JUL - 6 2005

TO: Dennis Smith, Director
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services

FROM: Joseph E. Vengrin
Deputy Inspector General for Audit Services

SUBJECT: Multistate Review of Medicaid Drug Rebate Programs
(A-06-03-00048)

The attached final report provides the results of our audits of Medicaid drug rebate programs in 49 States[1] and the District of Columbia. The Medicaid drug rebate program requires drug manufacturers to pay rebates to the States in exchange for Medicaid coverage of their drugs. The drug manufacturers, the Centers for Medicare & Medicaid Services (CMS), and the States share responsibility for the program.

Our objective was to determine whether States had established adequate accountability and internal controls over their Medicaid drug rebate programs.

Audits in 49 States and the District of Columbia found that only 4 States had no weaknesses in accountability and internal controls over their drug rebate programs. For the remaining 45 States and the District of Columbia, we identified weaknesses. Federal regulations (45 CFR § 74.21(b)(3))[2] require that financial management systems provide for effective control over and accountability for all funds, property, and other assets.

Although accountability had improved since our 1993 report, improvements were needed in most States in the areas listed below:

- unreliable information submitted to CMS on the Medicaid Drug Rebate Schedule (Form CMS 64.9R) (37 States),
- improper accounting for interest on late rebate payments (27 States),
- an inadequate rebate collection system (17 States),
- an inadequate dispute resolution and collection process (15 States), and
- other significant problems (13 States).

[1] Arizona does not operate a drug rebate program.

[2] Subsequent to our audit, the financial management system requirements were transferred under 45 CFR § 92.20(b)(3).

These weaknesses occurred primarily because the States did not have adequate policies, procedures, and controls over their drug rebate programs. Some States did not have adequate staff resources and/or sufficiently detailed collection systems to monitor drug rebate collections. In addition, we believe that frequently changing unit rebate amounts, as well as $0 unit rebate amounts that CMS transmitted to the States, added to the States' administrative burden and contributed to the inaccuracy of the rebate collection systems.

As a result, States lacked adequate assurance that all drug rebates due the States were properly recorded and/or collected. Additionally, CMS did not have reliable information to properly monitor the drug rebate program.

We recommend that CMS (1) reemphasize the requirement that States submit accurate and reliable information on Form CMS 64.9R and (2) emphasize to States their need to place a priority on their billing and collecting of drug rebates. CMS agreed with our recommendations.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please contact me, or have your staff contact George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through e-mail at george.reeb@oig.hhs.gov. Please refer to report number A-06-03-00048 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MULTISTATE REVIEW OF MEDICAID DRUG REBATE PROGRAMS

Daniel R. Levinson
Inspector General

JULY 2005
A-06-03-00048

Office of Inspector General

http://oig.hhs.gov

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

EXECUTIVE SUMMARY

BACKGROUND

Drug Rebate Program

The Omnibus Budget Reconciliation Act of 1990 established the Medicaid drug rebate program to allow Medicaid to receive pricing benefits commensurate with its position as a high-volume purchaser of prescription drugs. The drug manufacturers, the Centers for Medicare & Medicaid Services (CMS), and the States share responsibility for the program.

Previous Office of Inspector General Review of Medicaid Drug Rebate Program

In June 1993, the Office of Inspector General issued a report entitled "Review of Management Controls Over the Medicaid Prescription Drug Rebate Program" (A-06-92-00029). The review, conducted in eight randomly selected States, determined that CMS had not ensured that States had established proper accountability and controls over the billing and collection of drug rebates and drug rebate program funds. We also noted that CMS was unable to develop a nationwide total of the uncollected portion of Medicaid drug rebates because States were required to report only drug rebates collected. Subsequent to this review, CMS established a method designed to collect a nationwide total of the uncollected portion of Medicaid drug rebates.

OBJECTIVE

Our objective was to determine whether States had established adequate accountability and internal controls over their Medicaid drug rebate programs.

SUMMARY OF FINDINGS

Audits in 49 States and the District of Columbia[1] found that only 4 States had no weaknesses in accountability and internal controls over their drug rebate programs. For the remaining 45 States and the District of Columbia, we identified weaknesses. Federal regulations (45 CFR § 74.21(b)(3))[2] required that financial management systems provide for effective control over and accountability for all funds, property, and other assets.

Although accountability had improved since our 1993 report, improvements were needed in most States in the areas listed below. (See Appendix A for a summary of significant findings by State.)

[1]Arizona does not operate a drug rebate program. See Appendix B for a list of individual reports.

[2]Subsequent to our audit, the financial management systems requirements were transferred under 45 CFR § 92.20(b)(3).

- unreliable information submitted to CMS on the Medicaid Drug Rebate Schedule (Form CMS 64.9R) (37 States),

- improper accounting for interest on late rebate payments (27 States),

- an inadequate rebate collection system (17 States),

- an inadequate dispute resolution and collection process (15 States), and

- other significant problems (13 States).

These weaknesses occurred primarily because the States did not have adequate policies, procedures, and controls over their drug rebate programs. Some States did not have adequate staff resources and/or sufficiently detailed collection systems to monitor drug rebate collections. In addition, we believe that frequently changing unit rebate amounts, as well as $0 unit rebate amounts that CMS transmitted to the States, added to the States' administrative burden and contributed to the inaccuracy of the rebate collection systems.

As a result, States lacked adequate assurance that all drug rebates due the States were properly recorded and/or collected. Additionally, CMS did not have reliable information to properly monitor the drug rebate program.

RECOMMENDATIONS

We recommend that CMS:

- reemphasize the requirement that States submit accurate and reliable information on Form CMS 64.9R and

- emphasize to States their need to place a priority on their billing and collecting of drug rebates.

CMS agreed with our recommendations.

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INTRODUCTION

BACKGROUND

Drug Rebate Program

The Omnibus Budget Reconciliation Act of 1990 established the Medicaid drug rebate program, which became effective January 1, 1991. The program requires drug manufacturers to pay rebates to the States in exchange for Medicaid coverage of their drugs. The drug manufacturers, the Centers for Medicare & Medicaid Services (CMS), and the States share responsibility for the program.

Section 1927 of the Social Security Act requires drug manufacturers to enter a rebate agreement with CMS to participate in the Medicaid program. After a rebate agreement is signed, the manufacturer must submit a listing to CMS of all covered outpatient drugs and report, on a quarterly basis, its average manufacturer price and best price for each drug.

Drug Rebate Invoicing Process

Drug manufacturers must provide pricing information to CMS each quarter. CMS uses the pricing data to compute a unit rebate amount for each drug and supplies this amount to the States. The States then create rebate invoices by multiplying the Medicaid drug utilization data (maintained by the States) and the unit rebate for each drug. These invoices are sent to the drug manufacturers. However, CMS data may contain a $0 unit rebate amount if the pricing information is not provided timely or has a 50-percent variance from the previous quarter. In this instance, CMS instructs States to include the utilization data on the invoice for the $0 unit rebate amounts and have the manufacturer pay a rebate based on the manufacturer's unit rebate amount information. The process is further complicated by the volume of drugs and participating manufacturers—approximately 56,000 National Drug Codes and approximately 550 drug manufacturers. In addition, manufacturers often change unit rebate amounts in accordance with updated pricing information and submit this information to the States. Some price changes have dated back to the start of the program in 1991. In late 2003, after the start of our reviews, CMS issued regulations specifying that manufacturers could go back no more than 12 quarters to change pricing information.

Manufacturer Disputes

Manufacturers have 38 days from the day a State sends an invoice to pay the rebate to avoid interest charges. The manufacturers submit rebate payments to the State, along with the Reconciliation of State Invoice (ROSI), CMS-304. If the manufacturer questions the State's utilization/rebate invoice, the manufacturer has two options: to pay the State for the disputed items and then work with the State to resolve the dispute, or to pay the State for all units not in dispute and withhold payment for the disputed units. The manufacturer must submit the ROSI and documentation to the State to uniformly explain the adjusted rebate payment of dispute. After the State receives the ROSI, the State and the manufacturer should participate in an informal dispute resolution process. Both States and manufacturers may request assistance from

CMS Dispute Resolution Program (DRP) staff. If no resolution is reached, the State should make its hearing mechanism available to the manufacturer.

Dispute Resolution Program

In 1994, CMS began a pilot initiative with staff from the Boston Regional Office to assist manufacturers and States in resolving disputes. Based on the success of that pilot experience, CMS expanded the effort nationwide to other regions assisting with dispute resolution. Since 1996, national DRP meetings have been held both in Denver, CO, and in Baltimore, MD.

The voluntary meetings are usually held semiannually and give States and manufacturers the opportunity to meet face to face to resolve outstanding rebate disputes. Both States and manufacturers describe the DRP as a mutually beneficial process.

Previous Office of Inspector General Review

In June 1993, the Office of Inspector General issued a report entitled "Review of Management Controls Over the Medicaid Prescription Drug Rebate Program" (A-06-92-00029). The review, conducted in eight randomly selected States, determined that CMS had not ensured that States had established proper accountability and controls over the billing and collection of drug rebates and drug rebate program funds. We also noted that CMS was unable to develop a nationwide total of the uncollected portion of Medicaid drug rebates because States were required to report only drug rebates collected.

In our report, we recommended that CMS ensure that States implement accounting and internal control systems. We also recommended that CMS include a State reporting mechanism that would capture consistent and reliable drug rebate information for the amounts billed, collected, or written off and the amount that remained uncollected and/or in dispute. CMS agreed with our recommendations and subsequently implemented a requirement for States to report, on a quarterly basis, drug rebate information, including rebate billings, collections, adjustments, and the uncollected balance, on the Medicaid Drug Rebate Schedule (Form CMS 64.9R). Form CMS 64.9R is part of Form CMS 64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program. Drug rebate collections are reported as an offset to Medicaid expenditures.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether States had established adequate accountability and internal controls over their Medicaid drug rebate programs.

Scope

We performed audit work in 48 States and the District of Columbia. We also reviewed Medicaid drug rebate information in each State as of June 30, 2002.

We did not perform reviews in Arizona or Texas. Arizona does not operate a drug rebate program. (Almost all Medicaid beneficiaries are in managed care plans.) In Texas, the State auditor issued a report on the rebate program in April 2003 that had a timeframe comparable to that used in the other States. We included the Texas auditor's findings in our overall assessment of common control weaknesses. (See Appendix A.)

Cumulatively, the 49 States and the District of Columbia reported to CMS at least $4.2 billion in billings and $4.9 billion in collections during the 1-year period ended June 30, 2002.[3]

Methodology

We interviewed State agency officials to determine the policies, procedures, and controls that existed with regard to the Medicaid drug rebate program. In addition, we reviewed drug rebate accounts receivable records for each State and compared these data with the States' Forms CMS 64.9R for June 30, 2002.

We performed our audit in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

Although accountability had improved since our 1993 report, improvements were needed in most States. Only four States had no weaknesses in accountability and internal controls over their drug rebate programs. For the remaining 45 States and the District of Columbia, we identified the weaknesses listed below. See Appendix A for a summary of significant findings by State.

- unreliable information submitted to CMS on Form CMS 64.9R (37 States),
- improper accounting for interest on late rebate payments (27 States),
- an inadequate rebate collection system (17 States),
- an inadequate dispute resolution and collection process (15 States), and
- other significant problems (13 States).

As a result of the above weaknesses, States lacked adequate assurance that all drug rebates due to the States were properly recorded and/or collected. Additionally, CMS did not have reliable information to properly monitor the drug rebate program.

[3]Billing and collection information was not available from all States.

FEDERAL REQUIREMENTS

Federal regulations (45 CFR § 74.21(b)(3))[4] require that financial management systems provide for effective control over and accountability for all funds, property, and other assets.

CONTROL WEAKNESSES IDENTIFIED

We identified a variety of control weaknesses in our reports to the States. The examples below are the most common weaknesses. Thirty-three of the States had multiple weaknesses.

Unreliable Information Submitted on Form CMS 64.9R

In 74 percent of the reviews (37 States), we were unable to rely on the drug rebate information reported on the Form CMS 64.9R. The information was unreliable because the States:

- did not compare the information that was reported by the State on Form CMS 64.9R with their detailed records,
- did not perform a reconciliation between the general ledger and subsidiary ledgers,
- did not properly complete all parts of the Form CMS 64.9R, or
- did not maintain reliable or complete records.

To illustrate, two States (Colorado and New York) reported $0 balances, whereas seven other States (Alaska, Connecticut, Delaware, Indiana, Maine, Massachusetts, and New Hampshire) reported credit balances on Form CMS 64.9R for June 30, 2002. Credit balances and $0 balances are very unlikely because of the timeframes for filing Form CMS 64.9R. Manufacturer payments are not due until after the end of the quarter, so most of the payments are received in the following quarter. Therefore, States, at a minimum, should report nearly all of the current quarter's billings as a balance. A CMS official stated that there were no consequences for States' reporting inaccurate drug rebate information on Form CMS 64.9R. Without accurate information on Form CMS 64.9R, CMS cannot provide adequate oversight of drug rebate collections.

Improper Accounting for Interest on Late Rebate Payments

Twenty-seven States either did not verify that interest payments were accurate or did not properly accrue, bill, and/or track interest due for late rebate payments. The rebate agreement requires manufacturers to pay interest for late rebate payments, and CMS Program Release 29 requires that interest be collected and "may not be disregarded as part of the dispute resolution process by the State or manufacturer." These 27 States did not have adequate assurance that all interest was properly calculated and/or collected for late, unpaid, or disputed rebates.

[4]Subsequent to our audit, the financial management systems requirements were transferred under 45 CFR § 92.20(b)(3).

Inadequate Rebate Collection System

Seventeen States had weaknesses in their rebate collection systems that resulted in inaccurate and/or insufficiently detailed rebate collection information. Eleven of these States did not maintain a rebate general ledger control account. Other States did not make rate adjustments to the system, make billing and payment adjustments to the National Drug Codes level, or maintain records throughout the history of the rebate program. As a result, these States could not be assured that all drug rebate revenue was collected.

Inadequate Dispute Resolution and Collection Process

Fifteen States did not have adequate dispute resolution policies and procedures and/or adequate staff to resolve disputes. Seven of the States did not devote adequate staff to resolving disputes. Weaknesses in the other eight States included a lack of a formal system to monitor dispute resolution, inaccurate or incomplete records, and a lack of policies and procedures. As a result, these 15 States did not resolve disputes timely and efficiently. This weakness may also lead to a loss of rebate revenue.

Other Significant Problems

Other significant problems included:

- inadequate procedures to track $0 unit rebate amounts,
- improper writeoffs and adjustments, and
- inadequate segregation of duties.

Six States had inadequate procedures to track $0 unit rebate amounts. In instances of $0 unit rebate amounts, CMS instructs States to invoice the units and have the manufacturer pay the rebate based on the manufacturer's information. However, these States generally did not have procedures in place to track whether $0 unit rebate amounts were ever paid. As a result, there was no assurance that States collected all rebate revenue due from manufacturers.

Six States improperly made writeoffs of drug rebates. CMS Program Release 19 permits States to write off disputed amounts if these amounts are under $1,000 per drug per quarter up to a maximum of $10,000 per labeler per quarter. However, States may not arbitrarily write off or adjust rebate balances. For one State, an undetermined amount of writeoffs occurred during the transition to a new contractor in 1999. Another State made adjustments for the period 1991-97 for rebates that it deemed uncollectible. In addition, one State made adjustments for disputed or unpaid amounts to write off the balance when the manufacturer had paid at least 93 percent of the balance. As a result, there may have been additional drug rebates that should have been collected through the dispute resolution process.

Six States did not have a proper segregation of duties for billing and collection of drug rebates. The most common example was that the same staff member or members were responsible for

billing, collection, and adjustments to the drug rebate collection system. As a result, these States had an increased risk of fraud and abuse of drug rebates.

CAUSES OF CONTROL WEAKNESSES

The weaknesses identified in our State reviews occurred primarily because the States did not have adequate policies, procedures, and controls over the drug rebate program. Some States did not have adequate staff resources and/or sufficiently detailed collection systems to monitor drug rebate collections.

In addition, we believe that frequently changing unit rebate amounts, as well as $0 unit rebate amounts that CMS transmitted to the States, added to the administrative burden of States and contributed to the inaccuracy of rebate collection systems. However, we believe that the 12-quarter limit on prior-period adjustments to unit rebate amounts will eliminate a significant administrative burden on the States and help the States' efforts to improve accountability.

CONCLUSIONS

Our recent reviews showed improvement in the overall accountability in many States since our 1993 review. However, improvements are still needed in many States.

We believe that the corrective actions recommended in each of the State reports will provide States the opportunity to properly monitor their drug rebate programs (e.g., collection process). This monitoring may help increase drug rebate revenue and enable more reliable reporting of drug rebate information to CMS. We realize that many States may have to add staff resources and/or upgrade rebate collection systems in order to reduce the amount of uncollected drug rebates and improve their monitoring of the rebate collections.

We also believe that the Form CMS 64.9R can provide CMS with the information necessary to monitor and manage uncollected rebates. However, until the information reported on Form CMS 64.9R is accurate, CMS will not be able to provide adequate oversight.

CMS could further assist the States by reducing the number of $0 unit rebate amounts that are transmitted to the States. We are considering a review of $0 unit rebate amounts to identify the significance of and possible solutions to this problem.

RECOMMENDATIONS

We recommend that CMS:

- reemphasize the requirement that States submit accurate and reliable information on Form CMS 64.9R and

- emphasize to States their need to place a priority on their billing and collecting of drug rebates.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments to our draft report, CMS agreed with the recommendations. CMS also included some technical comments that we incorporated in the final report. The complete text of CMS's comments is included in Appendix C.

APPENDIXES

SIGNIFICANT FINDINGS BY STATE

Column 1 = Unreliable information submitted on CMS Form 64.9R
Column 2 = Improper accounting for interest on late rebate payments
Column 3 = Inadequate rebate collection system
Column 4 = Inadequate dispute resolution and collection process
Column 5 = Inadequate tracking of $0 unit rebate amounts
Column 6 = Inadequate controls over writeoffs and adjustments
Column 7 = Improper segregation of duties

	Columns						
State	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Alabama		X		X			
Alaska	X	X	X				X
Arkansas	X	X					
California	X		X	X			
Colorado	X				X	X	
Connecticut	X						
Delaware	X						
District of Columbia	X						
Florida	X	X		X			
Georgia	X					X	
Hawaii	X	X	X	X			
Idaho	X		X	X		X	X
Illinois[1]							
Indiana	X						
Iowa	X	X	X				
Kansas	X	X	X				
Kentucky	X						
Louisiana	X						
Maine	X	X		X			
Maryland[1]							
Massachusetts	X	X					
Michigan	X						
Minnesota[1]							
Mississippi		X					
Missouri	X	X					
Montana	X		X	X	X		
Nebraska	X	X	X				
Nevada		X	X	X			
New Hampshire	X	X					
New Jersey	X	X					
New Mexico	X	X	X	X			X
New York	X	X	X	X			
North Carolina[1]							
North Dakota					X		
Ohio		X					
Oklahoma	X		X				
Oregon	X	X	X				X
Pennsylvania	X	X	X	X			
Rhode Island	X			X			
South Carolina	X	X					
South Dakota	X	X			X	X	
Tennessee	X						
Texas		X	X	X		X	X
Utah	X	X	X		X		
Vermont		X					
Virginia[2]							
Washington		X		X		X	X
West Virginia	X			X			
Wisconsin	X	X					
Wyoming	X		X		X		
TOTAL	**37**	**27**	**17**	**15**	**6**	**6**	**6**

[1]No findings reported in Illinois, Maryland, Minnesota, or North Carolina.

[2]Virginia had only one minor issue in its report that we did not include in this review.

STATE REPORTS
(Available at http://oig.hhs.govT)

State	Report Number	Issue Date
Alabama	A-04-03-06005	July 30, 2003
Alaska	A-10-03-00006	July 23, 2003
Arkansas	A-06-03-00042	May 13, 2003
California	A-09-03-00038	December 23, 2003
Colorado	A-07-03-04018	October 28, 2003
Connecticut	A-01-03-00003	June 16, 2003
Delaware	A-03-03-00203	June 10, 2003
District of Columbia	A-03-03-00205	July 15, 2003
Florida	A-04-03-06016	August 29, 2003
Georgia	A-04-03-06010	August 29, 2003
Hawaii	A-04-03-06013	July 28, 2003
Idaho	A-10-03-00008	October 20, 2003
Illinois	A-05-03-00044	June 24, 2003
Indiana	A-05-03-00043	November 24, 2003
Iowa	A-07-03-04014	June 24, 2003
Kansas	A-07-03-04017	May 8, 2003
Kentucky	A-04-03-06006	July 22, 2003
Louisiana	A-06-03-00011	April 7, 2003
Maine	A-01-03-00007	September 19, 2003
Maryland	A-03-03-00204	May 8, 2003
Massachusetts	A-01-04-00005	August 12, 2004
Michigan	A-05-03-00047	September 19, 2003
Minnesota	A-05-03-00045	July 7, 2003
Mississippi	A-04-03-06015	July 21, 2003
Missouri	A-07-03-04011	May 6, 2003
Montana	A-07-03-04020	December 12, 2003
Nebraska	A-07-03-04013	July 16, 2003
Nevada	A-09-03-00033	August 15, 2003
New Hampshire	A-01-03-00013	January 22, 2004
New Jersey	A-02-03-01024	October 14, 2004
New Mexico	A-06-03-00012	April 30, 2003
New York	A-02-03-01009	August 18, 2004
North Carolina	A-04-03-06009	May 22, 2003
North Dakota	A-07-03-04019	October 28, 2003
Ohio	A-05-03-00042	September 22, 2003
Oklahoma	A-06-03-00044	July 14, 2003
Oregon	A-10-03-00005	June 27, 2003
Pennsylvania	A-03-03-00201	July 2, 2003
Rhode Island	A-01-03-00001	June 10, 2003
South Carolina	A-04-03-06011	August 29, 2003
South Dakota	A-07-03-04016	July 28, 2003
Tennessee	A-04-03-06012	September 2, 2003
Texas[1]	03-029	April 2003
Utah	A-07-03-04012	June 9, 2003
Vermont	A-01-03-00012	December 26, 2003
Virginia	A-03-03-00208	July 29, 2003
Washington	A-10-03-00007	July 31, 2003
West Virginia	A-03-03-00207	October 15, 2003
Wisconsin	A-05-03-00046	September 22, 2003
Wyoming	A-07-03-04015	May 21, 2003

[1]Texas State Auditor report available at http://www.sao.state.tx.us/Reports/report.cfm/report/03-029.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

MAY 26 2005

TO: Joseph B. Vengrin
Deputy Inspector General for Audit Services

FROM: Mark B. McClellan, M.D., Ph.D. Administrator
Centers for Medicare and Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: "Multi-State Review of Medicaid Drug Rebate Programs" (A-06-03-00048)

Thank you for the opportunity to review and comment on the above-referenced draft report. OIG's objective was to determine whether States had established adequate accountability and internal controls over their Medicaid drug rebate programs. OIG conducted audits in 49 states and the District of Columbia and found that only 4 states had no weaknesses in accountability and internal controls. CMS agrees with the recommendations in this report.

OIG Recommendation

That CMS reemphasize the requirement that states submit accurate and reliable information on Form CMS 64.9R.

CMS Response

We concur. States should submit accurate and reliable information on Form CMS 64.9R CMS' Center for Medicaid and State Operations is actively following up with states toward this end, and will provide operational assistance if necessary.

OIG Recommendation

That CMS emphasize to states their need to place a priority on their billing and collecting of drug rebates.

CMS Response

CMS continues to make significant progress in communicating with states about the need to place a priority on their billing and collecting of drug rebates. Staff regularly addresses issues regarding manufacturers who have repeatedly not paid rebates or made late rebate payments and have intervened on behalf of the states in those instances. CMS is using an updated internal manufacturer reinstatement process to assist the states in collecting outstanding rebates while ensuring manufacturer compliance with the payment provisions of the national rebate agreement.

In addition, CMS works with states on an on-going basis to provide guidance regarding the collection of outstanding drug rebates and emphasizes the importance of dispute resolution through the periodic release of program memos. We will continue to issue such memos as necessary to remind states of the importance of rebate collection.

General Comment

On page 3 of the report, the OIG notes that as a result of this review, 15 states were identified as having an inadequate dispute resolution and collection process. In response to this finding, CMS has the following comments:

Section 1927 of the Social Security Act requires that manufacturers enter into an agreement with CMS to provide rebates for their covered outpatient drugs paid for under Medicaid. One of the major challenges of the program has been to establish a system to enable states and manufacturers to come into accord on the data supporting states' claims for manufacturer rebates. As a result, CMS made the decision to develop a process for resolving drug rebate disputes between states and manufacturers. Since 1994, CMS has provided a leadership role in administering the Medicaid Drug Rebate Dispute Resolution Program (DRP) and has expanded the dispute resolution effort to the point where it exists in every state. In most cases, the states and manufacturers work together to resolve disputes; however CMS is committed to providing guidance, assistance and procedures to assist the dispute resolution process when necessary. A few examples include:

- A national DRP meeting is held semi-annually in Baltimore to provide facilitation/mediation at face-to-face meetings with manufacturers and states.
- A DRP Web page has been established to provide historical program information, best practices, current issues, etc.
- Staff from several CMS Regional offices have been assigned as DRP coordinators. These coordinators provide assistance to states and manufacturers regarding dispute issues.
- CMS participates in conference calls with states and manufacturers to assist in the resolution of disputes.
- CMS keeps manufacturers/states updated on various dispute-related issues by periodically sending out program releases.

It is important to note that the DRP is a voluntary program for states and that CMS works closely with those states that seek our assistance. Several of the states identified in Appendix B have attended the national DRP meetings and others have been personally invited at the request of individual manufacturers.

As a result of the findings of this report, CMS will be contacting the 15 states identified as having inadequate dispute resolution and collection processes to reemphasize that CMS is available to assist with any outstanding dispute issues and to provide additional guidance and procedural clarification pertaining to the DRP.

Page 3 - Joseph B. Vengrin

Technical Comments

1. Page 1- Executive Summary, Background - Previous Office of Inspector General Review of Medicaid Drug Rebate Program. "We also noted that CMS was unable to develop a nationwide total of the uncollected portion of Medicaid drug rebates because the States were required to report only drug rebates collected."

Since the previous report which the statement was taken from, CMS has established a method for collecting a nationwide total of the uncollected portion of Medicaid drug rebates. This went into effect in 1998. The form 64.9R traces the uncollected drug rebate by state. However, not all states complete the form properly or in its entirety.

2. Page 1 .Background, "Manufacturer Disputes"

This section contains some erroneous statements; therefore, beginning with the second sentence, we recommend that this paragraph be revised as follows:

"The manufacturers submit rebate payments to the State, along with the Reconciliation of State Invoice (ROSI), CMS-304. If the manufacturer questions the State's utilization/rebate invoice, the manufacturer has two options: to pay the State for the disputed items and then work with the State to resolve the dispute; or to pay the State for all units not in dispute and withhold payment for the disputed units. The manufacturer must remit the ROSI and documentation to the State to uniformly explain the adjusted rebate payment or dispute. After the State receives the ROSI, the State and the manufacturer should participate in an informal dispute resolution process. Both States and manufacturers may request assistance from CMS Dispute Resolution Program staff. If no resolution is reached, the State should make their hearing mechanism available to the manufacturer."

3. Page 2 - Background, "Dispute Resolution Project"

First, the title of this section should be changed from "Dispute Resolution Project" to "Dispute Resolution Program." In addition, to make this section more accurate, we recommend the following changes to this paragraph:

"In 1994, CMS began a pilot initiative with staff from the Boston Regional Office to assist manufacturers and states in resolving disputes. Based on the success of that pilot experience, CMS expanded the effort nationwide to other regions assisting with dispute resolution. Since 1996, national DRP meetings have been held both in Denver, Colorado and in Baltimore, Maryland.

The voluntary meetings are usually held semi-annually and give States and manufacturers the opportunity to meet face-to-face to resolve outstanding rebate disputes. Both States and manufacturers describe the DRP as a mutually beneficial process."

Page 4 - Joseph B. Vengrin

4. Executive Summary and Page 3 of the Draft Report

Both of these sections cite 45 CFR § 74.2 1(b)(3) as requiring that financial management systems provide for effective control over and accountability for all funds, property, and other assets. These sections should be revised to address revisions to the 45 CFR part 74 which were issued by the Department on September 8, 2003 (68 Fed. Reg.52843). In that final rule, the Department expanded the scope of 45 CFR part 92 to include the entitlement grant programs and remove such programs from the scope of part 74. Therefore, we recommend that the OIG update the citations in these sections to reflect this amendment.