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December 21, 2009

Report Number: A-01-09-00001

Ms. Brenda Harvey
Commissioner
Maine Department of Health and Human Services
221 State Street
Station Number 11
Augusta, Maine 04333

Dear Ms. Harvey:

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 Maine." 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 Curtis Roy, Audit Manager, at (617) 565-9281 or through e-mail at Curtis.Roy@oig.hhs.gov. Please refer to report number A-01-09-00001 in all correspondence.

Sincerely,

/Michael J. Armstrong/
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Jackie Garner, Consortium Administrator
Consortium for Medicaid and Children's Health Operations
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Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

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



Daniel R. Levinson
Inspector General

December 2009
A-01-09-00001

Office of Inspector General

<http://oig.hhs.gov>

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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 Maine, the Department of Health and Human 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 Maine drug rebate program (A-01-03-00007), we determined that the State agency's controls were generally in place to record and track the collection of drug rebates. However, the State agency had not established adequate procedures to ensure that it (1) adjusted its quarterly Form CMS-64.9R to reflect invoiced rebates and accounting adjustments, resulting in an inaccurate credit balance of \$98 million on the June 30, 2002, Form CMS-64.9R; (2) followed-up all disputed rebate amounts with the manufacturer in a timely manner, and (3) properly assessed all interest on unpaid or late drug rebate amounts. We recommended that the State agency establish procedures to (1) provide accurate pending rebate amounts and properly present drug rebate receivables in its quarterly reports to CMS, (2) resolve disputed items in a timely manner in accordance with CMS guidelines, and (3) collect interest on any disputed or unpaid drug rebate amounts and on any late payments.

The State agency agreed with our findings and recommendations.

This current review of Maine is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses found in the previous reviews in accountability for and internal controls over their drug rebate programs. 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 Maine drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF FINDING

The State agency had not implemented the recommendations from our prior audit. Specifically, the State agency had not established procedures to provide accurate pending rebate amounts and properly report drug rebate receivables in its quarterly report. In addition, although the State agency had developed policies for resolving disputed items, the State agency had not implemented these policies. The State agency also did not have a system to calculate and track the amount of interest owed on unpaid drug rebates.

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

RECOMMENDATIONS

We reiterate our recommendations that the State agency establish policies and procedures to:

- provide accurate pending rebate amounts and properly report drug rebate receivables in its quarterly report,
- resolve disputed items, and
- collect interest on any disputed or unpaid drug rebate amounts as well as any late payments.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency agreed in part with our first and second findings and recommendations and agreed with our third finding and recommendation.

The State agency stated that it had revised its drug rebate reporting procedures and implemented a reconciliation process to ensure compliance with the drug rebate reporting requirements beginning with the quarter ending June 30, 2008. The State agency said that a timing-related difference between the drug rebate system and the deposit function was responsible for the ongoing variations between the rebate receipts reported on the State agency's CMS 64.9R and the source documentation that we reviewed. Furthermore, although the State agency acknowledged that it was unable to provide sufficient dispute resolution documentation for all drug manufacturers, the State agency maintained that it had developed and implemented policies regarding dispute resolution.

The State agency noted that it was implementing a new claim system in March 2010 that it anticipates will be able to resolve these outstanding issues.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

We continue to recommend that the State agency provide accurate pending rebate amounts and properly report drug rebate receivables in its quarterly report. The State agency's revisions did not include the establishment of procedures to ensure that pending rebate amounts and drug rebate receivables are always properly presented in its quarterly reports to CMS.

We also continue to recommend that the State agency resolve disputed items. The State agency's inability to provide documentation supporting the resolution of all disputed items indicates that the State agency has not fully implemented its dispute resolution policies.

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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 Maine, the Department of Health and Human 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 identify, 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 form 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 Maine, physician-administered drugs are billed to the State Medicaid program on a physician claim form. The State agency uses the Form CMS-1500 as the physician claim form. The physician claim form uses the procedure codes that are part of the Healthcare Common Procedure Coding (HCPC) system instead of the NDC. The HCPC procedure code identifies a drug by its active ingredient(s) and identifies the number of drug units (billing units) allowed per reimbursement for that procedure code. Rebates are calculated and paid based on NDCs. In addition, the billing units for a procedure code may differ from the units used for rebate purposes (e.g., grams versus liters). Therefore, to determine rebates, procedure codes must be converted to NDCs for single source drugs, and procedure code billing units must be converted into equivalent NDC billing units.

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.² 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 Maine drug rebate program (A-01-03-00007), we determined that the State agency's controls were generally in place to record and track the collection of drug rebates. However, the State agency had not established adequate procedures to ensure that it (1) adjusted its quarterly Form CMS-64.9R to reflect invoiced rebates and accounting adjustments, resulting in an inaccurate credit balance of \$98 million on the June 30, 2002, Form CMS-64.9R; (2) followed-up all disputed rebate amounts with the manufacturer in a timely manner, and (3) properly assessed all interest on unpaid or late drug rebate amounts. We recommended that the State agency establish procedures to (1) provide accurate pending rebate amounts and properly present drug rebate receivables in its quarterly reports to CMS, (2) resolve disputed items in a timely manner in accordance with CMS guidelines, and (3) collect interest on any disputed or unpaid drug rebate amounts and on any late payments.

The State agency agreed with our findings and recommendations.

Maine Drug Rebate Program

Since 1996, the State agency has contracted with its fiscal agent, Goold Health Systems, to assist the State agency in managing the drug rebate program. The fiscal agent's responsibilities include maintaining the State's point of purchase systems, which track the drug rebate transactions, and providing the quarterly invoices both electronically and in hardcopies for the State agency to mail to manufacturers. The fiscal agent also converts the procedure code billing units into equivalent NDC billing units. The State agency performs all other functions related to the drug rebate program.

²“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.

For the fiscal year ending June 30, 2006, the State agency reported rebate billings of approximately \$98.7 million and collections of approximately \$112.6 million on its Forms CMS-64.9R.

This current review of the Maine drug rebate program is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses found in the previous reviews in accountability for and internal controls over their drug rebate programs. 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 Maine 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 that it reported on Form CMS-64.9R as of June 30, 2006.

We conducted our fieldwork at the State agency in Augusta, Maine, from February through July 2009.

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 policies and procedures related to the State agency's drug rebate accounts receivable system;
- reviewed the previous Office of Inspector General audit report on the drug rebate program in Maine;
- 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;
- reviewed supporting documentation for rebates invoiced, adjustments, and rebates collected for the four quarters that ended June 30, 2006 (July 1, 2005, through June 30, 2006); and
- reviewed fiscal agent documentation to determine the processes used in converting physician services claims data into drug rebate data related to single source drugs administered by physicians.

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

The State agency had not implemented the recommendations from our prior audit. Specifically, the State agency had not established procedures to provide accurate pending rebate amounts and properly report drug rebate receivables in its quarterly report. In addition, although the State agency had developed policies for resolving disputed items, it had not implemented these policies. The State agency also did not have a system to calculate and track the amount of interest owed on unpaid drug rebates.

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

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our prior audit of the Maine drug rebate program, we determined that the State agency had not established adequate procedures to ensure that it (1) adjusted its quarterly Form CMS-64.9R to reflect invoiced rebate adjustments or other accounting adjustments, resulting in an inaccurate credit balance of \$98 million on the June 30, 2002, Form CMS-64.9R; (2) followed-up all disputed rebate amounts with the manufacturer in a timely manner; and (3) properly assessed all interest on unpaid or late drug rebate amounts.

Reporting of Drug Rebates

Section 2500.7B of the CMS State Medicaid Manual requires States to “maintain in a formal system of records, in readily reviewable form, supporting documentation that provides detailed information on pending drug rebates at the beginning of the quarter, the amounts of drug rebates computed for each labeler, amounts written off, other adjustments made, amounts collected and remaining pending drug rebate at the end of the quarter. This information must be made available to Federal reviewers upon request”.

Our current review found that the State agency did not always include all of the categories of the drug rebate transactions on the Form CMS-64.9R summary submitted to CMS. Specifically, the State agency excluded the supplemental rebate agreement on the Form CMS-64.9R report for the quarters ending 9/30/2005, 3/31/2006, and 6/30/2006. In addition, the rebate receipts reported on the Form CMS-64.9R cost report for all four quarters of FY 2006 varied materially from the source documentation that the State agency provided. For example, for the quarter ending 6/30/2006, the State agency reported total receipts of \$28,713,599, whereas the source documentation provided by the State agency showed receipts totaling \$30,605,542, a variance of \$1,891,943.

As a result, we do not have reasonable assurance that the State agency's CMS-64.9R provided CMS with an accurate measure of (1) the rebate amounts that the State agency needed to collect and (2) the likelihood that these rebates would be collected.

Disputed Items

Section V(c) of the National Drug Rebate Agreement states: "The State and manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the manufacturer the State hearing mechanism available under the Medicaid Program." In addition, Section 2500.7D of the State Medicaid manual instructs the State to file page 2 of the CMS-64.9R form to explain significant problems in resolving disputed items that are over 12 months old.

Our current review found that the State agency had not implemented policies for resolving disputed items. Specifically, we reviewed three manufacturers' drug rebate accounts that had been outstanding for more than 1 year to determine what resolution process the State agency had used to resolve the outstanding accounts. The State agency was unable to provide any resolution documentation for one manufacturer and provided insufficient documentation for the remaining two manufacturers.

As a result, we do not have reasonable assurance that the State agency's CMS-64.9R provided CMS with accurate information regarding disputed items that were over 12 months old.

Interest Due for Late Drug Rebate Payments

Section V(b) of the National Drug Rebate Agreement mandates that drug manufacturers pay interest on any disputed or unpaid drug rebate amounts as well as on any late payments. The State must collect interest and may not disregard it as part of the dispute resolution process.

Our current review found that the State agency's new claim management system did not calculate interest due from manufacturers. As a result, the State agency did not know how much interest was due from the manufacturers and continued to rely on the manufacturers to calculate interest on unpaid balances and late payments.

As a result, we do not have reasonable assurance that the State agency properly collected all interest due on unpaid balances and late payments and offset this interest from Federal Medicaid reimbursement.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

During our audit period, the State agency did not claim rebates on single source drugs administered by physicians, as the DRA requires. However, in 2008 the State agency subsequently established controls over collecting rebates on single source drugs administered by physicians, as the DRA requires.

RECOMMENDATIONS

We reiterate our recommendations that the State agency establish policies and procedures to:

- provide accurate pending rebate amounts and properly report drug rebate receivables in its quarterly report,
- resolve disputed items, and
- collect interest on any disputed or unpaid drug rebate amounts as well as any late payments.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency agreed in part with our first and second findings and recommendations and agreed with our third finding and recommendation. Specifically:

- The State agency stated that it had revised its drug rebate reporting procedures and implemented a reconciliation process to ensure compliance with the drug rebate reporting requirements beginning with the quarter ending June 30, 2008. The State agency said that a timing-related difference between the drug rebate system and the deposit function was responsible for the ongoing variations between the rebate receipts reported on the State agency's CMS 64.9R and the source documentation that we reviewed. The State agency noted that it has requested that its new claim system, which will be implemented in March 2010, be able to resolve this problem.
- Although the State agency agreed that it was unable to provide sufficient dispute resolution documentation for all drug manufacturers, the State agency maintained that it had both developed and implemented policies that it actively used to resolve disputed items. However, the State agency acknowledged that the current drug rebate system had significant limitations, including difficulties documenting dispute resolution activity greater than 12 months old. The State agency noted that its new claim processing system, scheduled for release in March 2010, will include a fully functioning drug rebate subsystem that will be able to accurately report disputed items over 12 months old.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

We continue to recommend that the State agency provide accurate pending rebate amounts and properly report drug rebate receivables in its quarterly report. Although the State agency may have revised its drug rebate reporting procedures, these revisions did not include the establishment of procedures to ensure that pending rebate amounts and drug rebate receivables are always properly presented in its quarterly reports to CMS.

We also continue to recommend that the State agency resolve disputed items. The State agency's inability to provide documentation supporting the resolution of all disputed items indicates that the State agency has not fully implemented its dispute resolution policies. We therefore encourage the State agency to ensure that its new claim processing system will be able to resolve this ongoing problem.

APPENDIX



Department of Health
and Human Services

Maine People Living
Safe, Healthy and Productive Lives

John E. Baldacci, Governor

Brenda M. Harvey, Commissioner

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November 9, 2009

Mr. Michael J. Armstrong
Regional Inspector General for Audit Services
Office of Audit Services, Region 1
John F. Kennedy Federal Building
Boston, MA 02203

Re: *Follow-Up Audit of the Medicaid Drug Rebate Program in Maine* – Report Number A-01-09-00001

Dear Mr. Armstrong:

The State appreciates the opportunity to respond to the above mentioned draft audit report. We offer the following comments in relation to the recommendations on Pages 4-6 of this report.

Below we list each finding followed by our response. For some findings we have included a corrective action plan as the resolution will occur when Maine transitions to its new claims processing system in the second quarter of Federal Fiscal Year 2010. We believe that with the changes we have made and with our new system we will come into compliance with the requirements.

Reporting of Drug Rebates.

Maine did not provide reasonable assurance that the State agency's CMS-64.9R provided CMS with an accurate measure of the rebate amounts that the State agency needed to collect and the likelihood that these rebates would be collected.

Response:

Beginning in Federal Fiscal Year 2008, Quarter 3 (QE 6/30/08), the State addressed the issues identified in this audit finding. The State revised the CMS-64.9R reporting procedures and implemented a reconciliation process to ensure compliance with the drug rebate reporting requirements.

As noted in the finding, "the State agency excluded the supplemental rebate agreement on the Form CMS-64.9R report for the quarters ending 9/30/2005, 3/31/2006, and 6/30/2006." The Department's finance group, which is responsible for preparing the CMS-64.9R, has worked with key personnel in the drug rebate group to ensure that on-going communication between the two groups is adequate for proper identification and reporting of drug rebates. On-going communication between the two groups is a key control in ensuring that appropriate drug rebate information is accurately and completely presented on the CMS-64.9R report.

In response to the finding that, "...the rebate receipts reported on the Form CMS-64.9R cost report for all four quarters of FY 2006 varies materially from the source documentation that the State agency provided."

This finding is a result of a timing-related difference between the drug rebate system and the deposit function. The particular timing issue is that the drug rebate group receives rebate checks and updates the drug rebate system. Subsequently, they forward the rebate checks to the deposit group, who then process the collections (effectively posting them to the State's Accounting System). The period between when the drug rebate group post the collections in the drug rebate system and the point in which the collections are actually posted in the accounting system results in the variance identified in this finding. Essentially, most checks received by the drug rebate group in the last few days of a quarter, do not get posted in the accounting system until the following quarter. To address this issue, the drug rebate group provides the check detail maintained in the drug rebate system to the Department's finance group. The reconciliation between the data in the drug rebate system and the accounting system is a key control to ensure that the variance is due to timing. This variance is clearly identifiable on the CMS-64.9R back-up support provided quarterly to CMS.

The State has identified the need to be able to eliminate this on-going timing difference and has requested a solution in the new claims system. The timing issue noted above is currently being reviewed by UNISYS.

Disputed Items.

Maine did not provide reasonable assurance the the State agency's CMS-64.9R provided CMS with accurate information regarding disputed items that were over twelve months old.

Response:

We partially agree with the OIG audit findings concerning this topic. While we agree that we were unable to provide sufficient dispute resolution documentation for the three labelers identified, we do not agree that we "had developed policies regarding the resolution of disputed items... [but] had not implemented these policies."

Due to significant limitations of the current drug rebate system (such as lack of call tracking, reminder/recall features and front-end reporting), the ability of rebate staff to provide evidence of randomly selected dispute activity is likewise significantly impaired. Because the current database was not intended as a permanent solution, disputed items greater than 12 months old have proven to be particularly challenging.

Having said that, we have both developed and implemented policies that we actively use to resolve disputes including protocols for providing outstanding balance and claim level detail reports, resolving conversion issues, and corresponding with labelers via phone, fax and e-mail. We will continue with this dispute resolution approach in Maine until we implement our new CMS-certified MMIS in March 2010. The new MMIS will have a fully functioning drug rebate subsystem, including the ability to accurately report disputed items over 12 months old on the CMS-64.9R.

Interest Due for Late Drug Rebate Payments.

Maine did not provide reasonable assurance that the State agency properly collected all interest due on unpaid balances and late payments and offset this interest from Federal Medicaid reimbursement.

Response:

While the present drug rebate system is unable to calculate interest, a new vendor has been selected that will provide complete functionality with respect to this finding. The new vendor has described how this function will work when the new rebate system is implemented in March 2010, as follows:

Interest will be calculated based upon the outstanding dollar amount for a particular line item. The calculation then takes into account each labeler payment activity starting with the earliest, to determine if interest was due at the time of payment. If interest was due, the process then computes interest up to the payment date. Calculation of outstanding balance then occurs. This process is repeated until there are no more labeler payment activities for that invoice line item. It should be noted that all interest calculations are based upon a 365-day year (no leap year calculations) and that calculations will round up to the nearest cent.

We appreciate the time spent in Maine by OIG staff reviewing Maine's drug rebate processes. We believe this effort will enable us to perform this function more accurately in the future.

Sincerely,



Brenda M. Harvey
Commissioner

BMH/klv

cc: Russell Begin, Deputy Commissioner, Finance
Tony Marple, Director, Office of MaineCare Services