

**Memorandum**

APR 23 1992

Date

From

Richard P. Kusserow  
Inspector General

Subject

Medicaid Drug Rebates: Improvements Needed in the Health Care Financing Administration's Procedures to implement the Medicaid Drug Rebate Program (A-06-91 -00102)

To

William **Toby**  
Acting Administrator  
Health Care Financing Administration

Attached is our final management advisory report on the effectiveness of the Health Care Financing Administration's (HCFA) procedures to implement the Medicaid drug rebate provisions contained in the Omnibus Budget Reconciliation Act of 1990. This review identified weaknesses in **HCFA's** controls over the implementation of the rebate program.

The HCFA receives, from manufacturers, pricing information that includes the average manufacturers price (AMP) and best price. From this information, a unit rebate amount (**URA**) for each drug is computed and furnished to the States for their use in calculating the rebate due from a particular drug manufacturer. Our review identified 200 different drug codes in 3 States involving 22 different drug manufacturers where errors in the AMP, base AMP, and best price resulted in the **URAs** being overstated. At least nine States, **after** multiplying the **URAs** times their utilization data to determine the amount of rebates due from the manufacturers, compared the drug rebate amounts to their paid claims file and found that the rebate amounts were dramatically overstated compared to the actual drugs dispensed. Although 33 States expressed concern to us about the accuracy of the **URAs** furnished by HCFA, they still billed the drug manufacturers. Eleven States, at the time of our review, had not billed any drug manufacturers for rebates.

The HCFA has primary responsibility for the implementation of the rebate program. In our opinion, HCFA needs to establish controls and perform adequate analyses to confirm the accuracy of the pricing information supplied by the drug manufacturers. Pricing errors must be monitored and corrected, where

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appropriate, by HCFA before **URAs** are supplied to the States. The HCFA also needs to monitor the timeliness of the rebates through the States and assure that the States are billing the manufacturers timely.

We are recommending that HCFA establish the necessary systems edits and program controls that will help provide assurance that pricing data supplied to the States is accurate and timely. We are also recommending that HCFA consider imposing civil monetary penalties on those manufacturers that continue to provide inaccurate pricing information. In its response to our draft report, HCFA agreed with our recommendations to establish the necessary systems edits and program controls. The HCFA also will consider imposing civil monetary penalties on those manufacturers who knowingly submit incorrect data.

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 **FTS** 646-7104. Copies of this report are being sent to other interested top Department officials.

Attachment

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICAID DRUG REBATES:  
IMPROVEMENTS NEEDED IN THE HEALTH  
CARE FINANCING ADMINISTRATION'S  
PROCEDURES TO IMPLEMENT THE  
MEDICAID DRUG REBATE PROGRAM**



**Richard P. Kusserow  
INSPECTOR GENERAL**

A-06-91-00102

**Memorandum**

Date APR 23 1992  
From Richard P. Kusserow  
Inspector General  
Subject Medicaid Drug Rebates: Improvements Needed in the Health Care Financing Administration's Procedures to Implement the Medicaid Drug Rebate Program (A-06-91 -00102)  
To

William Toby  
Acting Administrator  
Health Care Financing Administration

This final management advisory report is to provide you with the results of our review on the effectiveness of procedures established by the Health Care Financing Administration (HCFA) to implement the Medicaid drug rebate provisions contained in the Omnibus Budget Reconciliation Act of 1990 (OBRA '90). Our review identified weaknesses in HCFA's controls over the implementation of the rebate program.

The HCFA receives, from manufacturers, pricing information that includes the average manufacturers price (AMP)<sup>1</sup>, base AMP<sup>2</sup> and, for single-source and innovator multiple-source drugs, the best price<sup>3</sup>. From this information, a unit rebate amount (URA) for each drug is computed and furnished to the States for their use in calculating the rebate due from a particular drug manufacturer. Our review identified 200 different drug codes in 3 States involving 22 different drug

**33 STATES EXPRESS CONCERN  
ABOUT THE ACCURACY OF THE  
UNIT REBATE AMOUNTS SUPPLIED  
BY HCFA**

<sup>1</sup>The average price paid to a manufacturer by retail pharmacies or by wholesalers for drugs distributed to the retail pharmacy class of trade.

<sup>2</sup>Base AMP is computed, as of October 1, 1990, from the average unit price paid to manufacturers during the July 1, 1990 through September 30, 1990 calendar quarter. The base AMP for new drugs marketed after October 1, 1990 means the AMP for the first day of the first full month in which the drug was marketed.

<sup>3</sup>Best price for single-source drugs or innovator multiple-source drugs is the lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or U. S. governmental entity.

manufacturers where errors in the AMP, base AMP, and best price resulted in the **URAs** being overstated. At least nine States, after multiplying the **URAs** times their utilization data to determine the amount of rebates due from the manufacturers, compared the drug rebate amounts to their paid claims file and found that the rebate amounts were dramatically overstated compared to the actual drugs dispensed. Although 33 States expressed concern to us about the accuracy of the **URAs** furnished by HCFA, they still billed the drug manufacturers. Eleven States, at the time of our review, had not billed any drug manufacturers for rebates.

The HCFA has primary responsibility for the implementation of the Medicaid drug rebate program. In our opinion, HCFA needs to establish controls and perform adequate analyses to confirm the accuracy of the pricing information supplied by the drug manufacturers. Pricing errors must be monitored and corrected, where appropriate, by HCFA before **URAs** are supplied to the States. The HCFA also needs to monitor the timeliness of the rebates through the States and assure that the States are billing the manufacturers timely.

We are recommending that HCFA establish the necessary systems edits and program controls that will help provide assurance that pricing data supplied to the States is accurate and timely. We are also recommending that HCFA consider imposing civil monetary penalties (CMP) on those manufacturers that continue to provide inaccurate pricing information.

In its response to our draft report, HCFA agreed with our recommendations for establishing systems edits and program controls to assure that pricing data supplied to the States is accurate and timely. The HCFA will also only consider imposing **CMPs** for those manufacturers which knowingly supply incorrect data. See pages 10 and 11 of this report for our complete analysis of HCFA's comments. The text of HCFA's response is included as an attachment to this report.

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## BACKGROUND

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The Congress enacted section 4401 of **OBRA '90** to allow States to receive rebates for drug purchases. 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). A total of 407 manufacturers have entered into agreements to provide the State agencies with quarterly rebates in order to participate in the Medicaid

program. In return, States will pay for all of the manufacturers' covered outpatient drugs used by their Medicaid recipients. The rebate program was implemented, effective January 1, 1991.

The manufacturers are required to furnish HCFA with drug pricing information for all their covered outpatient drugs within 30 days after the end of each calendar quarter. This pricing information identifies the drug product by:

- o National Drug Code (NDC), an 11 digit number maintained by the Food and Drug Administration (FDA) that identifies the manufacturer, product or formulation, and package size for each drug;
- o quarterly AMP, the average unit price paid by wholesalers in the States for the manufacturer's drugs distributed to the retail pharmacy class of trade during the calendar quarter of the rebate; and
- o quarterly best price, the lowest price at which a manufacturer sold the single-source and innovator multiple-source drugs' to any purchaser in the United States in any pricing structure for that calendar quarter.

During the first calendar quarter of the rebate program and when a new drug is marketed, manufacturers are also required to supply base AMP data. The base AMP, as of October 1, 1990, is computed from the average unit price paid to manufacturers during the July 1, 1990 through September 30, 1990 calendar quarter. The base AMP for drugs marketed after October 1, 1990 is the AMP for the first day of the first full month in which the drug was marketed.

The HCFA uses the manufacturers' information to calculate the **URA** for each drug code and furnishes the unit data to the States. The States, in turn, multiply the **URAs** times the total dosage units (tablets, capsules, ounces, etc.) dispensed for each Medicaid drug product and bill the manufacturers for the resultant rebate. **The** States must submit billing information to the manufacturers within 60 days after the end of each calendar quarter. The manufacturers then have 30 days to make rebate payments to the States.

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<sup>4</sup>"Single-source drug' is defined by OBRA '90, section 1927, to mean a covered outpatient drug which is produced or distributed under an original new drug application approved by FDA, including a drug product marketed by any cross-licensed producer or distributor operating under the new drug application. 'Innovator multi-source drug' is defined to mean a multiple-source drug that initially was marketed under an original new drug application approved by FDA.

The States were originally required to provide utilization data to the manufacturers by May 30, 1991. The HCFA extended that date to July 30, 1991. The HCFA also gave the States the option of billing the drug manufacturers by using the **URAs** supplied by HCFA or by simply providing utilization data to the manufacturers without actually preparing a billing.

The **OBRA '90** legislation includes penalty provisions for manufacturers, wholesalers, or direct sellers that provide false information on drug pricing or fail to provide the information timely. Under the provisions of the rebate agreements signed by the manufacturers, if the manufacturer knowingly provides false information, HCFA may impose **CMPs** on a manufacturer up to \$100,000 for each violation and a CMP for the manufacturer's failure to provide timely information on AMP, best price, and base data AMP. The amount of the penalty is increased by \$10,000 for each day in which such information has not been provided.

The HCFA is required to implement the Medicaid drug rebate program and monitor the timeliness of the rebate payments through the States. If the manufacturer believes the State's drug invoice information is not correct, it can deny payment for the amount in dispute. After the dispute is resolved, the balance due plus a reasonable rate of interest, must be paid.

The HCFA has strengthened its implementation procedures for the drug rebate program by issuing a series of instructions to the manufacturers and the States. These instructions, called Release Memorandums, deal with a number of topics and provide technical assistance to the rebate program participants.

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#### REVIEW METHODOLOGY

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The objective of our review was to determine whether the drug pricing information sent to the States was reliable and whether the States successfully met the July 30, 1991 billing deadline. The review did not include an evaluation of the accuracy of the drug utilization data submitted by the States, nor did it evaluate the timeliness of the manufacturers' rebate payments to the States.

As part of the review, we contacted 50 State Medicaid agencies representing 49 States and the District of Columbia. One State, Arizona, is exempted from the Medicaid drug rebate program. Each State provided information to us on: (1) the rebate billings made to the manufacturers and (2) problems encountered in making these billings.

We reviewed the Medicaid drug rebate provisions of OBRA '90 and the standard rebate agreement between HCFA and the drug manufacturers. We also contacted HCFA personnel and reviewed correspondence related to its readiness and ability to implement and monitor rebate payments through the States. Additionally, we reviewed Medicaid drug rebate program Release Memorandums issued by HCFA to the States and participating drug manufacturers regarding unit rebate calculations. We also interviewed State officials charged with administering the Medicaid Prescription Drug Program.

We obtained comparative data from nine States showing rebates billed to manufacturers and expenditure data from the States' paid claims file for each drug code. We performed detailed analyses of three of the nine States.

Our review was performed during August 1991 with the data representing conditions, as of August 28, 1991.

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## RESULTS OF REVIEW

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Our review identified two areas for which improvements are needed in **HCFA's** implementation of the rebate program.

First, some manufacturers provided erroneous AMP and best price data to HCFA. The HCFA then used that data to calculate **URAs** that were subsequently sent to the States to use in billing the manufacturers. The HCFA did not, in our opinion, perform adequate systems edits to identify aberrant pricing errors and as a result, States' billings to manufacturers have been overstated. Second, 11 States, at the time of our review, had not billed the manufacturers for rebates, even though the deadline for providing the information was July **30**, 1991. Two of these States did not know when they would provide the manufacturers with billing information. The HCFA needs to monitor the timeliness of the States' billings to manufacturers to assure that the Medicaid drug program is receiving program revenue as well as interest that would be earned on the revenue.

## UNIT REBATE TAPES SUPPLIED BY HCFA WERE INCORRECT

Thirty-three States expressed concern about the accuracy of the **URAs** provided by HCFA. Upon receiving the AMP and best price information from the manufacturers, HCFA calculated **URAs** for each drug product. Data tapes showing the **URAs** were then transmitted to the States. Upon receipt, at least nine States applied the **URAs** to their utilization data for each drug and found that the

rebates due from the manufacturers were greater, for some drugs, than the total amount the States reimbursed all pharmacists for the drugs.

We identified 200 different drug codes in 3 States involving 22 different drug manufacturers where the **URAs** resulted in billings to the manufacturers which were greater than the amount these States paid for the drugs. One State provided us with billing information for one manufacturer that showed it owed the State a rebate of \$170,267. Information in the State's paid claims file showed that it only paid \$2,477 for all of that manufacturer's drugs.

We examined pricing information provided to us by three States and found instances where the amount of the specific rebate was dramatically overstated compared to the actual Medicaid payment for the drug dispensed. For example, our review showed instances where the rebate amount was as much as **400** times the amount the States reimbursed the pharmacists for the drugs. The following are examples of comparisons made by the States of Louisiana, Rhode Island, and Vermont.

<b>EXAMPLES OF REBATES COMPARED TO AMOUNTS REIMBURSED BY STATE</b>				
<u>State</u>	<u>Drug</u>	<u>Calculated Rebate</u>	<u>Amt. Reimb. by State</u>	<u>Amt. Rebate &gt; Reimb.</u>
LA	Drug A	\$ 74,700.00	\$ 195.78	382 times
	Drug B	72,548.50	7,401.81	10 times
	Drug C	34,019.22	3,851.22	9 times
	Drug D	31,462.67	2,917.86	11 times
RI	Drug E	\$101,014.83	\$2,377.53	42 times
	Drug F	78,362.40	3,738.82	21 times
	Drug A	53,640.00	126.87	423 times
	Drug G	18,919.37	1,616.13	12 times
VT	Drug F	\$100,336.84	\$5,073.40	20 times
	Drug E	49,799.37	1,260.66	40 times
	Drug A	49,500.00	119.18	415 times
	Drug H	32,577.67	2,668.22	12 times

We compared HCFA's URAs to published retail prices<sup>5</sup> per unit and found that if HCFA had established procedures to edit manufacturers' AMP, base AMP, and best price, it could have identified and possibly prevented pricing errors. Manufacturers provided this erroneous data to HCFA for its calculation of URAs. As a result, there were significant errors in the URAs. For example, HCFA calculated the URA for one drug to be \$33.50 per capsule when the published retail price per unit for that drug was \$2.50.

EXAMPLES OF UNIT REBATE AMOUNTS AS COMPARED TO PUBLISHED RETAIL PRICES			
Drug	Rebate Amt. Per Unit	Published Retail Price Per Unit	Unit Size
Drug 1	\$33.50	\$2.50	Capsule
Drug 2	7.14	.05	Tablet
Drug 3	6.76	.46	Capsule
Drug 4	3.70	.59	Tablet
Drug 5	2.66	.53	Tablet
Drug 6	1.95	.34	Tablet

The objective of our review was to obtain an early indication of whether the drug rebate program was being implemented adequately. Although we have yet to analyze all the associated causes with the early problems in calculating the rebates, some States speculate that the cause of these incorrect rebate amounts was the method used in calculating the unit sizes. The OBRA '90, as implemented by HCFA, required that the rebate amount be determined on the lowest possible unit size, for example, on tablets rather than on a container size. If the drug manufacturers provided rebate information, based on a unit size different from what State agencies used, the resulting rebate calculations could be considerably over or understated.

The HCFA recognized in its Release Memorandum No. 2, dated August 9, 1991, that some manufacturers were having difficulty with package sizes where the smallest dispensable number of units was a package size holding more than one

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<sup>5</sup>Published retail prices per the 1991 Drug Topics Red Book.

tablet, ounce, gram, etc. The HCFA stated that for these unit types, where the NDC is for a package size holding more than one tablet, etc., and the pharmacist is expected to dispense the entire container, the unit would be the package size instead of the smallest dispensable unit.

**With** the issuance of Release Memorandum No. 2, we believe that HCFA has taken a step in the right direction. However, we also believe that HCFA needs to establish edits and controls in its system that will identify and allow further review of aberrant pricing information supplied by the manufacturers.

The HCFA should also require and set a time frame for the drug manufacturers to resubmit corrected data for previously reported inaccurate pricing information. Additionally, as the resubmitted pricing information is analyzed, HCFA should identify those manufacturers which continue to provide inaccurate data and, if warranted, institute CMP authorities on them for providing inaccurate or untimely data. By its Release Memorandum No. 1, dated June 28, **1991**, HCFA provided each manufacturer with a copy of the drug information it had received from them, and requested that they review the data to ensure its accuracy so that it could be provided to the States for billing purposes. Based upon the number of problems that have since been identified with this data, it is evident that the manufacturers have not taken timely action on **HCFA's** request and, as a result, inaccurate data has been provided to the States.

#### STATES EXPERIENCE PROBLEMS IN BILLING DRUG MANUFACTURERS

Our review showed that the States were experiencing problems in providing billing information to drug manufacturers for rebates. During the **9-day** period ending August 13, 1991, we contacted 49 States and the District of Columbia to determine whether they had provided drug manufacturers with billing information. Through their responses, we found that 17 States had not provided billing information to the manufacturers. The deadline for submission of rebate invoices by States to drug manufacturers was extended by HCFA from May 30, 1991 to July 30, 1991.

On August 28, 1991, we followed-up with the 17 States who had not previously provided drug manufacturers with billing information and found that 11 States still had not sent in rebate information. The following table summarizes the 11 States' billing status and their related problems.

State	Systems Problems	Problems with HCFA's Data	Anticipated Billing Date
Alaska	X		September 2, 1991
Delaware	X		October 1991
Illinois		X	Unknown
Kansas	X		September 1991
Michigan	X		September 1991
Missouri		X	August 30, 1991
Nebraska	X		October 1991
North Carolina	X		Sept. or Oct. 1991
Texas		X	September 13, 1991
Washington		X	September 1991
West Virginia	X		Unknown

The above table shows that two States did not know when their billing information would be completed, and three States planned to provide their first quarter billing information as late as October 1991, even though the information was required no later than July 30, 1991. The table also shows that seven States have not provided billing information because of their own systems problems, and four States have not provided billing information because of reported problems with the **URA** data supplied by HCFA. In discussions with HCFA on October 23, 1991, we were informed that nine States still had not billed manufacturers for rebates.

We believe HCFA should monitor the status of States' billings on a continuous basis in order to assure that the billing information is provided to drug manufacturers within the required time frames. During our review, through discussions with HCFA officials, we noted that HCFA did not actually know how many States had provided billing information to the manufacturers.

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### CONCLUSIONS AND RECOMMENDATIONS

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In our opinion, HCFA needs to improve its controls over the accuracy of **URA** data and the timeliness of the rebate billing process. Because gross errors exist in the **URAs** supplied by HCFA to the States, disputes between the States and the manufacturers will no doubt become a serious detriment to the implementation of

the rebate program. Also, the Medicaid drug program is being deprived of program revenue as well as interest that would be earned on the revenue due to delays in receiving the rebates from the manufacturers. We, therefore, recommend that HCFA:

- o Establish a system of edits that will identify and allow further review of aberrant pricing information supplied by the manufacturers.
- o Require the drug manufacturers to resubmit corrected data for the first calendar quarter of 1991. As the drug submission data is analyzed, identify manufacturers that continue to provide incorrect pricing data and institute CMP authorities.
- o Monitor the status of States' quarterly billings to manufacturers in order to assure that they are completed within required time frames.

#### HCFA'S COMMENTS

in its response dated February 18, 1992, HCFA stated that our recommendations indicated misunderstandings of how the rebate program operates, what problems exist, and how to correct perceived problems.

However, HCFA then proceeded to agree with our recommendations for:

- o establishing a system of edits for identifying and allowing further review of aberrant pricing information supplied by the manufacturers,
- o requiring the drug manufacturers to resubmit corrected pricing data for the first quarter of 1991, and
- o monitoring the status of States' quarterly billings to manufacturers in order to assure that they are completed within required time frames.

Additionally, HCFA believed that we recommended that **CMPs** be automatically initiated against drug manufacturers who continue to provide incorrect data. The HCFA responded that it will consider imposing a CMP when it is decided that a manufacturer knowingly supplies incorrect data, but that **CMPs** will not be automatically initiated against manufacturers.

OIG RESPONSE

The HCFA basically agreed with our specific recommendations. Accordingly, we do not understand the basis for its statement that our recommendations indicate our misunderstandings of how the rebate program operates. We have had several briefings with HCFA officials to apprise them of our current and future audit efforts and we will continue to do so. And, we welcome any input HCFA would like to provide.

**The** HCFA implied in its response that the majority of the aberrant prices identified in this report were the fault of one large company which marketed drug products under five different labeler codes. The HCFA also stated that although our recommendations are based on first quarter data, we used second quarter pricing information. This is not true. We analyzed data obtained from a number of States representing 23 manufacturers (labelers) and cited examples in this report representing **5** different labelers. These labelers were not owned by one large company and are not the five different labelers cited in **HCFA's** response. Additionally, all data cited in this report related to the first quarter of 1991. We will share this information with HCFA under separate cover from this report.

Regarding the imposition of **CMPs**, we did not intend to imply that such penalties be imposed automatically when manufacturers provide incorrect pricing data. We agree that HCFA should consider imposing **CMPs** only when manufacturers "knowingly" provide false information.

We are continuing our reviews on issues involving the implementation of the Medicaid drug rebate program. We will report further to you on the results of these reviews.