DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date .JUN 9 1993

From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Review of Management Controls Over the Medicaid Prescription Drug Rebate Program (A-06-92-00029)

To Bruce C. Vladeck
Administrator
Health Care Financing Administration

Attached is a final management advisory report providing you with the results of our review of selected aspects of the management controls established over the Medicaid prescription drug rebate program. The purpose of our review, which was conducted in eight randomly selected States, was to determine whether the Health Care Financing Administration (HCFA) had ensured that the States had established adequate accountability and internal controls over their rebate billings to drug manufacturers, the resultant rebate collections, and the resolution of any disputes. Additionally, since HCFA did not have national totals on the amount of rebates billed, collected, uncollected or in dispute, we attempted to develop, for Calendar Year (CY) 1991, a nationwide statistical estimate of these amounts using the States' information.

We found that HCFA has not ensured that States have established adequate accountability and controls over the Medicaid drug rebate program. At the eight sampled States, we found that: (1) proper accountability had not been established over billing and collection of rebates, (2) six of the States did not have policies and procedures for settling disputes within the required time frame, (3) conflicting HCFA guidelines caused confusion regarding what a State is required to bill drug manufacturers, and (4) internal controls had not been established over rebate program funds.

Additionally, we were unable to develop a nationwide statistical estimate of the total amount of rebates billed, collected, and uncollected by the States. At three of the eight States reviewed, we found that the data was unreliable or inaccurate. Since we could not make national projections based on the data from these 8 States, we contacted the remaining 41 States and the District of Columbia to determine whether they could provide reliable information on the amounts billed, collected, and uncollected. After we made numerous contacts over a period of 3 months, only 30 States and the District of Columbia were able to reply with data which appeared

to be reasonable based on our knowledge of their drug expenditures. The remaining States were excluded from our analysis because they appeared to have data and systems problems similar to those in our sampled States.

The data from the 30 States and the District of Columbia, however, indicated that $111 million or 23.4 percent of the total $475 million in rebates billed by these States (after write-offs and adjustments) remain uncollected for CY 1991. The rebates were based on total expenditures of $3.1 billion in these 30 States and the District of Columbia. Also of significance is the fact that the 19 States which were unable to provide us with usable data had Medicaid prescription drug program expenditures totaling $2.9 billion in CY 1991. Therefore, the total amount of rebates billed and rebates remaining uncollected are most likely substantially higher.

Although Federal regulations require States to establish accountability and controls over program funds, States have not established proper accountability and internal controls over their Medicaid drug rebate programs. Further, the Office of Management and Budget requires executive Departments to establish management systems that provide for adequate financial information and effective control over revenue, expenditures, and other assets. However, HCFA has not established a reporting mechanism to capture consistent and reliable information from the States which would provide it with the means to effectively monitor and manage the drug rebate program. As a result, hundreds of millions of dollars in drug rebate funds are vulnerable to fraud, waste, and abuse.

The Federal Government shares in the payment of Medicaid drug expenditures and the collection of revenues from rebates at an average of about 57 percent. It is essential to HCFA's oversight responsibility that it ensure that States implement proper accountability and internal controls over drug rebate funds, and that it obtain the information necessary to effectively monitor and manage the rebate program.

We are recommending that HCFA ensure that States implement accounting and internal control systems in accordance with applicable Federal regulations for the Medicaid drug rebate program. Such systems should provide for accurate, current, and complete disclosure of drug rebate transactions and provide HCFA with the financial information it needs to effectively monitor and manage the Medicaid drug rebate program. We are also recommending that HCFA include a State reporting mechanism that will capture consistent and reliable data from the States on rebate transactions. This should include capturing amounts billed, collected, written-off, and what remains uncollected and/or in dispute by calendar quarter. In addition, HCFA should establish a limit on the dollar amount of rebates which can be written-off without HCFA's approval.

The HCFA responded to our draft report in a memorandum dated April 5, 1993. In that memorandum, HCFA agreed with our recommendations for (1) ensuring that the State implement accounting and internal control systems, (2) implementing a reporting mechanism to capture consistent and reliable data from the States on rebate transactions, and (3) establishing a limit on the dollar amounts which can be written-off without HCFA's approval. The HCFA also provided some technical comments regarding the report.

Please advise us, within 60 days, on actions taken or planned on our recommendations. If you have any questions, please call me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 966-7104. Copies of this report are being sent to other interested top Department officials.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MANAGEMENT CONTROLS OVER THE MEDICAID PRESCRIPTION DRUG REBATE PROGRAM

JUNE 1993 A-06-92-00029

Memorandum

Date JUN 9 1993

From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Review of Management Controls Established Over the Medicaid Prescription Drug Rebate Program (A-06-92-00029)

To Bruce C. Vladeck
Administrator
Health Care Financing Administration

This final management advisory report provides you with the results of our review of selected aspects of the management controls established over the Medicaid prescription drug rebate program. The purpose of our review, which was conducted in eight randomly selected States, was to determine whether the Health Care Financing Administration (HCFA) had ensured that the States had established adequate accountability and internal controls over their rebate billings to drug manufacturers, the resultant rebate collections, and the resolution of any disputes. Additionally, since HCFA did not have national totals on the amount of rebates billed, collected, uncollected or in dispute, we attempted to develop, for Calendar Year (CY) 1991, a nationwide statistical estimate of these amounts using the States' information.

STATES DO NOT HAVE PROPER ACCOUNTABILITY OVER BILLING AND COLLECTION OF REBATES

We found that HCFA has not ensured that States have established adequate accountability and controls over the Medicaid drug rebate program. At the eight sampled States, we found that: (1) proper accountability had not been established over billing and collection of rebates, (2) six of the States did not have policies and procedures for settling disputes within the required time frame, (3) conflicting HCFA guidelines caused confusion regarding what a State is required to bill drug manufacturers, and (4) internal controls had not been established over rebate program funds.

THE HCFA LACKS MANAGEMENT INFORMATION TO MONITOR AND MANAGE THE REBATE PROGRAM

Additionally, we were unable to develop a nationwide statistical estimate of the total amount of rebates billed, collected, and uncollected by the States. At three of the eight States reviewed, we found that the data was unreliable or inaccurate. For example, in one calendar quarter, two of the eight States' rebate billings represented 248 to 320 percent of their total drug expenditures in their Medicaid program. In this particular quarter, the major problem was that the unit rebate amounts supplied by HCFA and used by the States to bill drug manufacturers was in error. As a result, drug manufacturers were sending rebate checks to the States that were different than the State rebate billings. Specific reasons for the reductions, however, were not provided by the drug manufacturers and some States, therefore, did not correct their billings. At a third State, drug manufacturers were only sent utilization data (not an actual bill of rebates owed) and no records to support what was billed or uncollected were maintained.

Since we could not make national projections based on the data from these 8 States, we contacted the remaining 41 participating States and the District of Columbia to determine whether they could provide reliable information on the amounts billed, collected, and uncollected. After we made numerous contacts over a period of 3 months, only 30 States and the District of Columbia were able to reply with data which appeared to be reasonable based on our knowledge of their drug expenditures. The remaining States were excluded from our analysis because they appeared to have data and system problems similar to those identified above.

AS MUCH AS $111 MILLION REMAINS UNCOLLECTED IN 30 STATES AND THE DISTRICT OF COLUMBIA

The data from the 30 States and the District of Columbia, however, indicated that $111 million or 23.4 percent of the total $475 million in rebates billed (after write-offs and adjustments) remain uncollected for CY 1991. These rebates were based on total Medicaid expenditures for prescription drugs of $3.1 billion in the 30 States and the District of Columbia. Also of significance is the fact that the 19 States, which were unable to provide us with usable data, had Medicaid prescription drug program expenditures totaling $2.9 billion in CY 1991. Therefore, total rebates billed and uncollected can be expected to be substantially higher.

Although Federal regulations require States to establish accountability and controls over program funds, States have not established proper accountability and internal controls over their Medicaid drug rebate programs. Further, the Office of Management and Budget (OMB) requires executive Departments to establish management systems that provide for adequate financial information and effective control over revenue, expenditures, and other assets. However, HCFA has not established a reporting mechanism to capture consistent and reliable information from the States which would provide it with the means to effectively monitor and manage the drug rebate program. As a result, hundreds of millions of dollars in drug rebate funds are vulnerable to fraud, waste, and abuse.

The Federal Government's share in the payment of Medicaid drug expenditures and the collection of rebates is about 57 percent. It is essential to HCFA's oversight responsibility that it ensure that States implement proper accountability and internal controls over drug rebate funds, and that it obtain the information necessary to effectively monitor and manage the rebate program.

We are recommending that HCFA ensure that States implement accounting and internal control systems in accordance with applicable Federal regulations for the Medicaid drug rebate program. Such systems should provide for accurate, current, and complete disclosure of drug rebate transactions and provide HCFA with the financial information it needs to effectively monitor and manage the Medicaid drug rebate program. We are also recommending that HCFA include a State reporting mechanism that will capture consistent and reliable data from the States on rebate transactions. This should include capturing amounts billed, collected, written-off, and remaining uncollected, and/or in dispute by calendar quarter. In addition, HCFA should establish a limit on the dollar amount of rebates which can be written-off without HCFA's approval.

The HCFA responded to our draft report in a memorandum dated April 5, 1993. In that memorandum, HCFA agreed with our recommendations for (1) ensuring that the State implement accounting and internal control systems, (2) implementing a reporting mechanism to capture consistent and reliable data from the States on rebate transactions, and (3) establishing a limit on the dollar amounts which can be written-off without HCFA's approval. Some technical comments regarding the report were also provided.

See page 15 of this report for more discussion of HCFA's comments, and see the report Appendix for a complete text of the comments.

BACKGROUND

On November 5, 1990, the Congress enacted the Omnibus Budget Reconciliation Act of 1990 (OBRA '90). This legislation, among other provisions, established the Medicaid prescription drug rebate program. Responsibility for the rebate program is shared among the drug manufacturers, HCFA, and the States. Under OBRA '90, for payment to be made for Medicaid covered outpatient drugs, a manufacturer must enter into a rebate agreement with the Department of Health and Human Services *(acting for the States)*. The legislation was effective January 1, 1991.

The HCFA receives pricing information from manufacturers that includes the average manufacturer's price and best price. From this information, a unit rebate amount is computed for each drug and is furnished to the States for their use in calculating the rebate amount due from the drug manufacturer. The States are responsible for identifying the number of units dispensed *(drug utilization data)* by manufacturer for each covered drug. The States have the option of either calculating the rebate amounts due from a manufacturer or supplying only the utilization data to the manufacturer without actually computing the rebate amount due. The manufacturer has 30 days after receipt of the utilization data to make the rebate payments to the States.

If a manufacturer discovers a material discrepancy in a State's drug utilization data, which the manufacturer and the State, in good faith, are unable to resolve, the manufacturer is to provide written notice of the discrepancy to the State. The State and the manufacturer are required to use their best efforts to resolve the discrepancy within 60 days of receipt by the State. If the State and the manufacturer are not able to resolve the discrepancy within 60 days, the State must make a hearing mechanism available to the manufacturer in order to resolve the dispute.

The HCFA requires States to report Medicaid expenditures, including outpatient drug expenditures, and rebate collections, on the Form HCFA-64 quarterly reports. The HCFA-64 report summarizes actual expenditures *(hereinafter referred to as cash expenditures)* for each quarter and is used by HCFA to reimburse the Federal share of these expenditures. States are also required to report statistical data on Form HCFA-2082. This report generates information that includes the total number of Medicaid recipients and payments broken down by factors such as eligibility group and service type.

METHODOLOGY

Our review included a random sample of eight States that were participating in the Medicaid drug rebate program. The eight States reviewed were California, Kansas, Louisiana, Ohio, Oklahoma, Oregon, Pennsylvania, and Tennessee.

The objectives of our review were to determine whether the States established adequate accountability and internal controls over their rebate funds and to develop a nationwide statistical estimate on the amount of rebates billed to drug manufacturers, the amount collected, and the amount remaining uncollected or in dispute for CY 1991.

To accomplish our objectives, we reviewed the provisions of OBRA '90 pertaining to the Medicaid outpatient prescription drug rebate program. Additionally, we reviewed the standard Medicaid drug rebate agreement and the program releases *(Release Memorandums)* regarding the drug rebate program issued by HCFA to the States and to participating drug manufacturers. We also contacted HCFA personnel in the Dallas region and reviewed correspondence related to implementation and monitoring of the rebate program. Further, at the eight randomly selected States we performed on-site interviews with States' officials and reviewed records and documents related to the Medicaid outpatient prescription drug rebate program. Our field work covered CY 1991 and was conducted during the period February through September 1992.

Since we could not make national projections based on our visits to 8 States, we contacted the remaining 41 participating States and the District of Columbia to determine whether they could provide reliable information on the rebate amounts billed, collected, and uncollected. Based on our knowledge of problems encountered by the States in billing for CY 1991 second quarter data, we eliminated from our analysis any State where the amounts provided to us appeared unreasonable for the second quarter.

RESULTS OF REVIEW

The HCFA has not ensured that States established proper accountability and control over their rebate funds in accordance with OMB and other Federal requirements. At the eight sampled States we found that:

- proper accountability had not been established over billing and collection of rebates;

- six of the States did not have written policies and procedures for settling disputes within the required time frame and, although four States told us that they had implemented a hearing mechanism, none of the States had conducted a dispute hearing;

- conflicting HCFA guidelines confused one State regarding billing drug manufacturers for rebates; and

- internal controls have not been established over rebate program funds.

We were unable to make a statistical estimate of the amount of rebates billed, collected, uncollected or in dispute for CY 1991 because of obvious errors in State data that would invalidate a statistical projection. Through telephone contacts or site visits, we obtained data from 30 States and the District of Columbia that appeared to be accurate. This data analysis indicated that as much as $111 million or 23.4 percent of the $475 million in rebates billed remain uncollected in these 30 States and the District of Columbia.

Hundreds of millions of dollars in drug rebate funds are vulnerable to fraud, waste, and abuse because States have not established proper accountability and internal controls over their Medicaid drug rebate programs. Also, HCFA has not established a reporting mechanism to capture consistent and reliable information to effectively monitor and manage the drug rebate program.

The Federal Government shares in the payment of Medicaid drug expenditures and the collections of revenues from rebates at an average of about 57 percent. It is, therefore, essential to HCFA's oversight responsibility that it ensure that States implement proper accountability and internal controls over drug rebate funds and that it obtain the information necessary to effectively monitor and manage the Medicaid drug rebate program.

States Do Not Have Proper Accountability Over Billing and Collection of Rebates

The Federal regulations, at 45 CFR 74, subpart H, require that States meet certain standards for grant financial management systems which provide for (1) accurate, current, and complete disclosure of the financial results of programs; (2) accounting records which identify adequately the source and application of program funds; and (3) effective internal controls and accountability over all grant cash, property, and other assets so that these assets are safeguarded.

Our review showed that none of the eight States reviewed on-site maintained general ledger control accounts for drug rebates, and only four States maintained even informal receivable listings for each manufacturer. Additionally, it did not appear to us that the States reviewed were generally using their best efforts to collect the billings or to resolve disputes with manufacturers. Also, there was virtually no system of internal control in place in these States for drug rebate program funds.

Lack of General Ledger Accounts

None of the eight State Medicaid agencies selected for on-site visits used general ledger control accounts to establish accountability and control over drug rebate billings. Only four of the States maintained even informal receivable listings to identify the rebate billings and collections for each manufacturer.

While the States' Medicaid agencies have accounting systems, including general ledger accounts, these accounts contain only the information necessary for purposes of preparing the quarterly Medicaid statement of expenditures, Form HCFA-64 report. With respect to the Medicaid drug rebate program, the only requirement for the HCFA-64 report is that States report on a quarterly basis the Medicaid drug program expenditures, drug rebate receipts and, where applicable, interest income from settled disputes. No other detailed rebate information was required to be reported. As a result, we were unable to determine from the States' accounting systems the total amounts that were billed, received, outstanding, or in dispute from each manufacturer or whether the manufacturer was paying the rebates within the required 30-day time limits. Without such information, the States have no assurance

as to the status of billings and, therefore, would be unable to identify and pursue disputed items.

One State did not know the total amount of drug rebates due because its billing to the manufacturers provided only drug utilization data. Since the State billed only utilization data, there is no assurance that the manufacturers paid the proper amount of rebates. Four States maintained informal receivable listings that included information which identified the manufacturer, amount billed, and amount collected. These listings were generally maintained on a personal computer by pharmacy program personnel, not the Medicaid agencies' accounting staffs. Additionally, the listings were never summarized to show the total amount due from each manufacturer. Three of these four States maintained logs of rebate payments received from manufacturers but did not reconcile their informal receivable listings to the total rebates received as recorded in these logs. Two of these four States did not have controls to ensure that the posting to the informal receivable listings were made from manufacturers' remittance vouchers. Although these informal receivable listings and logs provided some accountability for drug rebates, the amounts were not recorded in the States' official accounting system.

While an informal receivable listing is preferable to no records being maintained at all, we do not believe that such informal records should be the primary means for recording and controlling rebate receivables. These records could be easily discarded, lost, altered, or misused without knowledge of State Medicaid officials. Since these systems of informal listings and logs are unofficial, it is likely that they are undocumented and probably known only to the individual who currently maintained them. If this individual leaves or assumes other duties, there is no assurance that these records would continue to be maintained since they are not part of the already existing State Medicaid agencies' accounting systems.

Uncollected Billings and Dispute Resolution

According to the rebate agreements, the States are required to use their "best efforts" to resolve disputed rebate amounts within 60 days of receipt of a dispute notification from the drug manufacturer. In the event the States and the manufacturers are not able to resolve a discrepancy within 60 days, the States are required by 42 CFR 447.253(c) to provide a hearing mechanism to the manufacturer. Additionally, the rebate agreements require the assessment of interest on disputed balances ultimately owed by manufacturers.

Our reviews in the eight States showed that they were generally not following these requirements.

- Six of the eight States reviewed did not have policies and procedures for adjudicating drug rebate disputes within 60 days of receipt of a discrepancy notification by the drug manufacturers. Some manufacturers told us and the States, that they interpret this to mean that the disputes are automatically resolved in their favor if the States do not formally respond to their disputes within 60 days.

- Although four States told us that they have implemented hearing mechanisms for drug rebates, none of the States conducted dispute hearings, no disputes had been resolved through the hearing processes, and no disputed amounts were pending in the hearing processes.

- Only two of the eight States had formal procedures for writing off rebate receivables and obtaining approval for the write-offs by senior State officials. Neither of the two States, however, had notified or sought approval for the write-offs from HCFA.

- Although the rebate agreement provides for the assessment of interest on amounts that are disputed by the manufacturers and later resolved in the State's favor, none of the States reported any interest income under the drug rebate program.

We believe HCFA took a step in the right direction regarding dispute resolution with its issuance of Medicaid Drug Rebate Program Release No. 19. This document, dated May 18, 1992, provided much needed guidance on the steps that should be followed in the dispute resolution process. However, in order to be assured that the States use their best efforts to collect the uncollected rebate funds, HCFA should address the problems above.

Conflicting Guidelines Cause Confusion

Although OBRA '90 required that States provide quarterly drug utilization data to the manufacturers, it did not specifically require that the States calculate and bill the drug manufacturers for the actual rebates due based on this data. The HCFA, however, issued guidelines which allow States to calculate and bill drug

manufacturers for the rebates. Because HCFA did not provide clear guidelines on billing drug manufacturers, one of the eight States in our sample provided only utilization data to the drug manufacturers and allowed them to compute the rebate balances owed.

The rebate agreements give the States the option of computing the total rebate amounts due from the drug manufacturers based on the State's own records. However, Enclosure E of the standard rebate agreement requires that the total amount billed each drug manufacturer was to be computed for each National Drug Code by the State and supplied to the drug manufacturers. Based on these conflicting guidelines, one State chose to provide only utilization data to the drug manufacturers.

In order for States to establish accountability and controls over rebates, they must know how much is due from each drug manufacturer. We believe that the States should be required to compute the total amount owed by each drug manufacturer for each calendar quarter. The States should then be required to establish those amounts as accounts receivable in their formal accounting records.

Internal Controls Over Drug Rebate Funds

Our review of the eight States showed that virtually no internal controls have been established at the States over the rebate program funds. We noted significant departures from acceptable internal control procedures during our review. For example, we found that in one of the eight States the same employee prepared the billings, received the drug rebate payments from the manufacturers, established the initial records of cash received from the manufacturers, and posted the informal manufacturer accounts receivable records. In another of the eight States, we found two uncashed rebate checks totaling $6,495 in the files for which no accountability had been established, and of which the State's officials were unaware. The checks were between 2 and 4 months old.

We also found that four of the eight States did not maintain logs to establish immediate control over the rebate checks received from manufacturers. Failure to establish immediate control makes the checks particularly vulnerable to abuse. Of the remaining four States that did maintain logs of drug rebate payments received from manufacturers, none of the States reconciled the receipts deposited in the States' treasury accounts to those logs. Therefore, those States have no assurances

that all rebate payments received from drug manufacturers were deposited and used to reimburse HCFA for the Federal share of the rebate collections. Additionally, officials in seven of the eight States reviewed did not place restrictive endorsements upon the rebate checks at the time they were received. As a result, these States created an environment for abuse by failing to limit the negotiability of the rebate checks.

HCFA Lacks Management Information to Monitor and Manage the Rebate Program

Since HCFA did not have national totals on the amount of rebates billed drug manufacturers, and the value of uncollected or disputed amounts, we attempted to develop a nationwide statistical estimate at the State level for CY 1991. We were unable to make a statistical projection because much of the necessary information was unavailable or unreliable. Because we could not make statistical projections, we contacted 41 participating States and the District of Columbia and were able to obtain data from 30 States and the District of Columbia that appeared reasonable. Although OMB requires executive Departments to establish management systems over revenue, expenditures, and other assets, HCFA has not established such a system over the Medicaid drug rebate program.

Statistical Projections Not Possible

As noted, we were unable to develop a nationwide statistical estimate of the total amount of rebates billed, collected, uncollected or in dispute. We found that the States had not been required to gather financial data for the drug rebate program in a standardized manner and much of the needed information was either not available or not reliable. In fact, the billings calculated by two of the eight States were grossly inaccurate for at least one calendar quarter of the period under review. For example, two of the eight States' rebate billings were 248 and 320 percent of their total drug expenditures in the Medicaid program. In this particular quarter, the major problem was that the unit rebate amounts supplied by HCFA and used by the States to bill drug manufacturers was in error. Drug manufacturers recognized these erroneous unit rebate amounts and sent rebate checks to the States that were different than the State rebate billings. Specific reasons for the difference, however, were not provided by the drug manufacturers and some States did not correct their

billings. Another State only provided utilization data to manufacturers and did not calculate and bill dollar amounts. These problems would invalidate a nationwide statistical projection. The following table illustrates these problems:

State	Quarters Billed	Total Expenditures Reported (Millions)	Rebates Billed to Manufacturers (Millions)	Billings as a Percentage of Total Expenditures
A	4	$ 237.1	$ -0-	N/A
B	1	43.3	138.5	320%
C	1	13.3	33.0	248%

This table shows that the dollar amounts calculated as rebates billed to the manufacturers for these States, and for the quarters in question, were either greater than the total reported drug program expenditures for the same periods, or was not available because only utilization information was provided to the manufacturers.

Thirty States and the District of Columbia Report $111 Million Uncollected

Because we could not make national projections based on the data from these 8 States, we contacted the remaining 41 participating States and the District of Columbia to determine whether they could provide reliable information on the rebate amounts billed, collected, and what remained uncollected. We encountered considerable difficulty in obtaining this information. After we made numerous contacts over a period of 3 months, only 30 States and the District of Columbia were able to reply with data which appeared to be reasonable. We excluded the remaining States because they appeared to have data and systems problems similar to those that were identified above.

The data from the 30 States and the District of Columbia indicated, however, that $111 million *(or 23.4 percent)* of the $475 million in rebates billed by these States (after write-offs and adjustments) remain uncollected for CY 1991. These rebates were based on total expenditures of $3.1 billion in these 30 States and the District of Columbia. Also of significance is the fact that those States which were unable to provide us with usable data had Medicaid prescription drug program expenditures totaling $2.9 billion in CY 1991.

Therefore, the total amount of the actual rebates billed and uncollected can be expected to be substantially higher.

Reporting Mechanism Needed to Capture Consistent and Reliable Information

The OMB Circular A-127 requires executive Departments to establish management systems that provide for adequate financial information and effective control over revenue, expenditures, and other assets. However, HCFA has not established a reporting mechanism to capture consistent and reliable information from the States which would provide it with the means to effectively monitor and manage the drug rebate program. As a result, hundreds of millions of dollars in drug rebate funds are vulnerable to fraud, waste, and abuse.

Currently, with regard to the Medicaid drug rebate activities, States are required to report their drug expenditures and their rebate and interest collections on the Form HCFA-64 reports. Only the cash expenditures and collections in that particular calendar quarter are reported. The HCFA-64 reporting mechanism establishes overall accountability for cash expenditures and, in the case of the Medicaid drug rebate program, rebate receipts. In that regard, it serves a useful but limited purpose.

The Federal Government shares in the payment of Medicaid drug expenditures and the collection of revenues from rebates at an average of about 57 percent. It is, therefore, essential to HCFA's oversight responsibility that it ensure that States implement proper accountability and internal controls over drug rebate funds and that it obtain the information necessary to effectively monitor and manage the Medicaid drug rebate program.

Our review showed that the States had not established proper accountability and internal controls over drug rebate funds. As a result, we could not determine how much in drug rebates was due from the drug manufacturers, how much the manufacturers had paid or disputed by quarters, or whether the payments were being processed in a timely manner. The fact that we could not determine this information is indicative of the serious problems present in the accountability of rebate program funds. These noted problems are not easily identifiable based on the very limited information HCFA requires the States to provide. These problems clearly show that, to effectively fulfill its responsibilities to monitor and manage the Medicaid drug

rebate program, HCFA needs much more information than it currently requires the States to provide. At a minimum, the collection of the following type of information is essential:

- **Reporting of Status of Rebate Billings**

  There is no requirement or mechanism for reporting the total dollar amounts billed, adjusted, disputed, and/or written-off for the Medicaid drug rebate program. This data should be collected on a current and cumulative basis by quarter for each CY. After the first year, cumulative yearly totals should be carried forward and summarized until such time that there are no rebates outstanding for the period. This would provide HCFA with information on the status of State collections efforts and an aging of outstanding balances so that it can identify those States which are not following "due diligence" in their collection activities.

- **Documentation and Approval of Write-Offs**

  There is no requirement or mechanism for States reporting to HCFA or documenting in their files, the basis of their Medicaid rebate write-offs. Considering the extent of Federal sharing in the payment of drug expenditures and the rebates received, we believe that HCFA should establish limits on the dollar amounts that can be written-off by the States without HCFA's prior approval.

  In addition to providing this type of information, we believe that the States should also maintain, for reporting purposes, data on the status of rebate billings by individual drug manufacturers. This information needs to be maintained so that HCFA, as part of its oversight responsibility, can identify problem drug manufacturers based upon the summary data received from all States.

RECOMMENDATIONS

We recommend that HCFA ensure that States implement accounting and internal control systems in accordance with applicable Federal regulations for the Medicaid drug rebate program. Such systems should provide for accurate, current, and complete disclosure of drug rebate transactions and provide HCFA with the financial information it needs to effectively monitor and manage the Medicaid drug rebate program. We also recommend that HCFA include a State reporting mechanism that will capture consistent and reliable data from the States on rebate transactions. This should include capturing amounts billed, collected, written-off, and the amount that remains uncollected and/or in dispute. In addition, HCFA should establish a limit on the dollar amount of rebates which can be written-off without HCFA's approval.

HCFA COMMENTS

The HCFA responded to our draft report in a memorandum dated April 5, 1993. In that memorandum, HCFA agreed with our recommendation for ensuring that the States implement accounting and internal control systems and also agreed with our recommendation for implementing a reporting mechanism to capture consistent and reliable data from the States on rebate transactions. While HCFA agreed with our recommendation for establishing a limit on the dollar amount which can be written-off without HCFA's approval, we believe some clarification is needed. (See the Office of Inspector General response for more discussion of the dollar limits that can be written-off.) Additionally, technical comments regarding the report language were provided. We have considered those technical comments and have made changes to the report where appropriate. (See the Appendix for the complete text of the Acting Administrator's comments.)

OIG RESPONSE

We recommended that HCFA establish a limit on the dollar amount for rebates which can be written-off without HCFA's approval. The HCFA replied that policy has been established in Medicaid Drug Rebate Program Release Number 19 for States to write-off disputed rebate amounts under $10,000 per manufacturer, under $1,000 per product code or rebate amounts requested of $10 or less. While this policy may imply that amounts over the above dollar limits may require HCFA approval for write-offs, we believe clarification is needed to specifically identify the HCFA's responsibilities in the write-off process.