize new criteria.*

**Estimated Completion Date:** *Manual: July 31, 2003; Retroactive review: August 31, 2003.*

**Title of Responsible Person:** *PARC Manager*

Chapter 1-D

## **The Inappropriate Use of Credit and Payment Transactions in PRIMS Has Compromised the Integrity of Rebate Data**

PRIMS data for \$373 million in payments from drug labelers and \$30.2 million in rebate credits the Commission gave to drug labelers were not recorded using the appropriate types of transactions. As a result, PRIMS credit activity data and payment data are not consistent.

Currently, rebate staff use positive credit vouchers in PRIMS to record rebate payments and adjustments for periods prior to June 1995; as of July 2001, \$373 million of these transactions were recorded in PRIMS. However, PRIMS system documentation specifies that credit voucher transactions indicate only a payment source; credit vouchers do not indicate receipt of payment. Therefore, credit vouchers are not appropriate for recording rebate payment activity because they do not indicate receipt of funds. In addition, credit vouchers do not contain fields to record drug utilization or unit rebate data, which is the basis for all rebate payments in the Program. This limits the Commission's ability to support outstanding rebate balance calculations.

Rebate staff have also recorded at least \$30.2 million in rebate credits to drug labelers using negative payment records and other methods. However, PRIMS system documentation specifies that PRIMS was developed to record credit transactions using credit payment records, a method that staff have abandoned in favor of the informal method of using negative payment records. The informal method of recording credits circumvents the controls associated with credit transactions using credit payment records and limits the ability to distinguish each payment's source. This compromises the integrity of the Commission's outstanding rebate balance information.

## Recommendations

The Commission should:

- Develop criteria and application controls to ensure that staff record all credit activity using credit vouchers.
- Review drug utilization data associated with payment transactions recorded in credit vouchers and determine the possible impact on outstanding rebate revenue balance amounts recorded in PRIMS.
- Periodically review past transactions to identify and correct other non-standard methods of recording credits or using credit vouchers.

## Management's Response

**SAO Recommendation:** *The Commission should develop criteria and application controls to ensure that staff record all credit activity using credit vouchers.*

**Management Response:** *Agree. In March, 2003 all pre-PRIMS payment data previously stored in the Credit Voucher table was removed and put into the Payment Source table as the first phase of the payment posting project.*

**Action Planned:** *Pre-PRIMS payment data has already been removed from the Credit Voucher table. All remaining Credit Vouchers will be reviewed for correctness and standard coding. A better method of posting/commenting Credit Vouchers will be included in PARC procedure manuals with the concurrence of the Oversight Committee. PARC will also review the current method of posting PQAs, work with IRM to develop a timeline to implement any necessary system changes, and formalize the procedures.*

**Estimated Completion Date:** *May 31, 2003*

**Title of Responsible Person:** *PARC Manager*

**SAO Recommendation:** *The Commission should review drug utilization data associated with payment transactions recorded in credit vouchers and determine the possible impact on outstanding rebate revenue balance amounts recorded in PRIMS.*

**Management Response:** *Agree.*

**Action Planned:** The payment posting project will allocate all of the payments previously located in the Credit Voucher table to an actual NDC, year, and quarter so that associated units and payments can be verified. Other credit vouchers will be reviewed for association with payment transactions.

**Estimated Completion Date:** The timeline for the payment posting project will be developed once the Oversight Committee makes its recommendation by May 1, 2003.

**Title of Responsible Person:** PARC Manager

**SAO Recommendation:** The Commission should periodically review past transactions to identify and correct other non-standard methods of recording credits or using credit vouchers.

**Management Response:** Agree.

**Action Planned:** PARC will periodically gather information regarding credit transactions, review the information, and determine if the reasons for posting the credits were correct. Any discrepancies will be adjusted accordingly.

**Estimated Completion Date:** The process will be in place by August 2003.

**Title of Responsible Person:** PARC Manager

Chapter 1-E

## **Inadequate Supervision of Rebate Adjustments and Credits Increases the Risk of Inappropriate and Unauthorized Adjustments**

The Commission has not adequately reviewed staff's resolution of drug utilization disputes through which they have adjusted utilization data for \$66 million<sup>2</sup> in drugs (as of May 20, 2002). The absence of proper supervision and independent verification during the adjustment process limits the Commission's ability to identify erroneous data and subjects rebate revenue to the risk of loss.

If rebate staff encounter errors in drug utilization data during the rebate collection and dispute resolution process, they have authority to adjust drug utilization data. However, as discussed in Chapter 1-C, some staff have made arbitrary adjustments based on percentage reductions or undocumented benchmarks to resolve disputes. This practice violates federal guidelines, which allows states to make adjustments only on the basis of utilization data.

Given that negotiations with drug labelers have affected as much as \$66 million of adjusted drug units, a complete or representative review by the supervisor of the consistency and accuracy of adjustment records is necessary. Currently, however, supervisory involvement in drug utilization dispute resolution typically occurs only after staff have completed negotiations and have entered adjustment transactions into PRIMIS. While there is limited supervisory review, it is not formal or complete, and it does not evaluate the overall integrity of adjustment transactions because they do not review underlying supporting documentation that staff use to determine the

<sup>2</sup> The \$66 million amount represents the value of the drugs for which adjustments were made, not the amount adjusted.

amount of drug units adjusted. The following issues further complicate effective supervision of these adjustments:

- Supporting documentation for adjustments that staff make resides in spreadsheets and paper notebooks outside of PRIMIS and is not readily available for supervisory review.
- Three of the four staff members who make these adjustments are telecommuters working from their homes, which further reduces management's ability to supervise their work.
- The Commission does not require telecommuters to back up their adjustment work on the Commission's computer network; instead, telecommuters save adjustment work on their computers at their personal residences.
- Although there is a log on which staff are supposed to record information regarding communications with drug labelers, staff do not consistently enter on this log negotiations with drug labelers concerning discussions on disputed rebates and utilization data. Two staff members have never recorded anything on this log. Program management indicated that it is aware that staff do not comply with the procedure to document negotiations with drug labelers.

The lack of supervision regarding utilization adjustments increases the risk of loss of revenue due to fraud and abuse. The Commission's current process improperly empowers staff to negotiate away rebate revenues, which means that staff could make inappropriate or erroneous adjustments to utilization data that would alter the amount of rebates drug labelers owe. In addition, inadequate supervisory review also limits the Commission's ability to account for the validity of any credits that staff may issue to drug labelers as a result of drug utilization adjustments.

## Recommendations

The Commission should:

- Perform a complete and effective review of rebate adjustments and ensure that staff follow federal guidelines when resolving rebate disputes.
- Develop and standardize staff review criteria for the resolution of disputed and outstanding rebate revenue.

## Management's Response

**SAO Recommendation:** *The Commission should perform a complete and effective review of rebate adjustments and ensure that staff follow federal guidelines when resolving rebate disputes*

**Management Response:** *Agree.*

**Action Planned:** *HHSC will develop a review methodology that ensures staff follow federal guidelines when researching data disputes. It will define specifically what*

*should be reviewed, will include dollar thresholds above which review is required, and include an approach for reviewing the balance of staff work on a sample basis. The methodology will be included in the new DRP Procedures Manual in lieu of the current practice for the PARC Manager to review and approve proposals and supporting documentation for significant adjustments before the settlement letter is sent to the manufacturers.*

*In order to facilitate management review, all staff will back up their work to the HHSC network on a daily basis.*

***Estimated Completion Date:*** September 30, 2003

***Title of Responsible Person:*** PARC Manager

***SAO Recommendation:*** The Commission should develop and standardize staff review criteria for the resolution of disputed and outstanding rebate revenue.

***Management Response:*** Agree.

***Action Planned:*** Staff is performing a comprehensive review of rebate adjustment procedures as part of its effort to prepare a new DRP Procedures Manual. This review is to ensure that HHSC policies follow federal guidelines. In addition, PARC will present to Division senior management through the Oversight Committee recommendations regarding options for advancing dispute resolutions, including participation in CMS sponsored dispute resolution project meetings, and alternative means to achieve the same objective.

***Estimated Completion Date:*** July 31, 2003

***Title of Responsible Person:*** PARC Manager

Chapter 1-F

## **The Commission Has Not Collected or Accounted for All Outstanding Interest on Rebates Owed to the State**

Unaudited data in PRIMS indicates that the Commission has not collected \$4.3 million in interest that drug labelers owe on outstanding rebates made since June 1995. Because the Commission has not determined the *total* outstanding rebate revenue balance before June 1995, it does not have a record of interest drug labelers owe on rebates from that period.

In 1994, we reported that because the Program did not determine the amount of outstanding rebates, calculating the interest amounts that drug labelers owed was not possible. However, we reported in the same year that interest that could be earned on the disputes resolved in favor of the State was estimated to be over \$500,000 per year. For Medicaid rebates, the federal government indicates that the State is responsible for tracking the collection of interest due on late rebate payments and disputed rebate amounts resolved in the State's favor.

The Commission does not bill drug labelers for interest they owe; instead, it informs drug labelers that they owe an unspecified amount of interest on late payments or

disputed rebates. Drug labelers then remit interest payments based on their own calculations. However, because the Commission does not independently calculate the interest drug labelers owe, it is unable to determine whether drug labelers pay the appropriate amount of interest

The federal government has received complaints that some drug labelers allege they have no obligation to pay interest unless states send them an invoice for the interest. As a result, the federal government has issued numerous warnings to states regarding the collection of and the inappropriate procedures used by some manufacturers to calculate the interest. The federal government also has informed states that some drug labelers unreasonably and routinely fail to pay interest on late or disputed rebates. Given these concerns, the Commission should not assume that drug labelers' calculations of interest payments are complete and accurate.

## Recommendations

The Commission should:

- Use federal guidelines to accurately calculate and track interest owed to the State on rebates.
- Actively pursue and collect outstanding interest on rebates.
- Determine the accuracy of past interest payments and whether these payments encompass all outstanding interest owed to the State.

## Management's Response

**SAO Recommendation:** *The Commission should use federal guidelines to accurately calculate and track interest owed to the State on rebates.*

**SAO Recommendation:** *The Commission should actively pursue and collect outstanding interest on rebates.*

**SAO Recommendation:** *The Commission should determine the accuracy of past interest payments and whether payments encompass all outstanding interest owed to the State.*

**Management Response:** *Agree. HHSC agrees that it makes good business sense to actively pursue the outstanding interest. CMS' Medicaid Drug Rebate Operational Training Guide indicates, "The obligation for calculating interest due to the States on late rebate payments rests with the manufacturer. It is the State's responsibility to track the collection of interest due, and report those amounts to HCFA" (currently CMS). Interest is tracked at the NDC level by posting the interest payments, and reporting it to CMS on the HCFA64-9r Federal Funds report.*

*Since the PRIMS interest calculation was updated in February 2003 to meet revised CMS guidelines, HHSC is better able to calculate an outstanding interest balance. However, because the interest is compounded daily, and late interest becomes*

*principal, PARC cannot invoice for a specific amount, because the amount changes daily.*

***Action Planned:*** *PARC will proactively review the updated files to ensure all interest owed the State has been paid. PARC will notify manufacturers of the amount of interest due as of a specific date, and instruct them to recalculate interest as of the postmark date of the payment. Manufacturers will be notified on an annual basis of outstanding interest balances.*

***Estimated Completion Date:*** *Because the pre-PRIMS information must be completely entered into PRIMS for an accurate account of outstanding interest, PARC will inform manufacturers of outstanding interest balances with the mailing of the first rebate invoice after completion of the payment posting project, and annually thereafter.*

***Title of Responsible Person:*** *PARC Manager*

## ***Collection and Dispute Resolution Inefficiencies Increase the Risk that Rebate Revenue Could Go Uncollected***

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The Commission has not evaluated the Program's operations since the Program was transferred to the Commission in September 2001. In addition, the Commission has not critically assessed the rebate collection or dispute resolution processes as part of its business improvement initiatives. Despite the Program's history of significant weaknesses in collecting and accounting for rebate revenue, the Commission continues to support processes that present significant barriers to efficient rebate collection and dispute resolution. This could allow rebate revenue to go uncollected.

### Chapter 2-A

## **Rebate Collection and Dispute Resolution Processes Are Not Efficient**

Backlogs, delays, rework, and time-consuming manual processes render the Program's rebate collection and dispute resolution processes inefficient. Examples of inefficiencies include the following:

- Rebate collection and dispute resolution processes do not fully use automation available in PRIMS. While rebate billing is automated, rebate collection and dispute resolution processes involve multiple manual activities that require staff to manipulate PRIMS outputs to fit pre-existing processes, including benchmarking and adjusting claims and identifying errors in rebate data.
- Staff consistently resolve backlogged rebate disputes with drug labelers and make manual retroactive adjustments to rebate data that is not integrated into PRIMS. These adjustments are made to rebate data dating as far back as the Program's inception in 1991.
- Staff record details about collection and dispute resolution activities in the generic comments fields associated with individual records in PRIMS. However, because they do not record this information consistently, staff must review rebate transactions line by line to obtain necessary information about rebate coding and funds.

### **A Lack of Consolidated Data Has Led to Inefficiencies, Backlogs, and Delays**

A primary cause of the inefficiencies, backlogs, and delays in the collection and dispute resolution processes is the Program's failure to consolidate all rebate data in a single location. Specifically, the Commission has not integrated multiple sources of rebate data into PRIMS, the system of record for rebate data. These are the data that are necessary to determine outstanding rebate balances and perform collection activities. As a result, staff must consult multiple sources of rebate information stored outside of PRIMS during rebate collection and dispute resolution.

For example, when creating a rebate adjustment record, rebate staff must manually research multiple sources of data (see text box) and then enter rebate information on a spreadsheet stored outside of PRIMS. Spreadsheets are labor intensive to create as rebate staff must enter data fields that include the number of units billed, quantity paid, amount disputed, and amount paid. In addition to backlogs and delays, rebate staff estimated that resolving disputes with a single drug labeler can take as much as 25 percent of their time, or three months.

After rebate staff resolve disputed rebates, the spreadsheets they create become the support for rebate adjustment transactions. These spreadsheets, in turn, become an additional and duplicate source of data that staff must use to resolve future rebate disputes, which further complicates this process.

The lack of consolidated data is also a barrier to supervisory reviews that should be conducted after staff make rebate adjustments. In particular, information supporting adjustment transactions is not readily available for supervisory review of (1) staff adjustments to billings that result from dispute resolution and (2) verification of credits based on drug labeler pricing adjustments. (Additional details on issues surrounding supervisory reviews of the rebate collection and dispute resolution process are presented in Chapter 1-E.)

### **Unpaid Rebate Balances Are Not Aged to Prioritize Collection Activities**

Significant backlogs in the collection of rebates dating back to the Program's inception in 1991 still remain unaddressed. These backlogs exist because the Program's method of managing and prioritizing staff workload does not take into account the amount of time that rebates due from drug labelers have remained uncollected. The Program does not create aging data for receivables, and it does not use the time during which rebate balances remain outstanding to prioritize collection activities. Instead, the Program prioritizes rebate collection activities using a list, which includes more than 300 participating drug manufacturers, that is arranged in descending order by the amount of rebate revenue calculated as outstanding.

#### **Rebate Collection and Dispute Resolution Processes Involve Mission-Critical Rebate Information Stored in Multiple Locations Outside of PRIMS**

Rebate staff must use the following data stored outside of PRIMS when conducting rebate collection and dispute resolution activities:

- Hard copy rebate invoices sent to drug labelers prior to June 1995. These invoices contain billing, drug utilization, and unit rebate data required to determine the outstanding balance for the period prior to June 1995.
- Information staff record about rebate adjustments in spreadsheets. These spreadsheets are located on the Commission's network or on staff's personal computers. The spreadsheets are necessary during supervisory review because they support the aggregated adjustment transactions recorded in PRIMS.
- Information staff record about their activities in personal notebooks. Staff record their rebate claims review activities in individual paper notebooks. It would be necessary to review these notebooks to conduct a proper supervisory review because they support the aggregated adjustment transactions recorded in PRIMS.
- Duplicative rebate deposit data that staff record in CashTrac. CashTrac is a system of organized spreadsheets that are stored outside of PRIMS. The Program staff use this information as an intermediary step for reconciling deposits with the Commission's internal accounting system.
- Rebate "slow pay" collection spreadsheets. Staff regularly record this information on spreadsheets that are stored outside of PRIMS. This information is necessary to determine the result of collections activities.

Inefficiencies have limited the Program to focusing on roughly the first 15 to 20 drug manufacturers on this list each year.

The Commission's current method for prioritizing rebate collections, combined with the other inefficiencies noted above in the rebate collection and dispute resolution process, put uncollected rebate revenues at increased risk of loss. Without proper aging data for outstanding rebate revenue, the Commission is not able to track a significant portion of rebate staff's workload or identify rebates that are at risk of remaining uncollected for extended periods of time. Our 1994 audit report recommended that staff age rebate accounts receivable. In addition, CMS has recommended that states prioritize rebate dispute resolution through the aging of accounts receivable.

## Recommendations

The Commission should:

- Critically assess the rebate collection and dispute resolution processes to maximize the capabilities of PRIMS.
- Re-engineer rebate collection and dispute resolution activities that are not timely, efficient, or accurate. Develop performance measures to monitor the efficiency and effectiveness of the program's billing, collection, and dispute resolution activities.
- Require rebate staff to work exclusively from data in PRIMS.
- Create reports and automated procedures for common tasks performed using rebate data in order to improve the efficiency and accuracy of the rebate collection and dispute resolution process (including adjustment transactions, credit transactions, and a supervisory review of transactions).
- Consolidate and reconcile all mission-critical rebate data that is necessary for current processes (including hard copies of invoices from periods prior to June 1995, staff's spreadsheets and notebooks, CashTrac, and slow pay logs) into PRIMS.
- Follow federally recommended procedures for developing drug utilization estimates for cases in which rebate information is required but is not available.
- Use the amount of time an unpaid balance is outstanding as a factor to prioritize collection activity.

## Management's Response

***SAO Recommendation:*** *The Commission should critically assess the rebate collection and dispute resolution processes to maximize the capabilities of PRIMS.*

**Management Response:** Agree. When all of the invoice item activity for pre-PRIMS periods is entered in the system, PARC will be able to more effectively utilize the system to its full potential.

**Action Planned:** After reviewing current processes and utilization of PRIMS, PARC will develop a list of potential system enhancements which will be provided to IRM to determine which options are viable and request they begin system adjustments to achieve those goals.

**Estimated Completion Date:** June 1, 2003. IRM will develop a timeframe to address the system modifications requested by PARC.

**Title of Responsible Person:** PARC Manager

**SAO Recommendation:** The Commission should re-engineer rebate collection and dispute resolution activities that are not timely, efficient, or accurate. Develop performance measures to monitor the efficiency and effectiveness of the program's billing, collection, and dispute resolution activities.

**Management Response:** Agree. The program has some performance measures in place to monitor the efficiency and effectiveness of the Program's activities, but PARC agrees that these measures should be reviewed to determine if better or more efficient practices or performance measures are needed.

**Action Planned:** A complete review of current activities will be performed. An interdisciplinary group from appropriate HHSC Divisions will design improvements to existing performance measures activities. The Oversight Committee will recommend improvements to Division Senior Management on an annual basis in conjunction with the Program's participation in the development of the Medicaid/CHIP Division's biennial operating plan.

**Estimated Completion Date:** Revised performance measures will be in place by August 31, 2003.

**Title of Responsible Person:** PARC Manager

**SAO Recommendation:** The Commission should require rebate staff to work exclusively from data in PRIMS.

**Management Response:** Agree. The primary reason Rebate Specialists cannot currently work strictly from PRIMS is that pre-PRIMS invoice and payment information are not in the system. As previously mentioned, the invoicing information was loaded in March 2003. After completion of the payment posting project, all invoice and payment information will be available in PRIMS. This will allow the Rebate Specialists the opportunity work exclusively from the data in PRIMS.

**Action Planned:** Staff working on the payment posting project will create payment vouchers and post pre-PRIMS invoices per the submitted ROSI's and PQA's. This will allow all information to be accessed via PRIMS.

**Estimated Completion Date:** A timeline for completion of the payment posting project will be developed once the Oversight Committee recommends appropriate staffing levels to senior management by May 1, 2003.

**Title of Responsible Person:** PARC Manager

**SAO Recommendation:** The Commission should create reports and automated procedures for common tasks performed using rebate data in order to improve the efficiency and accuracy of the rebate collection and dispute resolution process (including adjustment transactions, credit transactions, and a supervisory review of transactions).

**Management Response:** Agree.

**Action Planned:** PARC will include this issue with the list of system enhancement requests.

**Estimated Completion Date:** On or before June 1, 2003, PARC will provide system enhancement requests to IRM for a plan to implement system improvements.

**Title of Responsible Person:** PARC Manager

**SAO Recommendation:** The Commission should consolidate and reconcile all mission-critical rebate data that is necessary for current processes (including hard copies of invoices from periods prior to June 1995, staff's spreadsheets and notebooks, CashTrac, and slow pay logs) into PRIMS.

**Management Response:** Agree.

**Action Planned:** Complete the payment posting project. PARC will work with IRM to identify ways to modify the system for integration to include slow pay logs, information currently posted in CashTrac, and supporting notes and spreadsheets. PARC will work with Fiscal to obtain Access data needed for PRIMS and federal reporting.

**Estimated Completion Date:** All invoice and payment information will be accessible in PRIMS after completion of the payment posting project. A timeline for completion of the payment posting project will be developed once the Oversight Committee recommends appropriate staffing levels to senior management by May 1, 2003. Proposed system integration modifications and enhancements will be presented to IRM by June 1, 2003, after which it will develop a timeline for development and implementation.

**Title of Responsible Person:** PARC Manager

**SAO Recommendation:** The Commission should follow federally recommended procedures for developing drug utilization estimates for cases in which rebate information is required but is not available.

**Management Response:** Agree. All original claim data is available for utilization review from 1991 to the present, therefore estimation is not necessary. If estimation becomes necessary, PARC staff will follow federally recommended procedures.

**SAO Recommendation:** *The Commission should use the amount of time an unpaid balance is outstanding as a factor to prioritize collection activity.*

**Management Response:** *Agree. Due to limited manpower and because of the lack of electronic data prior to June 1995, PARC used the current outstanding balances as an indicator of past performance to prioritize manufacturers. DRP processes are currently focused on the manufacturers with the highest outstanding balances, beginning with the oldest quarter in which each manufacturer has outstanding disputes.*

**Action Planned:** *Once the payment posting project is completed, PARC will be able to determine the amount of time an unpaid balance is outstanding and begin to use it as a factor in prioritizing collection activity. New procedures addressing how collection activity is to be prioritized will be included in the DRP Procedures Manual. PARC will also study the cost-effectiveness of working current activities first, then older disputes as time permits.*

**Estimated Completion Date:** *Completion and implementation of the DRP Procedures Manual is expected by July 31, 2003.*

**Title of Responsible Person:** *PARC Manager*

#### Chapter 2-B

### **The Commission Does Not Track Rebate Staff's Performance**

The Commission does not quantify rebate staff's workload or measure outputs of core business processes in sufficient detail to determine the Program's staffing needs. Rebate staff are not required to document their workload, the amount of time they work, or the work they perform in collection or dispute resolution activities.

Inconsistent data and processes also contribute to the Commission's inability to quantify rebate staff's outputs completely or accurately. Rebate staff do not document which claims they review and adjust in their work products. Therefore, the Commission does not have complete or reliable data with which to measure variables that contribute to the process inefficiencies and errors described in Chapter 2-A. Without collecting this information, the Commission cannot support business decisions regarding the activities of rebate staff.

The Commission has quantified staff's performance in the rebate dispute resolution process through an ad hoc report. However, the primary purpose of that ad hoc report is to quantify the number of claims that staff who telecommute have reviewed; the ad hoc report does not quantify the effectiveness of collection methods that all staff use. As a performance tool, the ad hoc report does not provide detail that would allow the Commission to gauge individual staff productivity or effectiveness. Because the report is aggregated for all staff, it does not reflect an individual's workload or productivity. In addition, while the report lists the dollar value of resolved disputes, it does not indicate whether the resolution resulted in the State collecting money owed or the issuance of a credit to the drug labeler. Not having this type of information prevents the Commission from assessing individual staff

performance and productivity, and it prevents the Commission from determining the amount it collects as a result of dispute resolution activities.

## **Recommendations**

The Commission should:

- Develop standard performance measures to evaluate the productivity and effectiveness of individual staff members. Performance measures should clearly define outputs and outcomes for collection and dispute resolution activities.
- Use the performance data it collects to evaluate the Program's appropriateness of staffing levels in relation to workloads.

## **Management's Response**

**SAO Recommendation:** *The Commission should develop standard performance measures to evaluate the productivity and effectiveness of individual staff members. Performance measures should clearly define outputs and outcomes for collection and dispute resolution activities.*

**Management Response:** *Agree.*

**Action Proposed:** *An interdisciplinary group from appropriate HHSC Divisions will design improvements to existing performance measures. The Oversight Committee will recommend improvements to Division Senior Management on an annual basis in conjunction with the Program's participation in the development of the Medicaid/CHIP Division's biennial operating plan.*

**Estimated Completion Date:** *August 31, 2003*

**SAO Recommendation:** *The Commission should use the performance data it collects to evaluate the Program's appropriateness of staffing levels in relation to workloads.*

**Management Response:** *Agree.*

**Action Planned:** *On a routine basis, PARC will provide performance data to the Medicaid/CHIP Senior Leadership Team for review and direction.*

**Estimated Completion Date:** *September 30, 2003*

**Title of Responsible Person:** *PARC Manager*

## ***Inadequate Controls Increase the Risk that Rebate Revenue Could Be Lost Through Fraud, Abuse, and Error***

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Serious weaknesses in the Program's control environment increase the risk that (1) rebate revenue could be lost through fraud, abuse, and error or (2) errors in rebate data could go undetected. We identified numerous instances in which inadequate controls prevented the Commission from accurately accounting for rebates that drug manufacturers owed the State. The control weaknesses we identified compromise rebate data integrity and put rebate revenue at risk. In addition, failure to promptly deposit rebate revenue cost the State an estimated \$343,000 in lost interest earnings between 1998 through 2001.

### Chapter 3-A

## **Inadequate Segregation of Duties Among Rebate Staff Working in PRIMS Could Subject Rebate Revenue to Loss and Misuse**

All rebate staff can add, modify, or delete any type of record in PRIMS; they can also alter the amount of rebate revenue drug labelers owe to the State. In addition, the structure of the PRIMS database does not allow for segregation of rebate collection and adjustment duties. The inability to segregate duties increases risk of loss or misuse of rebate revenue.

We identified rebate adjustment records in PRIMS that demonstrate inadequate segregation of duties because they were created by a user whose primary responsibility is entering payment records. While we did not identify any fraudulent transactions, we did identify 44 rebate invoices in PRIMS (7.2 percent of a judgmental sample of 610) that appeared to lack corresponding rebate transactions (based on gaps in sequence numbers that PRIMS assigns automatically). The Commission was not aware of this issue and was not able to explain it.

### **Recommendations**

The Commission should:

- Segregate duties related to rebate billing, payment, and adjustment.
- Limit access to billing, payment, and adjustment transactions in PRIMS.
- Periodically review PRIMS transactions for deleted records and staff compliance with their assigned duties.

### **Management's Response**

***SAO Recommendation:*** *The Commission should segregate duties related to rebate billing, payment, and adjustment.*

**SAO Recommendation:** *The Commission should limit access to billing, payment, and adjustment transactions in PRIMS.*

**Management Response:** *Agree.*

**Action Planned:** *A request was submitted to IRM on March 26, 2003, to limit access rights in PRIMS. Three existing functionally segregated groups of duties will be used: Rebate Specialists perform manual adjustments; IRM staff generate invoices; and the Rebate Accountant prints and mails invoices and process payments. These duties are defined in each position's functional job description. Only individuals in defined user groups will be authorized to process the specific types of transactions required to perform each of the duties noted above.*

**Estimated Completion Date:** *May 1, 2003*

**Title of Responsible Person:** *PARC Manager*

**SAO Recommendation:** *The Commission should periodically review PRIMS transactions for deleted records and staff compliance with their assigned duties.*

**Management Response:** *Agree.*

**Action Planned:** *An audit trail will be added to Invoice and Payment tables. This will track all inserts, updates and deletes made to the corresponding table. In addition PARC, in conjunction with IRM, will determine whether current Auto Post procedures need to be modified because of how they currently handle interest transactions.*

**Estimated Completion Date:** *June 30, 2003*

**Title of Responsible Person:** *Supervisor Application Development*

Chapter 3-B

### **The Commission's Informal and Ineffective Coding of Rebate Data in PRIMS Limits Its Ability to Ensure the Accuracy of Rebate Payments and Adjustments**

The Commission has an ineffective system of coding and recording the audit trail for credit vouchers recorded in PRIMS. In addition, PRIMS lacks controls to prevent staff from incompletely and inappropriately recording transactions. The Commission uses a manual process to record the audit trail for credit vouchers, but staff do not consistently follow this process. This limits the Commission's ability to review the accuracy of rebate payment, adjustment, and credit transactions recorded as credit vouchers. For example, staff must manually review queried records to determine whether these items meet the intended criteria for review.

The Commission requires staff using PRIMS to enter specific letters in the comments field of rebate transactions, but staff do not always comply with this requirement. We observed PRIMS transactions with blank comments fields and comments that were not in the prescribed format. We were not able to quantify the extent of coding

errors because this would have required an individual, qualitative review of each payment record comment field.

## **Recommendations**

The Commission should:

- Develop a method for recording appropriate audit trails for credit vouchers.
- Discontinue use of manual coding of the audit trail for rebate transactions.
- Integrate its prescribed coding process and associated controls into PRIMS to allow staff to perform accurate calculation and quantification of audit trail codes.

## **Management's Response**

**SAO Recommendation:** *The Commission should develop a method for recording appropriate audit trails for credit vouchers.*

**Management Response:** *Agree. Upon completion of the payment posting project only valid credit vouchers will be in the Credit Voucher table.*

**Action Planned:** *An audit trail will be added to Invoice and Payment tables. This will track all inserts, updates and deletes made to the corresponding tables. Current methods of coding will be reviewed and revised to allow for easier tracking and reporting.*

**Estimated Completion Date:** *June 30, 2003*

**Title of Responsible Person:** *Supervisor Application Development*

**SAO Recommendation:** *The Commission should discontinue use of manual coding of the audit trail for rebate transactions.*

**SAO Recommendation:** *The Commission should integrate its prescribed coding process and associated controls into PRIMS to allow staff to perform accurate calculation and quantification of audit trail codes.*

**Management Response:** *Agree.*

**Action Planned:** *As part of the review of current procedures, and in conjunction with IRM's implementation of audit trails in Invoice and Payment tables, PARC will review current methods of coding and make revisions to allow for easier, more uniform tracking and reporting. New procedures will address the proper posting of some information currently entered in the comment field.*

**Estimated Completion Date:** *August 31, 2003*

**Title of Responsible Person:** *Supervisor Application Development*

## Delays in Depositing Rebate Checks Result in Lost Interest

Unaudited data in PRIMS indicate that the State lost an estimated \$343,000 in interest between fiscal years 1998 and 2001 because rebate checks were not deposited into the State Treasury within three days of their receipt as Texas Government Code, Section 404.094(a), requires. On average, rebate checks were not deposited within six days of their receipt, based on a judgmental sample of 5,814 rebate checks totaling \$820 million. Although this average is an improvement from the 18-day average we reported in 1994, it is still not in compliance with the Texas Government Code.

It is important to note that in fiscal years 1998 through 2001, the Department of Health was responsible for depositing rebate checks (the rebate program was transferred to the Commission in September 2001).

### Recommendations

The Commission should:

- Maximize interest earned by requiring staff to deposit rebate checks within the statutory three-day requirement.
- Ensure that staff record rebate check receipt and deposit dates in PRIMS so that management can regularly review the timeliness of check deposits.

### Management's Response

**SAO Recommendation:** *The Commission should maximize interest earned by requiring staff to deposit rebate checks within the statutory three-day requirement.*

**SAO Recommendation:** *The Commission should ensure that staff record rebate check receipt and deposit dates in PRIMS so that management can regularly review the timelines of check deposits.*

**Management Response:** *Agree. Procedures have been put into place since the HHSC Fiscal Services Division began depositing checks on September 1, 2002, to ensure that deposits are made in a timely manner, based on statutory requirements. Those procedures have been documented and are being followed, except on rare occasions when an exception prevents funds from being deposited within those timelines.*

*Although the audit recommendation suggests that the PRIMS system maintain data on the deposit received and deposited date, it is alternatively recommended that this information be extracted directly from the Access database maintained in Fiscal since it is a more reliable, more direct, and more current source of this information.*

**Action Planned:** *A tracking mechanism for documenting that deposits are being made in a timely manner will be perfected and closely monitored. Fiscal will include the received date in the current Access database extract that they currently provide the Program on a monthly basis.*

***Estimated Completion Date:*** *The tracking mechanism will be in place by April 30, 2003.*

***Title of Responsible Person:*** *Director of Accounting Operations*

## ***The Commission Does Not Adequately Track or Report the Program's Performance***

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Because the Commission does not evaluate the efficiency and effectiveness of the Program, its ability to make sound business decisions is diminished. The Commission does not regularly collect information to measure the overall performance of the Program. Weaknesses in the availability, format, and consistency of rebate data also contribute to the Commission's inability to track Program variables accurately.

Since the Program was transferred to the Commission in 2001, the performance reporting by the Program to Commission management has lacked key elements necessary to evaluate the effectiveness of the Program's collection activities. While Commission management receives quarterly reports on the amount of rebates billed to manufacturers, these reports do not include the amount of rebates received or the amount of rebates outstanding. This lack of information on the collection rate for the Program precludes the Commission from determining the overall effectiveness of its collection function.

For federal fiscal quarters ending December 31, 1993 and March 31, 1997, the Program also did not comply with a requirement to submit a federal report to CMS summarizing the Program's performance in billing and collecting rebate revenue for all periods back to the beginning of the Program. The Commission confirmed the Program's continued noncompliance with the federal reporting requirements and indicated that this is occurring because of a lack of complete and automated data for the Program prior to June 1995 (as discussed in Chapter 1). The Program's inability to report for this period has affected the accuracy of subsequent federal reporting, and the Commission indicates that the Program cannot produce a complete report for CMS until all of the old invoices have been generated and the payments have been reconciled. The federal government initiated this reporting requirement in the first quarter of federal fiscal year 1994.

The Commission also has made decisions materially affecting the Program's ability to collect rebates without evaluating the effects of the decisions on the productivity and effectiveness of the Program. For example, in June 2002 the Commission terminated the Program's participation in CMS's Dispute Resolution Program, a federally sponsored and recommended collections program for disputed or delinquent rebates. The Commission made this decision in order to reduce travel expenses. However, according to staff, 68 percent of total rebate dispute resolution collections since the Program's inception in 1991 (totaling \$10.7 million) are directly attributable to the Commission's prior participation in this collections program. Not participating in this collections program limits the Commission's ability to enter into agreements with drug labelers regarding disputed rebate revenues.

## Recommendations

The Commission should:

- Establish performance measures for the timeliness, efficiency, and accuracy of the Program's dispute resolution and collections functions that include an average age of receivables, a unit-based collections rate, and quantification and stratification of all adjustments to invoices for drug labelers.
- Import, consolidate, and reconcile rebate data prior to 1995 with automated Program data in PRIMS.
- Ensure that future federal reports correctly account for invoiced, paid, and outstanding rebate revenues.

## Management's Response

**SAO Recommendation:** *The Commission should establish performance measures for the timeliness, efficiency, and accuracy of the Program's dispute resolution and collections functions that include an average age of receivables, a unit-based collections rate, and quantification and stratification of all adjustments to invoices for drug labelers.*

**Management Response:** *Agree.*

**Action Planned:** *PARC will develop meaningful performance measures with the assistance of the Committee and submit them to Division senior management for approval.*

**Estimated Completion Date:** *August 31, 2003*

**Title of Responsible Person:** *PARC Manager*

**SAO Recommendation:** *The Commission should import, consolidate, and reconcile rebate data prior to 1995 with automated Program data in PRIMS.*

**Management Response:** *Agree.*

**Action Planned:** *Invoices have already been loaded into the PRIMS system. HHSC will enter pre-PRIMS payment data as part of the payment posting project.*

**Estimated Completion Date:** *A timeline for completion of the payment posting project will be developed once the Oversight Committee recommends appropriate staffing levels to senior management by May 1, 2003.*

**Title of Responsible Person:** *PARC Manager*

**SAO Recommendation:** *The Commission should ensure that future federal reports correctly account for invoiced, paid, and outstanding rebate revenues.*

**Management Response:** *Agree.*

***Action Planned:*** *The planned system enhancements will allow us to accomplish this.*

***Estimated Completion Date:*** *August 31, 2003*

***Title of Responsible Person:*** *PARC Manager*

# Appendices

Appendix 1

## **Objective, Scope, and Methodology**

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### **Objective**

Our objective was to assess the effectiveness of the collection process of the Prescription Drug Rebate Program (Program) at the Health and Human Services Commission (Commission). The objective included answering the following questions:

- Is the rebate collection process efficient?
- Do the Program's accounting systems, policies, and practices ensure accurate drug rebate data?
- How timely is the collection of drug rebates?

### **Scope**

The scope of this audit included reviews and analyses of the Commission's core business processes and rebate data since the inception of the Program in 1991. At the time of our audit, the Program was staffed by six full-time equivalent (FTE) employees and was responsible for the collection of drug labeler rebates for the Medicaid, Kidney Health, Children With Special Healthcare Needs, and Children's Health Insurance Programs.

Specifically, we performed reviews and analyses of the Commission's:

- Oversight and management of the rebate collection and dispute resolution process.
- Inputs to and outputs from information systems, including quality of data and automation of processes.
- Key business processes to assess efficiency of operations, determine backlogs and delays, and evaluate use of resources.
- Performance reviews and reporting.
- Internal controls safeguarding rebate revenue.
- Compliance with key laws and statutes.
- Revenue forecasts provided to the Legislature regarding cost containment strategies.

## Methodology

This audit addressed the overall effectiveness of processes, control environments, and resulting integrity of data in data systems utilized in the Program. We addressed the controls and integrity of rebate data through review of activities, inputs, and outputs contributing to business processes. Standard activity-based costing techniques identified activities performed in the Program's billing, collection, and dispute resolution processes, including those specific to entering, utilizing, adjusting, and reporting rebate data in both automated and manual information systems.

We reviewed activities and related information system inputs and outputs in the collection and dispute resolution processes, including transactions in the Pharmacy Rebate Information Management System (PRIMS), a system of organized spreadsheets known as CashTrac, and various electronic and hard copies of spreadsheets created by staff or drug labelers. Testing performed on these data sources included the following:

- Review for segregation of duties based on access to information system components
- Verification of completeness of coding mechanisms, audit trails, and required data elements
- Comparison between data elements for consistency between different information systems and hard copy sources of rebate data
- Reconciliation of related data elements and transactions in PRIMS to determine data integrity
- Quantification of the effect of any observed control weaknesses

While the audit discusses information system controls and data integrity, the extent of our technology review was to assess the functional utilization of data systems and quantify the effect of observed weaknesses, not to perform a complete review of any specific data systems.

Information collected to accomplish our objective included the following:

- Interviews with Commission executive management, division directors, program management and staff, and a PRIMS software vendor representative
- Interviews with Centers for Medicaid and Medicare Services (CMS) and U.S. Health and Human Services Office of Inspector General representatives
- Commission planning documents, Program reports, interoffice memoranda, and rebate staff spreadsheets and journals
- Program applications and contracts
- PRIMS tables, procedure manuals, data definitions, transactions, procedures, reports, and logs
- Department of Health audit reports on the Program

- Information system planning documents including requests for proposals, contractor responses, and training documents
- Newspaper articles and reports relating to the Commission and the Medicaid program
- Prior State Auditor's Office audit reports

Procedures and tests conducted included the following:

- Test of PRIMS controls and data integrity
- Analysis of segregation of duties
- Analysis of specific transactions including disputes, adjustments, payments, credits, and interest
- Reconciliation and test of timeliness for deposits in PRIMS and the Uniform Statewide Accounting System (USAS)
- Reconciliation of outstanding balances and collections
- Direct observation of business processes and comparison with procedures and best practices
- Analysis of the Program's performance reporting

Analysis techniques used included the following:

- Control testing and review
- Reconciliation
- Data comparison
- Data completeness and standardization
- Workflow mapping
- Trend analysis

Criteria used included the following:

- Texas Statutes and Texas Administrative Code
- Social Security Act
- CMS State Medicaid Manual, Operations Guide, Program memoranda, and Best Practices Guide
- Office of Inspector General work plan and audits reports on the Program
- Commission plans, policies, and procedures, including the Rebate Operations Manual and PRIMS planning and procurement documents

- Department of Information Resources' *Practices for Protecting Information Resources*
- State Auditor's Office methodology manual

### **Other Information**

We conducted fieldwork from June 2002 through December of 2002. The audit was conducted in accordance with generally accepted government auditing standards, and there were no significant instances of noncompliance with these standards.

The following members of the State Auditor's staff performed the audit work:

- John C. Young, MPAff (Project Manager)
- Kels Farmer
- Ricardo A. Garcia, MPAff
- Willie Hicks, MBA
- Leslie Ashton, CPA (Quality Control Reviewer)
- Joanna B. Peavy, CPA (Audit Manager)
- Frank Vito, CPA (Audit Director)

## ***Background Information on the Medicaid Drug Rebate Program***

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### **The Medicaid Drug Rebate Program**

Title XIX, Section 1927, of the U.S. Social Security Act (Act) required the creation of a Medicaid Drug Rebate Program effective January 1, 1991. According to Section 1927, in order for federal Medicaid matching fund payments to be available to states for covered outpatient drugs of a drug labeler, the labeler must have entered into and have in effect a rebate agreement with the U.S. Secretary of Health and Human Services, on behalf of states. The U.S. Centers for Medicare and Medicaid Services (CMS), formerly referred to as the U.S. Health Care Finance Administration, indicates that states are ineligible to receive federal funding for outpatient drugs dispensed to Medicaid beneficiaries without a drug rebate agreement. State rebate revenues from drug labeler payments are set against state medical assistance expenditures under the Medicaid program.

Acting on behalf of the states, CMS enters into rebate contracts with each drug labeler desiring to have its products covered under a state's Medicaid drug formulary. Drug labelers are required by the terms of the contract to submit a quarterly rebate for covered outpatient drugs paid by a state during the quarter. The contract sets the rebate amount as the product of the number of drug units paid by the State and a unit rebate amount set by the federal government. Drug labelers provide quarterly pricing information to CMS, which uses the data to compute a unit rebate amount for each covered drug. CMS, in turn, provides the unit rebate amount to states, which maintain data on the number of units dispensed and paid for by the state Medicaid programs. States determine the rebate amounts owed by multiplying the unit rebate amount against their drug utilization.

According to CMS, approximately 520 drug labelers currently participate in the Medicaid drug rebate program. Nationally, 49 states and the District of Columbia participate in the Medicaid drug rebate program. CMS notes that as of January 1, 1996, the rebates for covered outpatient drugs were as follows:

- **Innovator Drugs.** The larger of 15.1 percent of the average manufacturer price (AMP) per unit or the difference between the AMP and the best price per unit as adjusted by the CPI for All Urban Consumers (CPI-U) based on launch date and current quarter AMP
- **Non-innovator Drugs.** 11 percent of the AMP per unit

Sources:

- Title XIX, Social Security Act, Section 1927
- *Drug Rebate Operational Training Guide*, CMS's Center for Medicaid and State Operations Finance, Systems and Quality Group, Division of State Systems, September 2001.
- CMS's Web site: [www.cms.gov](http://www.cms.gov)
- CMS's *Medicaid Drug Rebate Operational Training Guide*

- Health and Human Services Commission's *Pharmacy Rebate Information Management System*
- Uniform Statewide Accounting System

## **Federal Issues Affecting Administration of the Vendor Drug Rebate Program**

Issues at the federal level affect the Health and Human Services Commission's (Commission) ability to control variables that hinder administration of the Program. The U.S. Health and Human Services Office of Inspector General (OIG) has found deficiencies in the administration of the vendor drug rebate program at the federal level. The OIG has remarked that problems with the integrity of pricing data CMS forwards to states and state drug utilization data directly affect the ability of states to calculate rebate amounts owed by drug labelers. OIG has noted that CMS has not ensured that states have established adequate accountability and controls over the Medicaid drug rebate program.

The lack of adequate oversight by CMS contributes to problems at the Commission, including the Commission's inability to quantify the rebates owed before June 1995 and problems involving drug labeler pricing adjustments. Commission staff noted that errors in the pricing data CMS forwarded to the Commission alter the dollar amounts owed and affect retroactive pricing adjustments to the beginning of the rebate program in 1991. The Commission confirmed that deficiencies in CMS oversight create rework and delays.

In 2002, the OIG began an audit of Medicaid drug rebate programs to evaluate the sufficiency of internal controls and to quantify a nationwide accounts receivable balance. Previous OIG audit work has revealed the following:

- OIG reported in 2001 that some drug labelers excluded drug sales to health maintenance organizations (HMOs) when determining best price calculations used in the calculation of rebates.
- OIG reported in 1998 that it found inconsistencies in drug labeler methods of calculating average manufacturer price (AMP) used in the calculation of rebates.
- At the inception of the Medicaid drug rebate program, the OIG reported that the federal government needed to establish controls and perform adequate analyses on pricing data submitted by drug labelers in order to ensure that pricing data provided to the states is accurate and timely.

## Summary of Prior State Auditor's Office Findings

During our audit work in 2002, we identified multiple issues that we had also reported in our 1994 audit report on the Program, then administered by the Department of Health (Department) (see *An Audit Report on the Medicaid Vendor Drug Rebate Program*, SAO Report No. 94-143, April 1994). Although we did not attempt to verify whether all of the 1994 findings remain unresolved, we observed some significant issues in 2002 that we had also reported on in 1994. This demonstrates an increased risk that the Commission cannot identify, track, or resolve these issues. The findings identified in April 1994 that we also observed in 2002 are outlined in the table below:

Findings Identified by the State Auditor's Office in Both 1994 and 2002		
Finding Description	Management's Response in 1994	Status in 2002
The Department has no controls to ensure the accuracy of the rebates.	Department staff are developing a new rebate system that includes a billing system designed to ensure that rebate billings could be reconciled to claims.	Auditors verified that claims data are the basis for automated billing in the Pharmacy Rebate Information Management System (PRIMS). However, we noted that controls are not adequate to ensure accuracy of rebates because payment claims data contain errors and are not regularly reconciled to billed claims.
The current information system hampers the Program's ability to quickly resolve disputes with manufacturers.	The new rebate system is being designed to give staff a functional account receivable system with capabilities for line item resolution of receivables, interest computation, ad hoc research and report generation for dispute resolution, and compliance with federal reporting requirements.	Lack of automation and inconsistency in recording data prevent automation of dispute resolution activities in PRIMS. Staff continue to review disputes line by line, using PRIMS as a manual system.
The Program does not have an effective accounts receivable system.	(See above for management assertions regarding development of a rebate system with accounts receivable functions.)	Management does not have controls to ensure line item resolution, does not age receivables, and has not complied with federal reporting requirements using PRIMS.
The Program lacks the capability of computing interest on disputed amounts.	(See above for management assertions regarding development of a rebate system with capabilities for interest computation.)	The Commission does not collect, track, or reconcile interest.
Vendor drug rebate checks are being deposited an average of 18 days after initial receipt.	Early delays in deposits cited by the auditors resulted from initial confusion over where the rebate checks should be deposited. There was a temporary backlog due to an unexpected high turnover in this section. With the hiring of permanent staff... this function is now current and meeting statutory requirements for timeliness of deposits.	The Commission continues to exceed statutory requirements for timeliness of deposits.

## Summary of PRIMS Control Weaknesses and Data Integrity Weaknesses

### Pharmacy Rebate Information Management System (PRIMS) Control Environment Weaknesses

We noted several control weaknesses regarding data entry, processing, and reporting in PRIMS that increase the risk of inaccurate, incomplete, or unreliable rebate data. The table below provides details about these control weaknesses. These weaknesses are the basis for our overall assessment that the Health and Human Services Commission (Commission) has not implemented adequate controls to ensure the integrity of rebate data.

PRIMS Control Environment Weaknesses		
Weakness	PRIMS Table(s) Affected	Details
Segregation of duties	Invoice Item Activity	Access controls in PRIMS do not adequately ensure segregation of the billing, adjustment, and payment duties because all users assigned to the rebate section user groups have all (select, insert, update, and delete) privileges to the Invoice Item Activity table. While PRIMS access controls restrict access to this table, they do not restrict access to the billing, payment, and adjustment transactions individually.
No standard process for disputes	All	Rebate staff do not review or document PRIMS data based on a standardized set of criteria.
Manual coding	Credit Voucher, Invoice Item Activity	The rebate section has adopted manual coding in the comments of PRIMS records field by including specific text in the comments of transactions. This method of coding is not used consistently and results in manual use of an automated system because staff must review each relevant comment to determine the coding information.
Insufficient audit trail	Invoice Item Activity, Credit Voucher	We noted instances in which audit trails did not exist or consisted of a manual entry of initials and a date as the entire comment.
Adjustments without state utilization data	Credit Voucher	Prior-period adjustments that affect invoices issued prior to June 1995 are consistently processed without verification of state unit quantity and unit rebate amount (URA) data that are the basis of these transactions.
Payments without supporting unit data	Credit Voucher	Payments recorded as credit vouchers do not include unit quantity or URA information. Staff continue to record payment data and prior-period adjustments in this manner without recording the basis of the calculation. A review of these transactions would consist of manual verification with hard copy documents and recalculation by hand.
Amount of manufacturer dispute codes	Invoice Item Activity	PRIMS does not allow individual dollar amounts for each adjustment/dispute code if multiple codes are entered.
Interest calculation	Invoice Item	Management has not developed a reliable method of calculating interest in PRIMS.

### PRIMS Data Integrity Weaknesses

We also noted several PRIMS data integrity weaknesses. The following table provides details on these weaknesses. These weaknesses are the basis for our overall conclusion that the Commission's inability to establish an effective control environment has compromised the integrity of rebate data in PRIMS.

## PRIMS Data Integrity Weaknesses

Weakness	PRIMS Table(s) Affected	Details
Payment record data entry errors	Invoice Item Activity	Payment amount fields in payment records do not match the product of the unit quantity and URA in 11,356 records. These errors occurred in the amount, quantity, or URA. Auditors reviewed examples of these transactions with the Commission and concluded that they were due to errors caused by misplaced decimal places, reversed positive/negative values, omitted data, and transposed or deleted digits.
Auto Post procedure includes quantity	Invoice Item Activity	The Auto Post procedure in PRIMS populates the payment utilization data incorrectly if payments are not received for all outstanding invoices. The calculation is based on the outstanding amount of each invoice, and if a drug labeler does not pay for the entire outstanding balance, PRIMS creates an erroneous payment record that must be manually changed to zero dollars and units. If manually changed, these transactions will not result in an incorrect outstanding balance or units. However, staff do not consistently correct these situations, and approximately 1,341 of the data entry errors noted in payment records fit the Commission's definition of this error (with a net effect of overstating units collected by 25.8 million units).
Funds recorded in comment field	Credit Voucher	Some PRIMS payment and adjustment records prior to the third quarter of 1995 include dollar values in the comments field. This is not consistent with other financial data in PRIMS, and the data is not adequately controlled. In addition, PRIMS cannot compute values in the comments field, and staff must manually review these records line by line.
Payment and credit data not consistent	Invoice Item Activity, Credit Voucher	Payment data and credit data are not recorded as intended in PRIMS. PRIMS includes payments representing \$343 million dollars that are recorded as credit vouchers. PRIMS also includes credits representing \$30.2 million dollars that are not recorded as credit vouchers.
Sequenced records missing	Invoice Item Activity	Multiple invoices in PRIMS lack associated sequenced rebate records. The Commission was not able to provide any explanation or documentation regarding the missing records. This indicates either that PRIMS does not consistently number activities or that activity records have been deleted.
Inability to reconcile outstanding rebate balance	Invoice Item Activity, Invoice Item	Auditors were not able to reconcile outstanding balances recorded in PRIMS with supporting transactions in PRIMS for 1996 through 2000 within a material difference. Outstanding balances in PRIMS reconciled only for invoices issued during 2001.
Reversal/ adjustment errors	Invoice Item Activity	PRIMS automatically creates reversal records that overwrite manual adjustment transactions created by staff. The staff's adjustment records are based on supporting data that are not recorded in PRIMS. This is inefficient and creates potentially inaccurate data. Staff has identified and corrected 8.6 percent of these errors.

## Summary of Management's Responses

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### **HHSC Management Response to the State Auditor's Office Audit Report on the Health and Human Services Commission's Prescription Drug Rebate Program**

*The State Auditor's Office (SAO) review of the Program has identified a number of concerns which the Health and Human Services Commission (HHSC) agrees to address. To address the primary concerns reflected in the audit report, we have been conducting an extensive review of our processes, procedures, and management controls to ensure that system integrity is improved and that amounts due to the state are accurately identified, properly tracked, and timely collected on an on-going basis.*

#### **Explanation of Management Response Summary**

The Commission provided a response document that included a summary and detailed responses to individual recommendations. The Commission's detailed responses that originally followed this summary are now located in each chapter and section after the specific recommendations they address.

*The SAO findings fall into three general areas: calculation of outstanding rebate balances owed HHSC by pharmaceutical manufacturers; business process inefficiencies in the Program; and the weaknesses in performance measurement. Following are key findings and a summary of HHSC's management response in each instance.*

*SAO concluded that HHSC is unable to determine outstanding rebate balances because of unreliable and incomplete data.*

**Management Response:** *HHSC is in the process of identifying and dedicating the resources required to ensure that all relevant data and edits are included in our Pharmacy Rebate Information Management System (PRIMS) and that the system is cost-effective and provides the information needed to efficiently manage the Program.*

*SAO concluded that inefficient business processes in the Program result in delays and backlogs of potential rebate amounts due.*

**Management Response:** *HHSC will proceed with the entry of pre-PRIMS payment data into PRIMIS and revisions to the Program procedures manual for the resolution of disputed rebate amounts to include appropriate controls and to clarify staff authority to perform functions appropriate to their level. HHSC also is taking steps to put in place additional internal controls designed to further reduce errors in data entry and to minimize the Program's vulnerability to fraud and abuse.*

*SAO concluded that the Program has no performance metrics for assessing performance of the program.*

**Management Response:** *HHSC has created a Prescription Drug Rebate Program Oversight Committee that includes senior managers in the areas of information resources, accounting, and audit. The Oversight Committee will review existing*

*employee and program level performance measures to determine their adequacy, assess Program performance in relation to those measures and its implementation of continuous quality improvement in Program business processes, and otherwise advise HHSC Senior Management in its decision-making related to the Program.*

*In summary, HHSC already has begun addressing many of the issues identified in this report. The others will be addressed swiftly and comprehensively, but systematically as we continue the implementation of an aggressive action plan. That plan will ensure accuracy, accountability, management oversight, and fiscal due diligence in our Prescription Drug Rebate Program and in the process, will respond to the audit findings.*

*The following are the HHSC detailed management responses to the recommendations included in the SAO's draft audit report on The Health and Human Services Commission's Prescription Drug Rebate Program. When action is planned to address an issue in a recommendation, the HHSC action plan, along with the expected completion dates and the title of the individual responsible for implementing corrective action, is included as part of the response. HHSC will monitor staff's progress toward completing the plans outlined below.*

*To assist in resolving the issues identified in this report, HHSC will create a Rebates Billing and Collection Oversight Committee with a core membership that includes the Director of Medicaid/CHIP Program Operations, the HHSC Information Resources Management (IRM) Director, the HHSC Director of Accounting Operations, and the Medicaid/CHIP Audit Director. Other members may be added in the future if the Oversight Committee determines that additional membership would enhance its oversight ability. The Oversight Committee will assume a role of regularly reviewing progress on the implementation of the action plans detailed in the management responses, reviewing proposed process improvements, assisting in the development of meaningful performance and reporting criteria, and reviewing the impact and cost-effectiveness of implemented improvements. The Oversight Committee will periodically report to the Associate Commissioner for Medicaid and CHIP and the Deputy Commissioner for Health Services on the performance of the rebates billing and collection function.*

Copies of this report have been distributed to the following:

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The Honorable Tom Craddick, Speaker of the House, Chair  
The Honorable David Dewhurst, Lieutenant Governor, Vice Chair  
The Honorable Teel Bivins, Senate Finance Committee  
The Honorable Bill Ratliff, Senate State Affairs Committee  
The Honorable Talmadge Heflin, House Appropriations Committee  
The Honorable Ron Wilson, House Ways and Means Committee

### **Office of the Governor**

The Honorable Rick Perry, Governor

### **Health and Human Services Commission**

Mr. Albert Hawkins, Commissioner



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