DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF AUDIT SERVICES
233 NORTH MICHIGAN AVENUE
CHICAGO, ILLINOIS 60601

REGION V
OFFICE OF
INSPECTOR GENERAL

November 24, 2003

Report Number: A-05-03-00043

John Hamilton, Secretary
Indiana Family and Social Services Administration
402 West Washington Street
Indianapolis, Indiana 46207-7083

Dear Mr. Hamilton:

Enclosed are two copies of the Department of Health and Human Services, Office of Inspector General (OIG) final report entitled, "Review of Medicaid Drug Rebates Program - State of Indiana." This audit was conducted as part of a nationwide review of Medicaid drug rebate collections in various states. A copy of the report will be forwarded to the action official noted on page 2 for her review and any action deemed necessary.

Final determination as to actions taken on all matters reported will be made by the HHS action official named on page 2. We request that you respond to the HHS action official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

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Should you have any questions or comments concerning the matters contained in this report, please do not hesitate to contact Ross Anderson, Audit Manager, at (312) 353-8663 or through e-mail at RANDERSON@OIG.HHS.GOV. To facilitate identification, please refer to report number A-05-03-00043 in all correspondence.

Sincerely yours,

Paul Swanson

Paul Swanson
Regional Inspector General
for Audit Services

Attachments – as stated

Direct Reply to HHS Action Official:

Cheryl Harris, Associate Regional Administrator
Division of Medicaid and Children's Health
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
233 North Michigan Avenue, Suite 600
Chicago, Illinois 60601-5519

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

REVIEW OF MEDICAID DRUG REBATE PROGRAM STATE OF INDIANA

INDIANA FAMILY AND SOCIAL SERVICES ADMINISTRATION INDIANAPOLIS, INDIANA

NOVEMBER 2003
A-05-03-00043

Office of Inspector General

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OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed as well as other conclusions and recommendations in this report represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the awarding agency will make final determination on these matters.

EXECUTIVE SUMMARY

OBJECTIVE

The audit objective was to evaluate whether the Indiana Family and Social Services Administration (Agency) had established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDINGS

Generally, the Agency had established policies and procedures over operations of the drug rebate program, as required by Federal rules and regulations. However, the controls in place to comply with program reporting requirements are inadequate. Specifically, the Agency could improve its controls and policies regarding the preparation of the Medicaid Drug Rebate Schedule (Form CMS 64.9R).

Although Federal regulations at 45 CFR 74.21 require that financial management systems provide for effective control over and accountability for all funds, property, and other assets, the Agency's controls for reporting rebate information were inadequate and allowed inaccurate information to be submitted to the Centers for Medicare & Medicaid Services (CMS) on Form CMS 64.9R. The Agency correctly reported drug rebate collection amounts on line 5 of Form CMS 64.9R, but other reported amounts either contained glaring mathematical errors or were inaccurate. The Agency did not verify or reconcile reported amounts to supporting records. As a result, the Agency did not have reasonable assurances that amounts on Form CMS 64.9R were accurate. Additionally, the Agency did not have controls to ensure all necessary unit and rate conversions were performed to accurately calculate the Medicaid drug rebate accounts receivable. Until the records held by the current contractor are adjusted to accurately reflect the billing and payment history, the Agency cannot be assured that all rebates have been collected.

RECOMMENDATIONS

We recommend that the Agency:

- Prepare and submit revised Forms CMS 64.9R that correct inaccurate and misstated amounts;

- Establish controls and implement oversight procedures for the Form CMS 64.9R report preparation process that includes verification of contractor prepared amounts and reconciliation of Agency rebate accounts receivable to the Contractor's supporting records; and

- Establish controls and implement oversight to ensure all necessary Medicaid drug rebate unit and rate conversions are performed to conform to Federal financial reporting standards.

AGENCY COMMENTS

In written comments to our draft report, the Agency agreed with our findings. The Agency will make a correcting adjustment to the CMS 64.9R for the quarter ending September 30,2003. The Agency has already implemented policies and procedures regarding the oversight and accuracy of the Form CMS 64.9R and the unit and rate conversions.

OFFICE OF INSPECTOR GENERAL RESPONSE

We agree with the corrective action taken, to date, to correct the Form CMS 64.9R balance and in response to the procedural recommendations.

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Glossary of Abbreviations and Acronyms

Agency	Indiana Family and Social Services Administration
CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
EDS	Electronic Data Systems
Form CMS 64.9R	Medicaid Drug Rebate Schedule
HHS	Department of Health and Human Services
OIG	Office of Inspector General
URA	Unit Rebate Amount

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990 legislation, which established the Medicaid drug rebate program. Responsibility for the rebate program is shared among the drug manufacturers, the Centers for Medicare & Medicaid Services (CMS), and the States. The legislation was effective January 1, 1991. CMS also issued release memorandums to State agencies and manufacturers throughout the history of the rebate program to give guidance on numerous issues related to the Medicaid drug rebate program.

A drug manufacturer is required to have a rebate agreement in effect with CMS in order to have its products covered under the Medicaid program. After a rebate agreement is signed, the manufacturer is required to submit a listing to CMS of all covered outpatient drugs, and to report its average manufacturer price and best price information for each covered outpatient drug to CMS. Approximately 520 pharmaceutical companies participate in the program.

CMS approves the unit rebate amount (URA) for each drug based on pricing information and package size (units) supplied by the manufacturer. CMS provides the information to the State agency on a quarterly computer tape. However, the CMS tape may contain a $0 URA if the pricing information was not provided timely or if the pricing information has a 50 percent variance from the previous quarter. In instances of $0 URAs, the State agency is instructed to invoice the units and the manufacturer should pay the rebate based on the manufacturer's information. In addition, the manufacturers often change the URA based on updated pricing information and submit this information to the State agency in the Prior Quarter Adjustment Statement.

Each State agency is required to maintain drug utilization data for the number of units dispensed, by manufacturer, for each covered drug. State agencies use the URAs from CMS and the utilization data for each drug to determine the actual rebate amounts due from the manufacturer. When a State's utilization data contains units inconsistent with those used by CMS, the State must apply a conversion formula to attain an accurate rebate; otherwise, rebate requests may be inflated. CMS requires each State agency to provide drug utilization data to the manufacturer. Approximately 56,000 national drug codes are available under the program.

To avoid interest, the manufacturer must remit payment within 38 days of the invoice being sent. The manufacturers submit a Reconciliation of State Invoice to the State agency that details the current quarter's payment by national drug codes. A manufacturer can dispute utilization data that it believes is erroneous, but is required to pay the undisputed portion by the due date. If the manufacturer and the State agency cannot in good faith resolve the discrepancy, the manufacturer must provide written notification to the State agency by the due date. If the State agency and the manufacturer are not able to resolve the discrepancy within 60 days, the State agency must make a hearing mechanism available under the Medicaid program. The manufacturer is required to calculate and remit interest for any late payments or disputed rebates when settlement is made. Tracking interest owed to the State agency is required by CMS.

On a quarterly basis, each State agency reports outpatient drug expenditures and rebate collections on the Medicaid Drug Rebate Schedule (Form CMS 64.9R). This schedule is part of the Form CMS 64 report, which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse the Federal share of these expenditures. During the 1-year period ending June 30,2002, the Agency reported an average collection of $30.3 million per quarter. As a result of problems associated with preparing Form CMS 64.9R, average quarterly billings and an outstanding balance are unavailable (details provided in the FINDINGS and RECOMMENDATION section of this report).

For our review period, the Indiana Family and Social Services Administration (Agency) contracted with EDS (founded as Electronic Data Systems) to administer the operations of the drug rebate program. Agency staff prepares Form CMS 64.9R. Beginning January 1, 2003, the Agency contracted with Affiliated Computer Services to administer the operations of the drug rebate program.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The audit objective was to evaluate whether the Agency had established adequate accountability and internal controls over the Medicaid drug rebate program.

Scope

The drug rebate program was effective January 1, 1991. We concentrated our review on the current policies, procedures, and controls of the Agency, but also reviewed accounts receivable information related to prior periods and considered how the Medicaid drug rebate program has operated since 1991.

Methodology

To accomplish our objectives, we interviewed Agency, EDS, and Affiliated Computer Services representatives and staff members, that performed functions related to the drug rebate program, to determine the policies, procedures, and controls that existed with regard to the Medicaid drug rebate program. In addition, we obtained and reviewed drug rebate accounts receivable records and compared this data to Form CMS 64.9R for June 30,2002. The Affiliated Computer Services' contract was not fully operational at the time of our review. Therefore, we were unable to perform detail testing on the most recent Form CMS 64.9R.

Fieldwork was performed at the Agency office and our field offices in Springfield, Illinois and Madison, Wisconsin, during the months of April through July 2003.

Our audit was performed in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

Generally, the Agency had established policies and procedures over operations of the drug rebate program, as required by Federal rules and regulations. However, inadequate controls have been established to comply with program reporting requirements. Specifically, the Agency could improve its controls and accountability over Medicaid drug rebates by improving its policies regarding the preparation of Form CMS 64.9R.

Differences exist between rebate accounts receivable data held by the Agency and its previous and current contractor. Since neither the Agency nor its prior drug rebate contractor performed the necessary unit and rate conversions to accurately calculate the drug rebate invoiced amount, we were unable to determine an average amount for Agency reported billings. There were also numerous inconsistencies between the reported drug rebate records and the invoicing records. Therefore we were unable to quantify an outstanding rebate balance. Until records held by the current contractor are adjusted to accurately reflect the billing and payment history, the Agency cannot be assured that all rebates have been collected.

Form CMS 64.9R Preparation

The Agency did not prepare and submit accurate Forms CMS 64.9R. Although the Agency correctly reported drug rebate collection amounts on line 5 of Form CMS 64.9R, other reported amounts either contained mathematical errors or were inaccurate. Form CMS 64.9R was prepared by the Agency based on information provided by the drug rebate contractor. The Agency did not verify the accuracy of amounts reported on Form CMS 64.9R or reconcile reported amounts to supporting records. As a result, the Agency did not have reasonable assurances that Form CMS 64.9R was accurate. Additionally, the Agency did not have controls to ensure all necessary unit and rate conversions were performed to accurately calculate the Medicaid drug rebate accounts receivable.

Although Title 45 CFR 74.21 (b)(3) requires that financial management systems provide for effective control over and accountability for all funds, property, and other assets, the Agency reported amounts on Form CMS 64.9R that were often materially misstated and unreliable. We noted:

- The Agency overstated current quarter billings by $318,230,000 for the quarter ended June 30,2002 because it did not discover and correct an Agency typographical error while inputting data on Form CMS 64.9R. The Agency incorrectly reported $35,353,424 as $353,583,424.

- The Agency did not detect incorrect summary amounts prepared from supporting records which resulted in inaccurate outstanding rebate receivables being reported on Form CMS 64.9R for the quarter ended June 30,2002. The Agency reported a negative outstanding drug rebate balance of $19,475,171, while the supporting records indicate a positive

receivable balance of $43,990,599, a discrepancy of $63,465,770. For the quarter ended March 31,2003, the Agency reported an outstanding total drug rebate balance of negative $388,547,159, but the supporting records indicate the total receivable balance was a negative $6,851,389 or an unresolved reporting discrepancy of $381,695,770. The Agency does not have adequate controls to reconcile Form CMS 64.9R amounts to supporting records.

- The Agency lacks adequate procedures and oversight of unit and rate conversions of billing information to prepare an accurate Form CMS 64.9R. One national drug code has been billed to the labeler based on a microgram unit of measure, while the rebate program URA is based on a vial unit of measure. A vial contains 4,800 micrograms. Thus, application of the URA requires a formula conversion of micrograms to vials before invoicing the labeler. Otherwise, rebates will be inflated for invoicing and overstated for reporting. Due to the lack of controls, the Agency reported invoiced amounts of $701,028,490 for the quarter ended December 31,2000 that included approximately $668,000,000 in unconverted billings related to one national drug code. Similarly, for the quarter ended September 30, 2001, the same national drug code contributed approximately $662,000,000 towards inaccurately reported invoice amounts of $698,908,342. By comparison, properly converted billing information in this time frame indicates total billings should be in the range of $30 million to $40 million per quarter.

These inaccuracies occurred because the Agency did not establish adequate controls and oversight of the Form CMS 64.9R reporting process. The Agency did not have procedures to detect and correct errors, to reconcile Form CMS 64.9R amounts to supporting records, or monitor the process of converting billing information in accordance with the Medicaid drug rebate URAs standards. Until controls and oversight procedures have been implemented, the Agency cannot be assured that all rebates have been collected.

RECOMMENDATIONS

We recommend that the Agency:

- Prepare and submit revised Forms CMS 64.9R that correct inaccurate and misstated amounts;

- Establish controls and implement oversight procedures for the Form CMS 64.9R report preparation process that includes verification of contractor prepared amounts and reconciliation of Agency rebate accounts receivable to the Contractor's supporting records; and

- Establish controls and implement oversight to ensure all necessary Medicaid drug rebate unit and rate conversions are performed to conform to Federal financial reporting standards.

AGENCY COMMENTS

In written comments to our draft report, the Agency agreed with our findings. The Agency will make a correcting adjustment to the CMS 64.9R for the quarter ending September 30,2003. The Agency has already implemented policies and procedures regarding the oversight and accuracy of the Form CMS 64.9R and the unit and rate conversions.

OFFICE OF INSPECTOR GENERAL RESPONSE

We agree with the corrective action taken, to date, to correct the Form CMS 64.9R balance and in response to the procedural recommendations.

APPENDIX

"People helping people help themselves"

Joseph E. Kernan, Governor
State of Indiana

Indiana Family and Social Services Administration
402 W. WASHINGTON STREET, P.O. BOX 7083
INDIANAPOLIS, IN 46207-7083

Cheryl Sullivan, Secretary

November 6, 2003

Mr. Paul Swanson
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Audit Services
233 North Michigan Avenue
Chicago, Illinois 60601

Dear Mr. Swanson:

This letter is in response to the draft audit report completed by the Office of Inspector General for the Department of Health and Human Services entitled "Review of Medicaid Drug Rebate Program - State of Indiana" (A-05-03-00043).

The Indiana Family and Social Services Administration (FSSA), in full agreement with the current rebate contractor, ACS State Healthcare (ACS), concurs with the findings of this report. To that end, the issues outlined in the draft will be individually addressed below.

Recommendation

Prepare and submit revised Forms 64.9r that correct inaccurate and misstated amounts.

Response

In response to this recommendation, FSSA will make a correcting adjustment to the CMS 64.9r for the quarter ending 9/30/03 submission. This adjustment will increase the rebate receivable (Line 6 of the CMS 64.9r) to the current electronic information reflected in the rebate system of ACS. These electronic records may be overstated as explained below, but this adjustment will allow for the most aggressive rebate collection under the constraints of the present data.

Prior to the 4Q2002 invoicing, unit conversions (correcting units where the billing unit of measure differs from the CMS unit of measure) would occur manually at the invoice level. This

was also true of other unit adjustments such as billing errors identified through the dispute resolution process. These modifications to the number of units invoiced (only negative modifications have been observed) were manually specified on the invoices per reconciliation (ROSI/PQAS) adjustments submitted by the manufacturers and thus applied on an aggregate level. These modifications were not applied electronically to the units on the individual claims or to the electronic invoices. As a result, historical *electronic* claims and invoice data that was transferred to the current rebates contractor, ACS, by the former rebates contractor, EDS, reflects only the initial claims data and not the manual adjustments. The adjustment made by FSSA to the 9/30/03 CMS 64.9r will bring both the rebate account receivable records of FSSA and ACS into alignment. The increasing adjustment of $369,070,018 will correct both the previous incorrect entries as well as adjust the outstanding rebate receivables to reflect the present records of the ACS rebate system. If through dispute resolution and collection efforts, ACS determines that the receivables have been overstated (due to the previous manual adjustments not recorded electronically within the rebate system), an adjustment can be made to the claim level data (where available) and reflected on the current quarter's CMS 64.9r. Any adjustment would be verifiable through hard copy information if present and labeler information. (It is the experience of ACS that labelers put forth an effort to correctly pay rebates to stay in good standing with CMS.) Each adjustment will have an audit trail to validate the decrease (or increase) to the rebate receivable balance.

Recommendation

Establish controls and implement oversight procedures for the Form CMS 64.9r report preparation process that includes verification of contractor prepared amounts and reconciliation of Agency rebate accounts receivable to the Contractor's supporting records.

Response

Errors in the historical calculation methodology for the CMS 64.9r have been identified through the OIG audit. The current rebates contractor, ACS, calculates the CMS 64.9r values through use of its rebate application. All values on the report are based on claims data and payment data, derived from the 11 digit NDC level. Each line on the CMS 64.9r can be substantiated through queries of the rebate database. The report is also subjected to a manual review for identification of potential outlier amounts (as, historically, has been a problem in the context of rebates involving the product [redacted]). Once the contractor has validated the CMS 64.9r, it is forwarded to the FSSA for use in preparation of the larger CMS 64 Report.

ACS generates the CMS 64.9r systematically from claims data and payment data. However, the FSSA may subsequently have reason to modify amounts listed on the ACS report to reflect adjustments particular to the FSSA and not to the rebate system. An example of such an adjustment would be due to errors that may have appeared on prior CMS 64.9r forms While

the CMS 64.9r records ("rebate ledger") of ACS would remain static and verifiable to the NDC level each quarter, global adjustments needed at the FSSA level should be noted and recorded by

both parties. In that way, any review of these reports would be irrefutable, able to be substantiated through the records of either party. We believe that enhanced communication between the FSSA and ACS as to the final values submitted on the CMS 64.9r will ensure the validity of same.

Recommendation

Establish controls and implement oversight to ensure all necessary Medicaid drug rebate unit and rate conversions are performed to conform to federal financial reporting standards.

Response

The rebate application used by ACS has the capability to perform unit conversions systematically with each quarterly claim load. Each unit conversion (due to differing units of measure between the billing system and CMS) is applied as the claims are loaded into the rebate system. Each claim unit amount is converted to an amount that corresponds with the CMS unit type. Each conversion results in a claim audit. The claim audit alerts the rebate application user to review the claims converted, prior to invoicing, to ensure the conversion was appropriate.

The list of current unit conversions is a compilation of all identified problematic NDCs by the application user community. As a user identifies a new conversion, the NDC is researched, the information is shared, and the unit conversion is added to the rebate application. The conversions can also be deleted as unit types in the billing system or on the CMS tape may change as well.

Conclusion

In conclusion, FSSA agrees with and appreciates the opportunity to comment on the draft audit report. The current rebate contractor, ACS, and FSSA have already implemented policies and procedures covering the rebate quarters of 4Q2002 forward to adhere to all the listed recommendations regarding the oversight and accuracy of the CMS 64.9r and the unit and rate conversions. The correcting adjustment made by FSSA to align receivable balances to electronic data of ACS will secure an aggressive collection of outstanding balances as well as assure the maximum rebate dollars are collected

If you have any questions regarding this response, please contact Mr. Marc Shirley, RPh, of Office of Medicaid Policy and Planning Staff (317 232-4343).

Sincerely,

Cheryl Sullivan
Secretary

CS:MS

cc: Marc Shirley, RPh--OMPP
Pat Nolting--OMPP
Jerry Dubberly, RPh--ACS

ACKNOWLEDGMENTS

This report was prepared under the direction of Paul Swanson (RIGA). Other principal Office of Audit Services staff who contributed include:

Ross Anderson, *Audit Manager*
William Pedersen, *Senior Auditor*
Donna Kern, *Senior Auditor*
Michael Carr, *Auditor*

For information or copies of this report, please contact the Office of Inspector General's Public Affairs office at (202) 619-1343.