August 12, 2011

TO: Donald M. Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Nationwide Rollup Report for Medicaid Drug Rebate Collections
(A-06-10-00011)

The attached final report provides the results of our rollup review of Medicaid drug rebate collections.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that the Office of Inspector General (OIG) post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at http://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Brian P. Ritchie, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at Brian.Ritchie@oig.hhs.gov. We look forward to receiving your final management decision within 6 months. Please refer to report number A-06-10-00011 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

NATIONWIDE ROLLUP REPORT FOR MEDICAID DRUG REBATE COLLECTIONS

Daniel R. Levinson
Inspector General

August 2011
A-06-10-00011

Office of Inspector General

http://oig.hhs.gov

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Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

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 (the program) became effective in 1991 (section 1927 of the Social Security Act (the Act)). For a covered outpatient drug to be eligible for Federal Medicaid funding under the program, the drug's 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 have specific functions under the program. The Deficit Reduction Act of 2005 (DRA) amended section 1927 of the Act and requires States, as of January 1, 2006, to collect rebates for single-source drugs administered by physicians.

In 2005, we issued a report on the results of audits of the programs in 49 States and the District of Columbia (A-06-03-00048). Those audits found that four States had no weaknesses in accountability for and internal controls over their programs. The remaining 45 States and the District of Columbia lacked sufficient controls in (1) Medicaid Drug Rebate Schedule (Form CMS 64.9R) reporting, (2) interest accrual and collection, (3) rebate collection systems, and (4) dispute resolution and had other significant weaknesses.

We concluded that States lacked adequate assurance that they had properly recorded and collected all of the drug rebates due them. Additionally, CMS did not have reliable drug rebate billing and collection information from the States to properly monitor the drug rebate program. We recommended 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 billing and collecting drug rebates. CMS agreed with our recommendations.

OBJECTIVES

Our objectives were to determine whether States had (1) implemented recommendations made in previous audits of the programs and (2) established controls over collecting rebates on single-source drugs administered by physicians.

SUMMARY OF FINDINGS

Fourteen States and the District of Columbia implemented the recommendations from our previous audits. Twenty-seven of the remaining 31 States with previous audit recommendations implemented at least 1 recommendation, and 4 States did not fully implement any of the recommendations. We identified new weaknesses in four States. The weaknesses in the 31 States fell into the following categories:

- unreliable information submitted to CMS on Form CMS 64.9R (22 States),
- improper accounting for interest on late rebate payments (13 States),
- an inadequate rebate collection system (10 States),

- an inadequate dispute resolution and collection process (6 States), and

- other significant weaknesses (8 States).

Forty-two States established controls over collecting rebates for single-source drugs administered by physicians as required by the DRA. The remaining six States and the District of Columbia did not establish such controls. (See Appendix B for a summary of weaknesses by State.)

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

RECOMMENDATIONS

We recommend that CMS:

- continue to emphasize the requirement that States submit accurate and reliable information on Form CMS 64.9R,

- continue to emphasize to States the need to place a priority on billing and collecting drug rebates, and

- emphasize that States are required to collect rebates for single-source drugs administered by physicians.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

CMS agreed with our recommendations and stated that it would emphasize the importance of submitting accurate and reliable information, as well as the proper collection of rebates. CMS also stated that it would remind States of the requirement to bill and collect rebates on single-source drugs administered by physicians. CMS's comments are included in their entirety as Appendix C.

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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 States have considerable flexibility in designing and operating their Medicaid programs, they must comply with applicable Federal requirements.

Drug Rebate Program

The Medicaid drug rebate program (the program) became effective in 1991 (section 1927 of the Act). For a covered outpatient drug 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 manufacturers each have specific functions under the program.

Pursuant to section 1927(b) of the Act and section II of the rebate agreement, manufacturers are required to submit a list to CMS of all covered outpatient drugs (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 drug and provides the amounts to States quarterly.

Section 1927(b)(2)(A) of the Act requires States to maintain drug utilization data that identifies, by National Drug Code (NDC), the number of units of each drug for which the States reimbursed providers. The number of units is multiplied by 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 the Medicaid Drug Rebate Schedule (Form CMS-64.9R). This is part of Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program, which contains a summary of actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

Section (V)(c) of the rebate agreement requires manufacturers and States to do their best to resolve utilization discrepancies within 60 days after the State receives notice of a discrepancy. CMS developed the Dispute Resolution Program to help States and manufacturers resolve disputes.

Physician-Administered Drugs

Section 6002(a) of the Deficit Reduction Act of 2005 (DRA) amended 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.

In 38 States, physician-administered drugs are billed to the State Medicaid program on a claim form using procedure codes that are part of the Healthcare Common Procedure Coding System. The NDC is not included on the physician claim form. The procedure code identifies a drug by its active ingredient(s) and identifies the number of drug units (i.e., billing units) allowed per reimbursement for that procedure code. Because rebates are calculated and paid based on NDCs, each procedure code must be converted to an NDC. Additionally, the billing units for a procedure code may differ from the units used for rebate purposes (e.g., grams versus liters).

Prior Office of Inspector General Reports

In 2005, we issued a report on the results of audits of the programs in 49 States and the District of Columbia.[2] Those audits found that four States had no weaknesses in accountability for and internal controls over their programs. In the remaining 45 States and the District of Columbia, we identified:

- 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 weaknesses (13 States).

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

We recommended 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 billing and collecting drug rebates. CMS agreed with our recommendations.

After our report to CMS, we conducted 49 audits. (For a list, see Appendix A.) We summarize the results of those audits in this report.

[1] This provision of the DRA expanded the requirement to certain multiple-source drugs administered by physicians after January 1, 2008.

[2] *Multistate Review of Medicaid Drug Rebate Programs* (A-06-03-00048), issued July 6, 2005; Arizona did not operate a program.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to determine whether States had (1) implemented recommendations that we made in previous audits of the programs and (2) established controls over collecting rebates on single-source drugs administered by physicians.

Scope

We performed audit work in 48 States and the District of Columbia. We did not perform reviews in Arizona or Maryland. Arizona does not have a program. In Maryland, our prior review identified no weaknesses in accountability and internal controls. We limited our reviews in Illinois, Minnesota, and North Carolina to the controls over collecting rebates on single-source drugs administered by physicians because there were no previous audit recommendations on which to follow up.

Cumulatively, the 48 States and the District of Columbia reported to CMS at least $9.5 billion in billings and $11.0 billion in collections during the 1-year period ended June 30, 2006.[3]

Methodology

To accomplish our objectives, we

- reviewed section 1927 of the Act, the rebate agreement, section 6002(a) of the DRA, CMS guidance issued to State Medicaid directors, and other information pertaining to the program;

- reviewed the States' policies and procedures related to their drug rebate accounts receivable systems;

- interviewed State officials and/or fiscal agents to identify the policies, procedures, and controls that related to the program;

- reviewed a copy of each State's Form CMS-64.9R; and

- reviewed States' policies and procedures and interviewed State officials and/or fiscal agents to determine the process used to convert 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

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

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

Fourteen States and the District of Columbia implemented the recommendations from our previous audits. Twenty-seven of the remaining 31 States with previous audit recommendations implemented at least 1 recommendation, and 4 States[4] did not fully implement any of the recommendations. We identified new weaknesses in four States. The weaknesses in the 31 States fell into the following categories:

- unreliable information submitted to CMS on Form CMS 64.9R (22 States),
- improper accounting for interest on late rebate payments (13 States),
- an inadequate rebate collection system (10 States),
- an inadequate dispute resolution and collection process (6 States), and
- other significant weaknesses (8 States).

Forty-two States established controls over collecting rebates for single-source drugs administered by physicians, as required by the DRA. The remaining six States and the District of Columbia did not. (See Appendix B for a summary of significant weaknesses by State.)

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

FEDERAL REQUIREMENTS

Federal regulations (42 CFR § 433.32(a)) require States to "maintain an accounting system and supporting fiscal records to assure that claims for Federal funds are in accordance with applicable Federal requirements."

Section 2500.6 of the CMS *State Medicaid Manual* instructs States to present a complete, accurate, and full disclosure of all drug rebates and collections.

Section 6002(a) of the 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.

[4] Five of the twenty-seven States implemented recommendations related to minor findings that were included in their individual program reports but not included in our summary report (A-06-03-00048) issued in 2005.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

Unreliable Information Submitted on Form CMS-64.9R

In our prior audits of State programs, we determined that 37 States reported unreliable information on Form CMS 64.9R. Sixteen States have since implemented our recommendations on Form CMS 64.9R reporting, but 21 have not. Additionally, we identified control weaknesses in a State that did not previously have a weakness.

We were unable to rely on the drug rebate information reported on the Form CMS 64.9R because the States:

- did not reconcile the Form CMS 64.9R to supporting records (13 States),
- did not report accurate information on Form CMS 64.9R (7 States),
- did not maintain supporting records (3 States), and
- did not properly complete all parts of the Form CMS 64.9R (7 States).[5]

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

In our prior audits, we determined that 27 States either did not verify that interest payments for late rebate payments were accurate or did not properly accrue, bill, and/or track the interest due. Fifteen States have since implemented our recommendations on verifying and tracking interest, but 12 States have not. Additionally, we identified a control weakness in a State that did not previously have a reported weakness. As a result, these States did not have adequate assurance that all interest on late, unpaid, or disputed rebates was properly calculated, collected, and reported.

Inadequate Rebate Collection System

In our prior audits, we determined that 17 States had weaknesses in their rebate collection systems that resulted in inaccurate or insufficiently detailed rebate collection information. Since our prior audits, eight States have implemented our recommendations to address weaknesses in their rebate collection systems, but nine have not. Additionally, we identified weaknesses in the rebate collection system of one State that did not previously have any. Of these 10 States:

[5] Some States had more than one CMS 64.9R weakness.

- 4 did not track drug rebate activity at a sufficiently detailed level,

- 4 did not update accounts receivable data before converting to a new rebate collection system or fiscal agent, and

- 2 did not maintain a rebate general ledger control account.

As a result, these States could not be assured that all drug rebate revenue was collected.

Inadequate Dispute Resolution and Collection Processes

In our prior audits, we determined that 15 States did not have adequate rebate dispute resolution policies and procedures and/or adequate staff to resolve disputes. Eleven States have since implemented our recommendations on their dispute resolution processes, but four have not. Additionally, we identified weaknesses in the dispute resolution processes in two States that did not previously have any. Of these six States, three did not have adequate policies and procedures to resolve disputes, two did not have adequate staff, and one had unresolved disputes that were more than 3 years old. As a result, these States did not resolve disputes in a timely manner. Weaknesses in dispute resolution may also lead to a loss of rebate revenue.

Other Significant Weaknesses

In our prior audits, other significant weaknesses included inadequate procedures to track $0 unit rebate amounts,[6] improper writeoffs and adjustments, and inadequate segregation of duties.

Six States had inadequate procedures to track $0 unit rebate amounts. Two States have since implemented our recommendations related to $0 unit rebate amounts, but four have not. CMS instructs States to invoice these units and have the manufacturer pay the rebate based on the manufacturer's calculated unit rebate amount. However, these four 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 these States collected all rebate revenue due from manufacturers.

In our prior audits, we determined that six States improperly made writeoffs of drug rebates. Two States have since implemented our recommendations on writeoffs and adjustments, but four have not. Two of the States did not provide adequate management oversight of account adjustments and writeoffs. One State could not determine the amount of rebate writeoffs that occurred during the transition to a new contractor, and one State's policies for writeoff adjustments did not conform to CMS guidelines. As a result, States may have written off additional drug rebates that should have been collected through the dispute resolution process.

In our prior audits, we determined that six States did not have a proper segregation of duties for billing and collection of drug rebates. Five States have since implemented our recommendations on segregation of duties, but one has not. That State did not develop written policies and

[6] The phrase "$0 unit rebate amounts" refers to drugs that do not have a unit rebate amount included in the drug data that CMS reports quarterly to the States. CMS data may contain a $0 unit rebate amount if the pricing information is not provided in a timely manner or has a 50-percent variance from the previous quarter.

procedures that segregated duties for depositing and recording drug rebate receipts. As a result, the State still had an increased risk of fraud, waste, and abuse in drug rebate funds.

PHYSICIAN-ADMINISTERED SINGLE-SOURCE DRUGS

Forty-two States established controls over collecting rebates for single-source drugs administered by physicians, as required by the DRA. The remaining six States and the District of Columbia have not established such controls.

CONCLUSIONS

Thirty-seven States made improvements since our 2005 review. However, many States still need to make improvements. The corrective actions we recommended in each of the State reports may result in States' properly monitoring their drug rebate programs. This monitoring may help increase drug rebate revenue and enable more reliable reporting of drug rebate information to CMS. Until the information reported on Form CMS 64.9R is accurate, CMS will not be able to provide adequate oversight.

RECOMMENDATIONS

We recommend that CMS:

- continue to emphasize the requirement that States submit accurate and reliable information on Form CMS 64.9R,

- continue to emphasize to States the need to place a priority on billing and collecting drug rebates, and

- emphasize that States are required to collect rebates for single-source drugs administered by physicians.

CENTERS FOR MEDICARE & MEDICAID COMMENTS

CMS agreed with our recommendations and stated that it would emphasize the importance of submitting accurate and reliable information, as well as the proper collection of rebates. CMS also stated that it would remind States of the requirement to bill and collect rebates on single-source drugs administered by physicians. CMS's comments are included in their entirety as Appendix C.

APPENDIXES

APPENDIX A: STATE REPORTS

State	Report Number	Issue Date
Alabama	A-04-07-07024	8/21/2008
Alaska	A-09-08-00051	1/22/2009
Arkansas	A-06-07-00015	11/27/2007
California	A-09-07-00084	2/27/2008
Colorado	A-07-08-03108	8/25/2008
Connecticut	A-01-08-00002	6/12/2008
Delaware	A-03-07-00217	7/24/2008
District of Columbia	A-03-07-00216	1/4/2008
Florida	A-04-07-07022	4/11/2008
Georgia	A-04-07-07027	7/31/2009
Hawaii	A-09-07-00081	4/14/2008
Idaho	A-09-07-00064	4/15/2008
Illinois	A-05-08-00011	7/29/2008
Indiana	A-04-08-07006	10/29/2009
Iowa	A-07-07-03094	4/3/2008
Kansas	A-07-08-03102	12/19/2007
Kentucky	A-05-08-00015	3/31/2008
Louisiana	A-06-07-00067	11/27/2007
Maine	A-01-09-00001	12/21/2009
Massachusetts[1]	A-01-08-00005	10/20/2008
Michigan	A-05-08-00014	7/8/2008
Minnesota	A-05-08-00010	4/14/2008
Mississippi	A-04-07-07023	10/9/2008
Missouri	A-07-07-03096	2/7/2008
Montana	A-07-07-03101	6/6/2008
Nebraska	A-07-07-03097	4/10/2008
Nevada	A-09-08-00026	10/1/2008
New Hampshire	A-01-08-00013	8/25/2009
New Jersey	A-02-07-01056	6/12/2008
New Mexico	A-06-07-00071	5/20/2008
New York	A-02-07-01055	9/8/2008
North Carolina	A-04-07-07028	6/18/2008
North Dakota	A-07-08-03105	4/15/2008
Ohio	A-04-08-07005	2/24/2009
Oklahoma	A-06-07-00069	2/4/2008
Oregon	A-09-07-00052	3/14/2008
Pennsylvania	A-03-08-00201	2/27/2008
Rhode Island	A-01-08-00009	3/24/2009
South Carolina	A-04-08-07004	7/31/2009
South Dakota	A-07-08-03110	8/13/2008
Tennessee	A-04-07-07026	5/1/2008
Texas	A-06-08-00028	8/6/2008
Utah	A-07-07-03098	7/1/2008
Vermont	A-01-08-00004	8/13/2008
Virginia	A-03-07-00218	1/31/2008
Washington	A-09-07-00062	4/4/2008
West Virginia	A-03-08-00200	10/6/2008
Wisconsin	A-05-08-00012	3/24/2008
Wyoming	A-07-08-03106	5/27/2008

Note: These reports are available at http://oig.hhs.gov.

[1] We relied on the State's *Independent State Auditor's Report on the Administration by MassHealth of the Medicaid Drug Rebate Program June 30, 2006* to address the first objective in our report. It is available online at www.mass.gov. Accessed on October 1, 2010.

APPENDIX B: SIGNIFICANT PRIOR AND CURRENT WEAKNESSES BY STATE

Column 1 = Unreliable information submitted on CMS (Centers for Medicare & Medicaid Services) 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
Column 8 = Inadequate or missing controls over single-source drugs administered by physicians

P = Prior weaknesses
C = Current weaknesses

	1		2		3		4		5		6		7		8
State	**P**	**C**	**P**	**C**	**P**	**C**	**P**	**C**	**P**	**C**	**P**	**C**	**P**	**C**	**C**
Alabama			X				X								
Alaska	X	X	X	X	X	X							X		
Arkansas	X		X	X											
California	X	X			X		X								
Colorado	X	X						X	X		X				
Connecticut	X	X													
Delaware	X	X													
District of Columbia	X														X
Florida	X		X				X								
Georgia	X										X	X			
Hawaii	X	X	X	X	X	X	X								X
Idaho	X	X			X		X				X	X	X		
Illinois															X
Indiana	X	X													
Iowa	X	X	X		X										
Kansas	X		X		X										
Kentucky	X														
Louisiana	X														
Maine	X	X	X	X			X	X							
Massachusetts	X	X	X												
Michigan	X	X													
Minnesota															
Mississippi			X												X
Missouri	X	X	X												
Montana	X				X	X	X	X	X	X					
Nebraska	X	X	X	X	X										X
Nevada			X	X	X	X	X								
New Hampshire	X		X												
New Jersey	X	X	X	X											
New Mexico	X	X	X		X	X	X						X	X	
New York	X	X	X		X	X	X								
North Carolina															
North Dakota				X				X	X	X					
Ohio			X												
Oklahoma	X				X										
Oregon	X	X	X	X	X	X							X		
Pennsylvania	X		X		X		X								
Rhode Island	X						X								
South Carolina	X		X	X											
South Dakota	X	X	X						X	X	X	X			
Tennessee	X														
Texas			X		X		X				X		X		
Utah	X	X	X	X	X	X			X	X					X
Vermont		X	X	X											
Virginia						X									
Washington			X	X			X	X			X	X	X		
West Virginia	X						X	X							
Wisconsin	X		X												
Wyoming	X	X			X	X			X						X
TOTALS	**37**	**22**	**27**	**13**	**17**	**10**	**15**	**6**	**6**	**4**	**6**	**4**	**6**	**1**	**7**

APPENDIX C: CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Deputy Administrator
Baltimore, MD 21244-1850

DATE: MAY 1 1 2011

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner
Principal Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Nationwide Rollup Report for Medicaid Drug Rebate Collections" (A-06-10-00011)

Thank you for the opportunity to review and comment on the above-referenced report. In 2005, the OIG issued a report on the results of audits of the Medicaid drug rebate programs in 49 States and the District of Columbia. Those audits found that four States had no weaknesses in accountability for and internal controls over their programs. In this report, the OIG objectives were to determine whether States had implemented recommendations made in previous audits of the programs and established controls over collecting rebates on single-source drugs administered by physicians.

The OIG found that 14 States and the District of Columbia implemented the recommendations from the OIG's previous audits and that 27 of the remaining 31 States with previous audit recommendations implemented at least 1 recommendation. Four States did not fully implement any of the recommendations. Further, the OIG identified new weaknesses in four States. The weaknesses in the 31States fell into the following categories:

- unreliable information submitted to the Centers for Medicare & Medicaid Services (CMS) on Form CMS 64.9R (22 States);
- improper accounting for interest on late rebate payments (13 States);
- an inadequate rebate collection system (10 States);
- an inadequate dispute resolution and collection process (6 States); and
- other significant weaknesses (8 States).

Forty two States established controls over collecting rebates for single-source drugs administered by physicians as required by the Deficit Reduction Act. The remaining six States and the District of Columbia did not establish such controls. States lacked adequate assurance that all drug rebates due them were properly recorded and/or collected. Additionally, CMS did not have reliable drug rebate billing and collection information o properly monitor the program.

OIG Recommendation

CMS should:

- continue to emphasize the requirement that States submit accurate and reliable information on Form CMS 64.9R;
- continue to emphasize to States the need to place a priority on billing and collecting drug rebates; and,
- emphasize that States are required to collect rebates for single-source drugs administered by physicians.

CMS Response

We concur. While we are pleased with the progress that the States have made since the previous OIG report, we will again emphasize the importance of submission of accurate and reliable information as well as the proper collection of rebates. CMS has provided States with access to Drug Data Reporting for Medicaid System, so that they can more accurately and timely track changes to manufacturer rebate billing. Also, CMS has continued to notify States of the deletion of manufacturer-reported products that do not meet the definition of covered outpatient drugs. CMS will issue guidance to States via releases to remind them of their requirement to bill and collect rebates for single-source physician-administered drugs.

The CMS would again like to thank the OIG for their efforts in reviewing the compliance of States' participation in the Medicaid Drug Rebate Program for the reimbursement of drug expenditures.