



APR 04 2008

Region IX
Office of Audit Services
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

Report Number: A-09-07-00062

Mr. Douglas Porter
Assistant Secretary
Washington Department of Social and Health Services
Health and Recovery Services Administration
626 8th Avenue, SE.
Olympia, Washington 98504-5502

Dear Mr. Porter:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Follow-Up Audit of the Medicaid Drug Rebate Program in Washington State." We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this 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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If you have any questions or comments about this report, please do not hesitate to call me, or contact Alice Norwood, Audit Manager, at (415) 437-8360 or through e-mail at Alice.Norwood@oig.hhs.gov. Please refer to report number A-09-07-00062 in all correspondence.

Sincerely,

Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

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cc:

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Centers for Medicare & Medicaid Services
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Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FOLLOW-UP AUDIT OF THE
MEDICAID DRUG REBATE
PROGRAM IN
WASHINGTON STATE**



Daniel R. Levinson
Inspector General

April 2008
A-09-07-00062

Office of Inspector General

<http://oig.hhs.gov>

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Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, Office of Inspector General reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5).

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

BACKGROUND

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Social Security Act. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In Washington State, the Department of Social and Health Services (the State agency) administers the Medicaid drug rebate program.

In 2005, we issued a report on the results of audits of the Medicaid drug rebate programs in 49 States and the District of Columbia (A-06-03-00048). Those audits found that only four States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that States lacked adequate assurance that all of the drug rebates due to the States were properly recorded and collected. Additionally, CMS did not have reliable information from the States to properly monitor the drug rebate program.

In our previous audit of the Washington drug rebate program, we determined that the State agency had an adequate system to account for drug rebate activity that tracked receivables by National Drug Code (A-10-03-00007). However, the State agency had not established formal policies and procedures for the drug rebate program as required by Federal rules and regulations. We also identified internal control and accountability weaknesses in the State agency's informal procedures regarding (1) segregation of duties, (2) account adjustments and writeoffs, (3) the subsidiary ledger, (4) interest verification, and (5) dispute resolution. We recommended that the State agency establish (1) formal policies and procedures for its Medicaid drug rebate program and (2) internal controls to:

- provide for the proper segregation of duties between the rebate billing and collection functions;
- provide management oversight over adjustments and writeoffs;
- update subsidiary ledger accounts in a timely manner;
- calculate interest due, verify the accuracy of interest payments received, and accurately report interest received; and
- actively work to resolve manufacturer disputes and, when appropriate, use the State hearing mechanism to resolve longstanding disputes.

The State agency disagreed with the finding that duties were not properly segregated between the rebate billing and collection functions. However, the State agency generally concurred with the remaining findings and recommendations.

This current review of Washington is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses in accountability for and internal controls over their drug rebate programs found in the previous reviews. Additionally, because the Deficit Reduction Act of 2005 required States as of January 2006 to begin collecting rebates on single source drugs administered by physicians, this series of reviews will also determine whether States have complied with the new requirement.

OBJECTIVES

Our objectives were to determine whether the State agency had (1) implemented the recommendations made in our previous audit of the Washington drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF FINDINGS

Regarding the first objective, the State agency implemented the recommendations from our prior audit that related to establishing (1) formal policies and procedures for its drug rebate program and (2) internal controls for segregation of duties and updating of subsidiary ledger accounts. However, the State agency did not fully implement the recommendations related to management oversight over account adjustments and writeoffs, interest verification, and dispute resolution.

- **Account Adjustments and Writeoffs.** The State agency did not follow its policies and procedures for management oversight over account adjustments and writeoffs. A State agency official informed us that the only supporting documentation provided to management was the adjustment request form. As a result, the State agency could not be assured that all adjustments and writeoffs were supported.
- **Interest Verification.** The State agency did not have adequate controls to verify interest payments received on disputed, late, and unpaid rebate payments. When manufacturers paid interest, State agency officials recorded the interest payments without verifying their accuracy because the State agency did not accrue interest on disputed, late, and unpaid rebates. As a result, the State agency could not be assured that it had collected all of the interest due from manufacturers.
- **Dispute Resolution.** The State agency had not actively worked to resolve a portion of the longstanding disputes with manufacturers over drug rebate amounts and attributed the problem to limited resources. As a result, longstanding disputes continue to be unresolved.

Regarding the second objective, the State agency established controls over and accountability for collecting rebates on single source drugs administered by physicians.

RECOMMENDATIONS

We reiterate our recommendations that the State agency implement internal controls for management oversight over account adjustments and writeoffs, accrue interest to verify the accuracy of interest payments received, and actively work to resolve manufacturer disputes.

STATE AGENCY COMMENTS

In comments on the draft report (included in their entirety as the Appendix), the State agency described the status of actions taken on our recommendations.

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INTRODUCTION

BACKGROUND

Pursuant to Title XIX of the Social Security Act (the Act), the Medicaid program provides medical assistance to certain low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

Drug Rebate Program

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Act. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with CMS and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In Washington State, the Department of Social and Health Services (the State agency) is responsible for the drug rebate program.

Pursuant to section II of the rebate agreement and section 1927(b) of the Act, manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price. Based on this information, CMS calculates a unit rebate amount for each covered outpatient drug and provides the amounts to States quarterly.

Section 1927(b)(2)(A) of the Act requires States to maintain drug utilization data that identifies, by National Drug Code (NDC), the number of units of each covered outpatient drug for which the States reimbursed providers. The number of units is applied to the unit rebate amount to determine the actual rebate amount due from each manufacturer. Section 1927(b)(2) of the Act requires States to provide the drug utilization data to CMS and the manufacturer. States also report drug rebate accounts receivable data on Form CMS-64.9R. This is part of Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program," which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

Physician-Administered Drugs

Section 6002(a) of the Deficit Reduction Act of 2005 (DRA) amends section 1927 of the Act and requires States, as of January 1, 2006, to collect and submit utilization data for single source drugs administered by physicians so that States may obtain rebates for the drugs.¹ Single source drugs are commonly referred to as "brand name drugs" and do not have generic equivalents.

¹This provision of the DRA expands the requirements to certain multiple source drugs administered by physicians after January 1, 2008.

In Washington, physician-administered drugs are billed to the State Medicaid program on either a pharmacy or physician claim form.² The State agency collects rebates on both single source and multiple source drugs. Beginning May 1, 2006, the State agency required claim forms to include not only procedure codes that are part of the Healthcare Common Procedure Coding System but also the corresponding NDCs for all physician-administered drugs. Rebates are calculated and paid based on NDCs. The State agency contracted with a private company to compile invoice information for the rebate-eligible drug claims.

Prior Office of Inspector General Reports

In 2005, we issued a report on the results of audits of the Medicaid drug rebate programs in 49 States and the District of Columbia.³ Those audits found that only four States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that States lacked adequate assurance that all of the drug rebates due to the States were properly recorded and collected. Additionally, CMS did not have reliable information from the States to properly monitor the drug rebate program.

In our previous audit of the Washington drug rebate program, we determined that the State agency had an adequate system to account for drug rebate activity that tracked receivables by NDC.⁴ However, the State agency had not established formal policies and procedures for the drug rebate program as required by Federal rules and regulations. We also identified internal control and accountability weaknesses in the State agency's informal procedures regarding (1) segregation of duties, (2) account adjustments and writeoffs, (3) the subsidiary ledger, (4) interest verification, and (5) dispute resolution. We recommended that the State agency establish (1) formal policies and procedures for its Medicaid drug rebate program and (2) internal controls to:

- provide for the proper segregation of duties between the rebate billing and collection functions;
- provide management oversight over adjustments and writeoffs;
- update subsidiary ledger accounts in a timely manner;
- calculate interest due, verify the accuracy of interest payments received, and accurately report interest received; and
- actively work to resolve manufacturer disputes and, when appropriate, use the State hearing mechanism to resolve longstanding disputes.

²Drugs administered in a kidney center are billed using an outpatient pharmacy claim form. Drugs administered in facilities other than a kidney center are billed using a physician services claim form.

³"Multistate Review of Medicaid Drug Rebate Programs" (A-06-03-00048), issued July 6, 2005; Arizona was not included because it did not operate a drug rebate program.

⁴"Audit of the Medicaid Drug Rebate Program in Washington State" (A-10-03-00007), issued July 31, 2003.

The State agency disagreed with our finding that duties were not properly segregated between the rebate billing and collection functions. However, the State agency generally concurred with the remaining findings and recommendations.

Washington Drug Rebate Program

The State agency contracted with a private company, Affiliated Contract Services, to collect drug rebate claims and create and generate manufacturer's invoices.

The State agency reported an outstanding drug rebate balance of \$60,101,387 on the June 30, 2006, Form CMS-64.9R. However, \$29,502,777 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining \$30,598,610 that was past due, \$24,044,780 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately \$73.4 million and collections of approximately \$193.7 million.

This current review of the Washington drug rebate program is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses in accountability for and internal controls over their drug rebate programs found in the previous reviews. Additionally, because the DRA required States as of January 2006 to begin collecting rebates on single source drugs administered by physicians, this series of reviews will also determine whether States have complied with the new requirement.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to determine whether the State agency had (1) implemented the recommendations made in our previous audit of the Washington drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

Scope

We reviewed the State agency's current policies, procedures, and controls over the drug rebate program and the accounts receivable data reported on Form CMS-64.9R as of June 30, 2006.

We performed our fieldwork, which included visits to the State agency offices in Lacey and Olympia, Washington, from May through November 2007.

Methodology

To accomplish our objectives, we

- reviewed section 1927 of the Act, section 6002(a) of the DRA, CMS guidance issued to State Medicaid directors, and other information pertaining to the Medicaid drug rebate program;
- reviewed the State agency's policies and procedures related to the drug rebate accounts receivable system;
- interviewed State agency officials to determine the policies, procedures, and controls that related to the Medicaid drug rebate program;
- reviewed copies of Form CMS-64.9R for the period July 1, 2005, through June 30, 2006;
- interviewed State agency officials to determine whether our prior recommendations were implemented;
- interviewed State agency officials to determine the processes used in obtaining physician services claims data and collecting drug rebates related to single source drugs administered by physicians; and
- reviewed rebate billings and reimbursements for procedure codes related to single source drugs administered by physicians for the period January 1 through June 30, 2006.

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

FINDINGS AND RECOMMENDATIONS

Regarding the first objective, the State agency implemented the recommendations from our prior audit that related to establishing (1) formal policies and procedures for its drug rebate program and (2) internal controls for segregation of duties and updating of subsidiary ledger accounts. However, the State agency did not fully implement the recommendations related to management oversight over account adjustments and writeoffs, interest verification, and dispute resolution. Regarding the second objective, the State agency established controls over and accountability for collecting rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our prior audit of the Washington drug rebate program, we determined that the State agency had not established formal policies and procedures for the program. In addition, the State agency

had internal control and accountability weaknesses in the following areas: (1) segregation of duties, (2) account adjustments and writeoffs, (3) the subsidiary ledger, (4) interest verification, and (5) dispute resolution.

Since our prior audit, the State agency established formal policies and procedures for its drug rebate program and corrected its internal control and accountability weaknesses related to segregation of duties and the subsidiary ledger. However, the State agency still had weaknesses in the following areas: account adjustments and writeoffs, interest verification, and dispute resolution.

Federal Regulations

Pursuant to 42 CFR § 433.32(a), States are required to “[m]aintain an accounting system and supporting fiscal records to assure that claims for Federal funds are in accord with applicable Federal requirements.”

Account Adjustments and Writeoffs

The State agency did not follow its policies and procedures for management oversight over account adjustments and writeoffs. These policies and procedures require management review of supporting documentation and an office chief’s signature for adjustments and writeoffs that exceed the CMS-established threshold of \$10,000 per labeler code per quarter and \$1,000 per NDC per quarter. The signature indicates that management has reviewed the adjustment request and supporting documentation and agrees with the adjustment. However, a State agency official informed us that the only supporting documentation provided to management was the adjustment request form. As a result, the State agency could not be assured that all adjustments and writeoffs were supported.

Interest Verification

The State agency did not have adequate controls to verify interest payments received on disputed, late, and unpaid rebate payments. Section (V)(b) of the rebate agreement between CMS and manufacturers requires manufacturers to pay interest on late rebate payments, and CMS program release 29 requires interest to be collected.⁵ In addition, program release 65 to State Medicaid directors states that it is the manufacturer’s responsibility to calculate and pay interest for applicable rebate invoices and the State’s responsibility to track collections. When manufacturers paid interest, the State agency recorded the interest payments without verifying their accuracy because the State agency did not accrue interest on disputed, late, and unpaid rebates. As a result, the State agency could not be assured that it had collected all of the interest due from manufacturers.

The State agency is in the process of implementing drug rebate accounting system software that can invoice, bill, calculate, and track interest, as well as track accounts receivable and

⁵CMS has issued guidance to State Medicaid directors pertaining to the drug rebate program and posts the program releases on its Web site at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02_StateReleases.asp. Accessed December 17, 2007.

manufacturers' outstanding disputes. This system is scheduled to be in operation by December 2008.

Dispute Resolution

The State agency had not actively worked to resolve all of the longstanding disputes with manufacturers over drug rebate amounts. Section (V)(c) of the rebate agreement and CMS program release 105 require that the State and manufacturer use their best efforts to resolve utilization discrepancies within 60 days after receipt of notification to the State of the discrepancy. Since our prior audit, the State agency added a new policy to include use of the State hearing mechanism if all other avenues have been tried and failed. The State agency currently has a backlog of manufacturers willing to resolve disputed drug rebate amounts. However, a State agency official indicated that the State had not been able to work on its longstanding disputes because of limited resources. As a result, longstanding disputes continue to be unresolved.

As of May 2007, the State agency had an outstanding disputed rebate balance of approximately \$12.3 million dating through June 2006.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency established controls over collecting rebates for single source drugs administered by physicians as required by the DRA. The State agency paid \$3,883,786 in claims for physician-administered drugs from January through June 2006 and billed manufacturers for rebates totaling \$1,898,967.

RECOMMENDATIONS

We reiterate our recommendations that the State agency implement internal controls for management oversight over account adjustments and writeoffs, accrue interest to verify the accuracy of interest payments received, and actively work to resolve manufacturer disputes.

STATE AGENCY COMMENTS

In comments on the draft report (included in their entirety as the Appendix), the State agency described the status of actions taken on our recommendations:

- The State agency commented that it had amended its drug rebate manual for account adjustments and writeoffs to require that (1) drug rebate staff provide adequate supporting documentation to the cosignatory before requesting approval and (2) the office chief cosign the adjustment form and supporting documentation. The State agency provided additional information about the adjustment request process.
- The State agency commented that it was developing an accounts receivable system to bill, calculate, and process interest receivables and payments.

- The State agency provided details on how it would work to resolve longstanding disputes with manufacturers over drug rebate amounts.

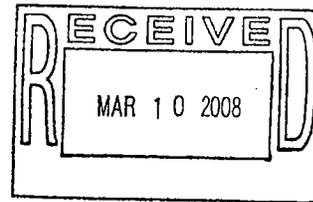
APPENDIX



STATE OF WASHINGTON
DEPARTMENT OF SOCIAL AND HEALTH SERVICES
P.O. Box 45502, Olympia, Washington 98504-5502

February 27, 2008

Lori A. Ahlstrand, Regional Inspector General
Region IX, Office of Audit Services
90 - 7th Street, Suite 3-650
San Francisco, California 94103



Dear Ms. Ahlstrand:

Enclosed is the Department of Social and Health Services response to your Draft report on the Follow-Up Audit of the Medicaid Drug Rebate Program in Washington State, (A-09-07-00062). These responses include the status of actions taken on your recommendations.

The final audit report, which contains the findings and responses, is an official public document and will be filed once you receive our responses. I am requesting that you notify my office when the report becomes public so we may prepare for any media coverage.

If you have any questions, or would like to discuss the responses or any new information being presented, please contact Louis McDermott at (360) 725-1973 or Don Mercer at (360) 664-5500.

Sincerely,

A handwritten signature in cursive script, appearing to read "Douglas Porter".

Douglas Porter, Assistant Secretary
Health & Recovery Services Administration

Enclosure

cc: Stan Marshburn, Chief Financial Officer
Susan Lucas, Director
Don Mercer, Financial Recovery Chief
Louis McDermott, Rates Development Chief
Mariann Schols, Accounting Services Chief
Edd Giger, OFR Fiscal Manager

Washington State Department of Social and Health Services
Report Number A-09-07-00062

WRITTEN COMMENTS ON THE OIG DRAFT REPORT
“FOLLOW-UP AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN
WASHINGTON STATE”

Finding #1: Account Adjustments and Writeoffs

“The State Agency did not follow its policies and procedures over adjustments and writeoffs. A State agency official informed us that the only supporting documentation provided to management was the adjustment request form. As a result, the State agency could not be assured that all writeoffs were supported.”

The department would like the report to reflect that in several instances, written documentation was prepared although it was not reviewed as required. DSHS would also like to clarify that though adjustments are loosely termed “write-offs” the items at issue in this finding were actually adjustments of quantities, not “write-offs”. DSHS is in the process of establishing a “write-off” threshold for disputes but until now, has rarely written off any debt.

DSHS Action taken: February 14, 2008, DSHS amended the language in the HRSA Drug Rebate desk manual as follows:

- When completing the OFR adjustment form, and this adjustment is not supported by claim adjustments through the POS, and the adjustment is *BOTH* over \$10,000.00 per labeler code per quarter, *AND* over \$1,000.00 per NDC per quarter, the drug rebate Office Chief must co-sign the adjustment form and the supporting documentation. The Office Chief’s signature indicates (s) he has reviewed the adjustment request and the supporting documentation and agrees with the unit adjustment(s).
- Drug Rebate staff must ensure that adequate documentation to support the adjustment is available to the co-signatory before requesting their signature; and that this documentation is maintained in the manufacturers’ file.
- Place an electronic copy of the adjustment and the supporting documentation in the folder at \\dshs\fsa\FSASHARES\OFRMAA\To OFR. OFR will not process any adjustment above this threshold where the supporting documentation is missing. Send the hard copy co-signed adjustment and supporting documentation to OFR at MS 45862.
- OFR staff will then process the adjustment request and provide adequate documentation to the OFR Fiscal Manager for signature, per OFR Signature Authority Policy, before sending back the completed and signed adjustment form and documentation to HRSA staff.
- The OFR Fiscal Manager will review the adjustment form and documentation provided by OFR fiscal staff before signing the adjustment form, to ensure the policy and procedures were followed.

Washington State Department of Social and Health Services
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Finding #2: Interest Verification

"The State agency did not have adequate controls to verify interest payments received on disputed, late, and unpaid rebate payments. When manufacturers paid interest, State agency officials recorded the interest payments without verifying their accuracy because the State agency did not accrue interest on disputed, late, and unpaid rebates. As a result, the State agency could not be assured that it had collected all of the interest due from manufacturers."

The department is in development of an accounts receivable system that will bill, calculate, and process interest receivables and payments. This system, the ProviderOne Drug Rebate Sub-system, is currently scheduled to be implemented and begin operation in December 2008. We would like the report to reflect this implementation date, instead of the date reflected in the report, which is February 2008.

Finding #3: Dispute Resolution

"The State Agency had not actively worked to resolve a portion of the longstanding disputes with manufacturers over drug rebate amounts and attributed the problem to limited resources. As a result, longstanding disputes continue to be unresolved." However, since the prior audit, the State Agency has added a new policy to include the use of the State hearing mechanism if all other avenues have been tried and failed. As of May 2007, the State agency had an outstanding disputed rebate balance of approximately \$12.3 million dating through June 30, 2006.

DSHS Actions Taken:

- HRSA has hired two drug rebate staff, one for invoicing, and the other for dispute resolution activities.
- Process improvements are underway to commit to paper the processes staff must take to review data for dispute resolution. The steps in dispute resolution will be documented using Visio to delineate clearly each step in the process and detailed directions for discovering claim discrepancies will be documented. Both of these process improvements will make training staff in dispute resolution much easier and will assist with eliminating the backlog of disputes.
- Staff is also doing a time study of dispute resolution activities to assess staffing needs and to assess their ability to adequately resolve disputes. This time study will allow us to elucidate the man hours required to keep current with the dispute resolution process so that there is no addition to the backlog. Hopefully, this time study will allow the department to establish a "write off" threshold where continuing dispute resolution activities are not cost effective to pursue. This threshold can then be applied to all current and past disputes, which will assist with decreasing the backlog. If the cost in man hours of collecting, researching, and reviewing claim level detail is more than the disputed amount, then the 'write off' threshold would be applied. The time study will also allow the department to

Washington State Department of Social and Health Services
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project the length of time, given the current staffing, it will take these staff to do their part of the dispute resolution process (collecting, researching, and reviewing claim level detail and contacting the manufacturer with our findings).

- The department's goal for 2008 is to resolve all 2007 disputes by the end of the year. This will in part be accomplished through better understanding of dispute resolution processes via the Visio and other documents created in the process improvement activities.