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January 6, 2009

Report Number: A-01-07-00003

Mr. Michael P. Starkowski  
Commissioner  
Department of Social Services  
25 Sigourney Street  
Hartford, Connecticut 06106

Dear Mr. Starkowski:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Review of Medicaid Outpatient Drug Expenditures in Connecticut for the Period October 1, 2003, Through September 30, 2005." 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](mailto:Curtis.Roy@oig.hhs.gov). Please refer to report number A-01-07-00003 in all correspondence.

Sincerely,

A handwritten signature in cursive script that reads "Michael J. Armstrong".

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  
Centers for Medicare & Medicaid Services  
233 North Michigan Avenue, Suite 600  
Chicago, Illinois 60601

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**REVIEW OF MEDICAID  
OUTPATIENT DRUG  
EXPENDITURES IN  
CONNECTICUT FOR THE PERIOD  
OCTOBER 1, 2003, THROUGH  
SEPTEMBER 30, 2005**



Daniel R. Levinson  
Inspector General

January 2009  
A-01-07-00003

# ***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**

Pursuant to Title XIX of the Social Security Act, the Medicaid program provides medical assistance to 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. In Connecticut, the Department of Social Services (the State agency) administers the Medicaid program.

In addition to providing mandatory Medicaid services, States may offer certain optional services, such as outpatient prescription drugs, to eligible Medicaid beneficiaries. Most States, including Connecticut, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program. The program generally pays for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. Under the drug rebate program, CMS provides the States with a quarterly Medicaid drug tape, which lists all covered outpatient drugs and indicates a drug's termination date, if applicable. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement. The Medicaid drug rebate program does not cover drugs dispensed after the termination date listed on the quarterly drug tape.

In Connecticut, the State agency claims Medicaid expenditures on the "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program." CMS reimburses the State agency based on the Federal medical assistance percentage for the claimed Medicaid outpatient drug expenditures. The State agency claimed \$944.8 million (\$481.9 million Federal share) for reimbursement of Medicaid outpatient drug expenditures during fiscal years (FY) 2004 and 2005.

### **OBJECTIVE**

Our objective was to determine whether the State agency's claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2004 and 2005 complied with Federal requirements.

### **SUMMARY OF FINDINGS**

The State agency's claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2004 and 2005 did not always comply with Federal requirements. The State agency claimed \$122,165 (\$61,732 Federal share) for terminated drug products that were not eligible for Medicaid coverage because the drugs were dispensed after the termination dates listed on the quarterly Medicaid drug tapes. The State agency also claimed \$18,479,683 (\$9,401,911 Federal share) for drug products that were not listed on the quarterly drug tapes. Because the State agency did not verify with CMS whether these drugs were covered by manufacturers' rebate

agreements with CMS, these drug expenditures may not have been allowable for Medicaid reimbursement. For the remainder of the \$944.8 million (\$481.9 million Federal share) claimed, we identified no other errors with respect to whether the drugs were either terminated or included on the CMS quarterly drug tapes.

The State agency had inadequate controls to ensure that all of its claims for outpatient drug expenditures complied with Federal requirements.

## **RECOMMENDATIONS**

We recommend that the State agency:

- refund \$61,732 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage,
- work with CMS to resolve \$9,401,911 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage, and
- strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements by:
  - reporting expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes and
  - verifying with CMS whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notifying CMS when drugs are missing from the tapes.

## **DEPARTMENT OF SOCIAL SERVICES COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, the State agency agreed with our first recommendation but disagreed, in part, with our other two recommendations. The State agency concluded that the issues that our review identified could only be resolved by more accurate and complete reporting on the drug rebate tapes, stronger enforcement of rebate provisions between CMS and drug manufacturers, and improved communications between CMS and the States.

We continue to recommend that the State agency work with CMS to resolve the \$9.4 million in payments for drugs that were not listed on the quarterly drug tapes and thus may not have been eligible for Medicaid coverage. We also continue to recommend that the State agency strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements.

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

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# INTRODUCTION

## BACKGROUND

### Medicaid Program

Pursuant to Title XIX of the Social Security Act (the Act), the Medicaid program provides medical assistance to 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. In Connecticut, the Department of Social Services (the State agency) administers the Medicaid program.

State Medicaid programs must provide certain medical services, including inpatient and outpatient hospital, physician, and family planning services. States also may offer certain optional services, such as outpatient prescription drugs, as long as the services are included in their approved State plans.

### Medicaid Outpatient Prescription Drug Program

All States offer outpatient prescription drugs to eligible Medicaid beneficiaries. Most States, including Connecticut, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program.<sup>1</sup> The program generally pays for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. The rebate agreements require manufacturers to provide a list of all covered outpatient drugs to CMS quarterly. CMS includes these drugs on a quarterly Medicaid drug tape, makes adjustments for any errors, and sends the tape to the States. The tape indicates a drug's termination date,<sup>2</sup> if applicable; specifies whether the drug is less than effective;<sup>3</sup> and includes information that the States use to claim rebates from drug manufacturers. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement and to calculate the rebates that the manufacturers owe. The drug rebate program does not cover drugs dispensed after the termination date listed on the quarterly drug tape.

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<sup>1</sup>The Omnibus Budget Reconciliation Act of 1990 established the Medicaid drug rebate program effective January 1, 1991. The program is set forth in section 1927 of the Act. Arizona is the only State that does not participate in the program.

<sup>2</sup>The termination date, which the manufacturer submits to CMS, reflects the shelf-life expiration date of the last batch sold for a particular drug code. However, if the drug is pulled from the market for health or safety reasons, the termination date is the date that the drug is removed from the market.

<sup>3</sup>The Food and Drug Administration determines whether drugs are less than effective. Such drugs lack substantial evidence of effectiveness for all conditions of use prescribed, recommended, or suggested in their labeling.

## **Reimbursement of Medicaid Expenditures**

In Connecticut, the State agency claims Medicaid expenditures on Form CMS-64, “Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program” (CMS-64). CMS reimburses the State agency based on the Federal medical assistance percentage (reimbursement rate) for the majority of claimed Medicaid expenditures, including outpatient drug expenditures.

For Federal fiscal years (FY) 2004 and 2005, Connecticut’s Federal reimbursement rate for Medicaid expenditures varied from 50.00 percent to 52.95 percent.

## **OBJECTIVE, SCOPE, AND METHODOLOGY**

### **Objective**

Our objective was to determine whether the State agency’s claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2004 and 2005 complied with Federal requirements.

### **Scope**

The audit scope included \$944.8 million (\$481.9 million Federal share) in Medicaid outpatient drug expenditures that the State agency claimed for FYs 2004 and 2005. We limited our testing of these expenditures to determining compliance with specific Federal requirements related to whether the drugs were eligible for Medicaid coverage and were accurately claimed for Federal reimbursement.

We limited our internal control review to the State agency’s procedures for determining whether the outpatient drugs were eligible for Medicaid coverage and were accurately claimed for Federal reimbursement. We did not review the accuracy or completeness of the quarterly Medicaid drug tapes.

We conducted fieldwork at the State agency’s offices in Hartford, Connecticut, from July 2007 through August 2008.

### **Methodology**

To accomplish our objective, we reviewed applicable Federal laws, regulations, and program guidance. We interviewed State agency officials responsible for identifying and monitoring drug expenditures and rebate amounts. We also interviewed staff responsible for reporting drug expenditures to CMS.

We used the CMS quarterly drug tapes for the period October 1, 1999, through June 30, 2006. We reconciled the amounts that the State agency reported on its CMS-64s to a detailed list of the State agency’s outpatient drug expenditures. We also used the detailed list of drug expenditures to determine whether the expenditures complied with Federal requirements. Specifically, we determined whether the drugs for which the State agency claimed reimbursement were dispensed

after the termination dates listed on the quarterly drug tape. To account for reasonable delays in processing data for terminated drugs, we used the first day of the quarter after the State received the tape as the termination date if the termination dates were provided to the State retroactively.

We also determined whether the drugs claimed for reimbursement were listed on the applicable quarterly drug tape. If the drugs were not listed on the tape, we determined if the State agency had verified whether the drugs were eligible for Medicaid coverage.

We calculated the Federal share of the expenditures using the reimbursement rate (50.00 percent to 52.95 percent) applicable for each quarter. We did not reduce the questioned drug expenditures by the rebate amounts that the State received.

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 objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

## **FINDINGS AND RECOMMENDATIONS**

The State agency's claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2004 and 2005 did not always comply with Federal requirements. The State agency claimed \$122,165 (\$61,732 Federal share) for terminated drug products that were not eligible for Medicaid coverage because the drugs were dispensed after the termination dates listed on the quarterly Medicaid drug tapes. The State agency also claimed \$18,479,683 (\$9,401,911 Federal share) for drug products that were not listed on the quarterly drug tapes. Because the State agency did not verify with CMS whether these drugs were covered by manufacturers' rebate agreements with CMS, these drug expenditures may not have been allowable for Medicaid reimbursement. For the remainder of the \$944.8 million (\$481.9 million Federal share) claimed, we identified no other errors with respect to whether the drugs were either terminated or included on the CMS quarterly drug tapes.

The State agency had inadequate controls to ensure that all of its claims for outpatient drug expenditures complied with Federal requirements.

### **CLAIMS FOR TERMINATED DRUGS**

Pursuant to 21 CFR § 211.137, each drug must have an expiration date to ensure that the drug meets certain standards, including strength and quality, at the time of its use. The expiration date effectively establishes a shelf life for the product. The termination date equals the expiration date of the last batch sold, except in cases when the product is pulled from the market. In those cases, the termination date may be earlier than the expiration date.

According to the CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 19, the States "must . . . assure that claims submitted by pharmacists are not for drugs

dispensed after the termination date. These should be rejected as invalid since these drugs cannot be dispensed after this date.”

The CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 130, states that “. . . the CMS [quarterly drug tape] is the one to use for ALL data when you are dealing with the drug rebate program . . . .” The quarterly drug tapes list the Medicaid-covered drugs’ termination dates as reported by the drug manufacturers.

For FYs 2004 and 2005, the State agency claimed \$122,165 (\$61,732 Federal share) in expenditures for drugs that, according to the State’s records, were dispensed after the termination dates shown on the quarterly drug tapes. For example, the State agency paid for the drug Nystatin, which was dispensed on December 31, 2003. However, the drug’s termination date was March 5, 2003, according to the tapes beginning with the quarter that ended March 31, 2002. The claimed expenditure was unallowable because it occurred after the drug’s termination date, which was listed on the quarterly drug tape at the time the State agency made the expenditures.

### **CLAIMS FOR DRUGS NOT LISTED ON QUARTERLY DRUG TAPES**

Section 1927(a)(1) of the Act generally conditions Medicaid reimbursement for covered outpatient drugs on a requirement that manufacturers of those products enter into rebate agreements with CMS under which they pay rebates to the States.<sup>4</sup> The rebate agreements require manufacturers to provide a list of all covered outpatient drugs to CMS quarterly. CMS includes these drugs on the quarterly drug tapes and makes adjustments for any errors.

Section 1927(k)(4) of the Act provides that covered outpatient drugs shall also include drugs that may be sold without a prescription (“over-the-counter” drugs), if these drugs are approved by the State plan and prescribed by a physician.

According to the CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 130: “. . . the CMS [quarterly drug tape] is the one to use for ALL data when you are dealing with the drug rebate program . . . . If [a drug code] that is not on the last CMS [quarterly drug tape] you received is billed to you by a pharmacy, . . . check with CMS to assure that the [drug code] is valid . . . .” Furthermore, the CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 44, provides that “States must check the [quarterly drug tape] to ensure the continued presence of a drug product . . . .”

The CMS “Medicaid Drug Rebate Operational Training Guide,” page S13, states: “If you have paid for [a drug code] that is NOT on [the quarterly drug tape] you should have checked to make sure it was correct. If you paid a pharmacy for utilization on an invalid [drug code], you may have to . . . recoup your funds.”

For FYs 2004 and 2005, the State agency claimed \$18,479,683 (\$9,404,911 Federal share) in expenditures for drug products that were not listed on the quarterly drug tapes. The majority of

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<sup>4</sup>Pursuant to Section 1927(a)(3) of the Act, a State may exempt single source or innovator multiple source drugs from the requirement to be covered by a drug rebate agreement if the State has determined that availability of the drug is essential to the health of Medicaid beneficiaries and if certain other conditions are met.

these expenditures (\$14.6 million) were for “over the counter” drugs that were generally covered under the State plan. For example, the State claimed approximately \$3 million for the nutritional supplement Ensure. However, Ensure was not listed on the CMS drug tape, which would have confirmed the existence of a national rebate agreement. The State agency did not contact CMS to determine that drugs not on the quarterly drug tapes were covered by manufacturers’ rebate agreements with CMS. As a result, the State agency did not have conclusive evidence that these payments were allowable Medicaid expenditures.

### **INADEQUATE CONTROLS TO DETECT UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES**

The State agency did not have adequate controls to ensure that all Medicaid drug expenditures complied with Federal requirements or to detect unallowable and potentially unallowable claims for reimbursement. The State agency did not check the quarterly drug tapes to ensure that the drugs were eligible for Medicaid coverage.

### **REIMBURSEMENT OF UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES**

The State agency claimed Federal reimbursement for certain drugs that were not eligible for Medicaid coverage because they were terminated. As a result, for FYs 2004 and 2005, the State agency claimed unallowable expenditures totaling \$122,165 (\$61,732 Federal share) for these drugs. The State agency also claimed Federal reimbursement for drug products that were not listed on the quarterly drug tapes. For these drugs, we set aside potentially unallowable expenditures totaling \$18,479,683 (\$9,404,911 Federal share) for CMS adjudication because the State agency did not verify with CMS whether the drugs were covered by Medicaid.

### **RECOMMENDATIONS**

We recommend that the State agency:

- refund \$61,732 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage,
- work with CMS to resolve \$9,401,911 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage, and
- strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements by:
  - reporting expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes and
  - verifying with CMS whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notifying CMS when drugs are missing from the tapes.

## **DEPARTMENT OF SOCIAL SERVICES COMMENTS**

In written comments on our draft report, the State agency agreed with our first recommendation but disagreed, in part, with our other two recommendations. Specifically:

- In response to our second recommendation, the State agency said that it had assumed that a Federal match, totaling \$7.3 million, would be available for drug expenditures for over-the-counter drugs because these drugs were covered in its CMS-approved State plan. The State agency maintained that its claim for the remaining \$2.1 million in drug expenditures was appropriate because it was for drugs for which the State agency had received rebates.
- In response to our third recommendation, the State agency said that it maintained sufficient controls to ensure that claimed Medicaid drug expenditures complied with Federal requirements. However, the State agency also stated that it would review and revise internal reporting requirements to address the appropriate reporting to CMS of covered over-the-counter drugs.

The State agency concluded that the issues that our review identified could only be resolved by more accurate and complete reporting on the drug rebate tapes, stronger enforcement of rebate provisions between CMS and drug manufacturers, and improved communications between CMS and the States.

## **OFFICE OF INSPECTOR GENERAL RESPONSE**

We continue to recommend that the State agency work with CMS to resolve the \$9.4 million in payments for drugs, the majority of which were over-the-counter drugs, that were not listed on the quarterly drug tapes and thus may not have been eligible for Medicaid coverage. We recognize that section 1927(k)(4) of the Act treats over-the-counter drugs as covered outpatient drugs when prescribed by a physician and allowed by the State plan. However, for drugs that are not listed on the CMS quarterly tape, CMS still requires that State agencies contact CMS first to determine whether the drugs are eligible. Moreover, receiving drug rebates does not, by itself, indicate that the drugs are eligible for Federal Medicaid reimbursement.

We also continue to recommend that the State agency strengthen its internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements. Because the State agency did not have sufficient internal controls to ensure that it followed Medicaid guidance, CMS reimbursed the State agency \$61,732 for terminated drugs that were not eligible for Medicaid coverage.

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

# **APPENDIX**

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MICHAEL P. STARKOWSKI  
Commissioner

STATE OF CONNECTICUT  
DEPARTMENT OF SOCIAL SERVICES  
OFFICE OF THE COMMISSIONER

November 4, 2008

Michael J. Armstrong  
Regional Inspector General for Audit Services  
U.S. Department of Health & Human Services  
John F. Kennedy Federal Building  
Boston, Mass. 02203

**Re: Report Number A-01-07-00003 "Review of Medicaid Outpatient Drug Expenditures in Connecticut for the Period October 1, 2003 through September 30, 2005"**

Dear Mr. Armstrong:

We have reviewed the above mentioned report and the recommendations made by your office. We appreciate the opportunity to review this draft report and provide you with a response. Our response to the draft audit report will address the findings and recommendations contained in the report and will briefly address issues that have a significant impact on the operational component of the drug rebate program.

**Recommendation:** Refund \$61,732 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage:

**Response:** The Department concurs with the recommendation. However, manufacturers provide the termination date to CMS and it is then included in the CMS quarterly rebate tape. Often, manufacturers are not timely in reporting this information to CMS and therefore, not provided to states in a timely manner. We suggest that CMS require manufacturers to report termination dates in a timely manner. CMS should hold manufacturers accountable for this reporting, otherwise, we will continue to reimburse for an NDC after the termination date.

**Recommendation:** Work with CMS to resolve \$9,401,911 in payments for drugs that were not listed on the quarterly tapes and that may not have been eligible for Medicaid coverage.

**Response:** In part, the Department concurs with the recommendation. \$7.3 million of these dollars were associated with covered over-the-counter drugs (OTCs). The Department has an approved state plan amendment to cover OTCs and assumed that a federal match would be available for these items. The Department did bucket these drugs inappropriately in their reporting to CMS and will take action to correct and allocate appropriately as state only drug expenditures. The Department feels that the remaining \$2.1 million were appropriately reported/claimed expenditures for legend drugs that we did receive rebate. This again, relates to the receipt of the quarterly rebate tape from CMS in reporting current labeler participation in a timely fashion.

**Recommendation:** Strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements by:

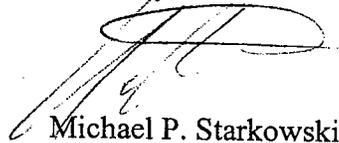
- Reporting expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes, and
- Verifying with CMS whether drugs not listed on the quarterly tapes are covered under the Medicaid program and notifying CMS when drugs are missing from the tape.

**Response:** The Department believes that they maintain sufficient controls to ensure claimed Medicaid drug expenditures comply with Federal requirements. The Department will review and revise internal reporting requirements to address the appropriate bucketing and reporting to CMS of covered over-the-counter drugs going forward.

Overall, the Department believes that resolution of the issues that resulted in the audit findings can be facilitated by: improved accuracy and completeness of data provided by CMS on quarterly rebate tapes; improved enforcement of provisions of the rebate agreement between CMS and the drug manufacturers; better-defined communication protocols between CMS and the states to ensure timely response to any problems that may rise, etc. Additionally, the Department feels that it is not good practice for CMS to provide quarterly rebate tapes as a source of information to be used for real time pharmacy claims process; as states receive in most instances weekly updates from their drug data services for claims processing purposes. In many instances a new NDC will come on the market after the quarterly CMS tape has been produced and prior to the next quarter. It is not practical to have states call and inquire about the coverage of a labeler when the drug has already been in the marketplace and the drug data service has received the labeler participation information. In addition, it is not appropriate to expect states to recoup a pharmacy claim after the prescription has left the pharmacy and has already been dispensed.

Many of these issues are national issues and CMS should be the party responsible for leading the rebate program to a successful resolution of these issues. The Department fully supports any efforts to resolve these issues for the future and again, appreciates the opportunity to comment.

Sincerely,



Michael P. Starkowski  
Commissioner

c: J. Wietrak J. McCormick  
D. Parrella M. Mains  
L. Voghel E. Dudley  
S. Dorval