DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date NOV 16 1992

From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program (A-06-91-00092)

To William Toby, Jr.
Acting Administrator
Health Care Financing Administration

The attached final management advisory report is to provide you with the results of our review of the need for the Health Care Financing Administration (HCFA) to provide additional guidance to drug manufacturers to better implement the rebate program. This report is part of a series of reviews we have underway concerning the Medicaid drug rebate program.

We reviewed the average manufacturer price (AMP) and best price calculation policies of four major U.S. drug manufacturers. Although we found that best price determinations were acceptable, manufacturers' calculations of AMP were inconsistent. We found major variations in the methods used by manufacturers to determine AMP. The variations occurred because HCFA has not provided instructions in sufficient detail to manufacturers on acceptable methods for calculating AMP. Accordingly, we were unable to evaluate the acceptability of the AMP calculations.

The calculation method used impacts on the AMPs, the resulting rebates, and the accuracy of the pricing information provided to HCFA. Additionally, the manufacturers can be adversely impacted because of the lack of specific instructions for computing AMP. Those manufacturers that attain a high degree of accuracy in computing AMPs will incur higher administrative costs than those that do not. This is not equitable to the manufacturers and affects the reliability, consistency, and integrity of the AMP data.

We also found major differences in the manufacturers' policies on the Office of Inspector General's (OIG) right of access to company records and the length of time records relating to drug rebates are retained. Again, these differences occurred because HCFA has not provided specific instructions to manufacturers regarding access to or retention of rebate records.

We are recommending that HCFA: (1) survey drug manufacturers to identify the various calculation methods being used to develop the AMP and (2) provide more specific policies based on the survey results for calculating AMP which would protect the interests of the Government and which would be equitable and the least burdensome to the manufacturers. We are also recommending that HCFA establish records access and retention requirements for the drug manufacturers.

The HCFA did not concur with our recommendations regarding manufacturers' AMP calculations. However, HCFA was not responsive to the issues raised in our report. The HCFA took the position that the drug rebate law and the rebate agreements have already established a methodology for computing AMP. We disagree. The law and rebate agreements define AMP in very broad terms but do not provide a specific methodology for ensuring uniform and accurate calculations of AMP by the manufacturers. Although HCFA stated that it has responded to many written requests on AMP calculations, there is nothing in writing that further defines how AMP should be computed. The variations we found at the manufacturers showed that the AMP definition is subject to considerable interpretation and that HCFA needs to establish specific written policies for computing AMP.

The HCFA stated that it has undertaken numerous activities since the enactment of the law to assure uniform and correct AMP calculations. For example, HCFA believes that with its guidance, manufacturers have increasingly been able to correctly compute AMP. However, HCFA's comments did not specify how AMP should be calculated or how the variations we found at the manufacturers should be handled.

The HCFA concurred, in part, with our recommendation for the OIG and other oversight authorities to have unrestricted access to manufacturers' records but stated that it must consider the confidentiality provisions of the manufacturers. We believe that current law and OIG policy protects the rights of the manufacturers.

The HCFA is proposing a 3-year record retention period which is in agreement with the recommendation in our final report.

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. We would appreciate receiving your comments within 60 days from the date of this memorandum.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICAID DRUG REBATES: THE HEALTH CARE FINANCING ADMINISTRATION NEEDS TO PROVIDE ADDITIONAL GUIDANCE TO DRUG MANUFACTURERS TO BETTER IMPLEMENT THE PROGRAM

NOVEMBER 1992 A-06-91-00092

Memorandum

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From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program (A-06-91-00092)

To William Toby, Jr.
Acting Administrator
Health Care Financing Administration

This final management advisory report provides you with the results of our review of selected drug manufacturers' methods used to determine average manufacturer prices (AMP) and best prices under the Medicaid drug rebate program. The AMP calculations and best price are critical components of the rebate program. This report is one of a series of reports on the Medicaid drug rebate program that we have issued or will be issuing to you in the near future.

The objectives of our review were to evaluate the methods used by selected manufacturers to determine AMP and best price and verify the accuracy of pricing information supplied to the Health Care Financing Administration (HCFA) for use in calculating manufacturer rebates. We will also be issuing, under separate cover, an audit guide to HCFA for use in having audits of manufacturers performed.

MANUFACTURERS NEED MORE SPECIFIC INSTRUCTIONS FOR CALCULATING AMP

Although we found that best price determinations were acceptable, manufacturers' calculations of AMP were inconsistent. We found major variations in the methods used by manufacturers to determine AMP. For example: (1) one manufacturer based the calculations on gross sales to wholesalers, (2) two manufacturers based the calculations on net sales to wholesalers, and (3) one manufacturer specifically identified sales at the retail level for its calculations. These variations occurred because HCFA has not provided sufficiently detailed instructions to manufacturers on acceptable methods for calculating AMP for drugs distributed to retail pharmacies. Accordingly, we were unable to evaluate the acceptability of the AMP calculations.

The calculation method used impacts on the AMPs, the resulting rebates, and the accuracy of the pricing information provided to HCFA. Additionally, the manufacturers can be adversely impacted because of the lack of specific instructions for computing

AMP. Those manufacturers that attain a high degree of accuracy in computing AMPs will incur higher administrative costs than those that do not. This is not equitable to the manufacturers and affects the reliability, consistency, and integrity of the AMP data provided to HCFA for computing rebate amounts.

We also found major differences in the manufacturers' policies as to the Office of Inspector General's (OIG) right of access to company records and the length of time records relating to drug rebates should be retained. These differences occurred because HCFA has not provided specific instructions to manufacturers regarding access to or retention of rebate records. These policy differences could impact on the ability to conduct future audits of drug manufacturers.

We are recommending that HCFA: (1) survey other manufacturers to identify the various calculation methods used to determine AMP, (2) develop and disseminate to interested parties a more specific policy based on the survey results for calculating AMP which would protect the interests of the Government and which would be equitable to the manufacturers, (3) establish requirements which provide for unrestricted access by Federal oversight agencies to manufacturers' records which pertain to the drug rebate program, and (4) establish requirements which direct drug manufacturers to retain rebate records for a period of 3 years which is consistent with other record retention requirements of Medicaid.

In its September 3, 1992 reply to our draft report, HCFA stated that it did not concur with our recommendations regarding manufacturers' AMP calculations. However, HCFA was not responsive to the issues raised in our report. The HCFA contended that the drug rebate law and the rebate agreements had already established a methodology for computing AMP. We disagree. The law and rebate agreements defined AMP in very broad terms but did not provide a specific methodology which ensured uniform and accurate calculations of AMP by the manufacturers. Although HCFA stated that it has responded to many written requests on AMP calculations, HCFA did not provide anything in writing to us that further defines how AMP should be computed. The variations we found at the manufacturers showed that the AMP definition is subject to considerable interpretation and that HCFA needs to establish specific written policies for computing AMP.

The HCFA stated that it has undertaken numerous activities since the enactment of the law to assure uniform and correct AMP calculations. For example, HCFA believes that with its guidance manufacturers have increasingly been able to correctly compute AMP. However, HCFA's comments did not specify how AMP should be calculated or how the variations we found at the manufacturers should be handled.

The HCFA concurred, in part, with our recommendation for the OIG and other oversight authorities to have unrestricted access to manufacturers' records but stated that it must consider the confidentiality provisions of the manufacturers. We believe that current law and OIG policy protects the rights of the manufacturers.

The HCFA is proposing a 3-year record retention period which is in agreement with the recommendation in our final report. See page 12 of this report for a more complete discussion of HCFA's comments and the OIG's response to the comments. The complete text of the Acting Administrator's comments is included as Appendix A.

BACKGROUND

On November 5, 1990, the Congress enacted legislation (effective January 1, 1991) to require drug manufacturers to pay States rebates for outpatient prescription drugs through a drug rebate program. This legislation, section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), added a new section 1927 to the Social Security Act which requires drug manufacturers to enter into and comply with rebate agreements with the Secretary in order for States to receive Federal financial participation for a manufacturer's covered outpatient drugs. Responsibility for the rebate program is shared among the drug manufacturers, HCFA, and the States.

Drug manufacturers are required to provide a listing to HCFA of all covered outpatient drugs. In addition, the manufacturers are required to report their AMP to HCFA for each covered outpatient drug for a base period. Then, on a quarterly basis, the manufacturers report the AMP and the best price for each covered outpatient drug to HCFA.

The HCFA calculates a unit rebate amount for each drug based on the AMP and best price data from the manufacturers and the applicable Consumer Price Index-Urban (CPI-U). The unit rebate amount is the per unit (i.e. per pill) dollar value that should be paid by the manufacturer to the States for each unit of a specifically dispensed drug. It consists of two elements: (1) a basic rebate amount (payable on all covered outpatient drugs) and (2) an additional rebate amount applicable to single source or innovator drugs (the amount by which the increase in the AMP exceeds the increase in the CPI-U from the base period to the month before the calendar quarter of the rebate).

The unit rebate amounts are provided by HCFA to the States to be used to calculate the actual rebate amounts owed by each manufacturer. The States are responsible for maintaining the number of units of each drug that is dispensed (drug utilization data) by manufacturer for each covered drug. The States multiply the unit rebate amounts by the number of units dispensed to determine the actual rebate amounts due from a manufacturer.

METHODOLOGY

The objectives of our review were to: (1) evaluate the methods used by selected manufacturers to determine AMP and best price and (2) verify the accuracy of pricing information supplied to HCFA by the drug manufacturers.

We conducted on-site reviews at three major drug manufacturers which elected to participate in the Medicaid drug rebate program. We selected the first manufacturer because it supplied innovator brand name products. We selected the second manufacturer because it supplied generic or multiple source products and the third was selected because it supplied both brand name and generic products and marketed a number of products in cream, ointment, and liquid forms. Our selection of manufacturers was based on our analysis of HCFA's "Combined Baseline and Quarterly Pricing Reports." We also obtained information on another major manufacturer that voluntarily supplied us with information on its pricing policies for the drug rebate program. We did not perform an on-site review or independently verify the information obtained from the fourth manufacturer.

Section 1927 (b)(3)(D) of the Social Security Act, as added by OBRA '90, prohibits the Secretary from disclosing prices charged by the manufacturer or the identity of the manufacturers reviewed. Therefore, we are not disclosing the names or locations of the manufacturers reviewed.

To accomplish our objectives, we:

- reviewed the provisions of OBRA '90 pertaining to Medicaid covered outpatient drugs under drug rebate agreements with manufacturers.

- reviewed HCFA's Medicaid drug rebate program releases to State Medicaid agencies and participating drug manufacturers.

- reviewed other drug data used in the pricing computation such as HCFA's "Combined Baseline and Quarterly Pricing Reports," drug manufacturers' pricing data including sales journal entries and transactions/trade codes used in calculating base quarter AMP and best price, contracts with buying groups/government agencies, chargeback invoices, and State Medicaid drug rebate billing invoices.

- contacted HCFA personnel, interviewed drug manufacturer officials responsible for administering the prescription drug rebate program, and interviewed State pharmacy consultants involved with the prescription drug program.

Our review was performed from August to December 1991 at three drug manufacturers and HCFA central office in Baltimore, Maryland.

RESULTS OF REVIEW

Although we found that best price determinations were acceptable, manufacturers' calculations of AMP were inconsistent. The four drug manufacturers reviewed used three different methods to determine AMP. For example, one manufacturer based its calculations on gross sales to wholesalers, two manufacturers based their calculations on net sales to wholesalers, and one manufacturer specifically identified sales at the retail level for its calculations. These variations occurred because HCFA has not provided sufficiently detailed instructions to manufacturers on acceptable methods for calculating AMP. Accordingly, we were unable to evaluate the acceptability of the AMP calculations. The method used impacts on the AMPs, the resulting rebates, and the accuracy of the pricing information provided to HCFA. Additionally, the manufacturers can be adversely impacted because of the lack of specific instructions for computing AMP. Those manufacturers that attain a high degree of accuracy in computing AMPs will incur higher administrative costs than those that do not. This is not equitable to the manufacturers and affects the reliability, consistency, and integrity of the AMP data.

We also found significant differences among manufacturers' policies on the OIG's right of access to company records and the length of time records relating to drug rebates are retained. These differences occurred because HCFA has not provided specific instructions to manufacturers regarding access to or retention of rebate records. These policy differences could impact on the ability of oversight agencies to conduct future audits of drug manufacturers.

GUIDANCE NEEDED FOR CALCULATING MANUFACTURERS' AMP

The OBRA '90 legislation defines AMP as the average price which wholesalers pay to manufacturers for drugs distributed to retailers in the United States. Additionally, the rebate agreements between the Secretary of Health and Human Services and individual manufacturers instruct manufacturers to consider the following in computing AMP:

- Exclude direct sales to hospitals, health maintenance organizations, and drug relabelers.
- Exclude Federal supply schedule prices.
- Use cash discounts and all other price reductions.

Retail Sales

We interpret OBRA '90 and HCFA's rebate agreements to mean that manufacturers must determine AMP based on the drugs actually distributed to retail pharmacies. However, OBRA '90 and HCFA's rebate agreements do not specify the extent to which a manufacturer should go to identify these drugs. Manufacturers normally sell to wholesalers and are unaware of how many of their products wholesalers actually distribute to retailers.

Chargebacks

The rebate agreements and HCFA instructions also do not address how "chargebacks" are to be handled in determining AMP. Manufacturers often enter into arrangements with buyers such as hospital groups; whereby, the groups purchase drugs under contract from the manufacturers at prices that are lower than wholesalers' prices. Although a contract is between a manufacturer and a buying group, the buyer actually takes delivery from a wholesaler. Accordingly, the purchase and sale of the drugs go through the wholesaler's books and records. Since the wholesaler's sales price to a buying group is less than the wholesaler actually paid the manufacturer, the wholesaler receives a monetary credit from the manufacturer known as a chargeback. Chargebacks are very common and their treatment impacts the AMP calculations.

Returns

We believe that the rebate agreements suggest that returns should be considered but do not specify how these should be handled. For example, the price (original or current) at which returns should be valued is not specified. Sales returns are common and can impact on the computation of AMP.

Different AMP Calculations

In the absence of specific guidance from HCFA, the manufacturers we reviewed have used at least three different methods to determine AMP. The following is a description of each method.

Gross Sales To Wholesalers. One manufacturer used its gross selling price to wholesalers with no adjustments to sales in determining its AMPs. We were told that since the manufacturer sells each type of product at the same price to everyone, it did not have to go through mathematical computations in order to arrive at its AMPs. Its AMP would be the same for all classes of trade. In the interest of simplicity, this manufacturer apparently did not attempt to identify its products actually distributed to the retail pharmacy class of trade or adjust for chargebacks.

The HCFA is opposed to this method for identifying AMPs. A policy directive issued by HCFA on March 21, 1991 contained questions and answers regarding the rebate program. This directive contained the following question and answer:

Question: *Can I (manufacturer) send HCFA as the "AMP" my catalogue price for some products? That price would always be higher than my real AMP, so giving you catalogue prices means I'll pay a bigger rebate. But its simply not worth the bother of calculating the "real" AMP for every such product.*

Answer: *No. You have to calculate the AMP for every product. The law (at 1927 (k) (1)) specifies how AMP is to be calculated, so HCFA doesn't have latitude to accept other approaches. Anyway, we have to ensure that AMP is computed consistently across the board.*

Section 1927 (k) of the Social Security Act, as added by OBRA '90, provides definition of terms only. It states the following in subsection (1) regarding AMP:

> *The term 'average manufacturer price' means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.*

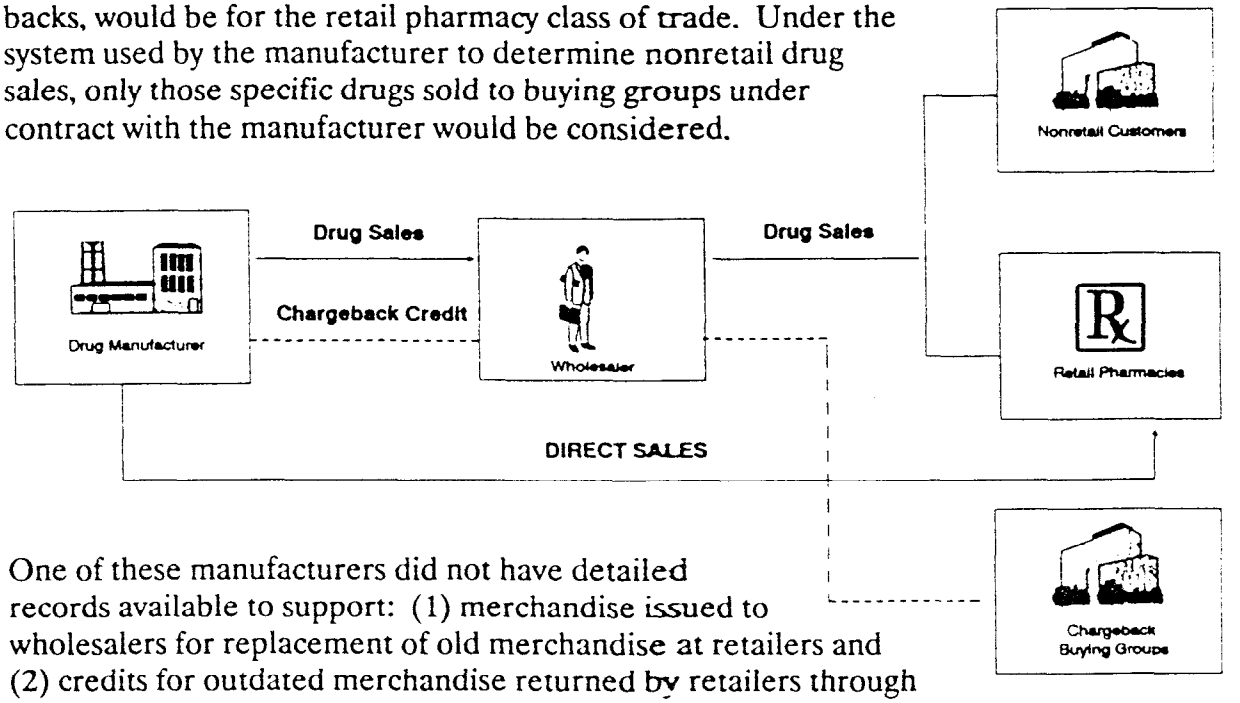
We disagree that this requires every manufacturer to calculate AMP on every drug in the same manner. A manufacturer who is willing to provide AMPs, based upon catalog prices as a concession against the burden and costs of calculating actual AMPs, is in effect providing the Medicaid program with the highest AMPs and rebate payments possible. Additionally, the manufacturer who provided the AMPs based on a gross price which is the same for all wholesalers, before considering adjustment for chargeback sales, is providing the Medicaid program with AMPs which seem to be accurate even though it did not specifically identify the sales to the retail class of trade. We believe that HCFA should reevaluate its position.

Although the gross sales approach did not affect the AMPs provided to the Medicaid program for the manufacturer in our review, the gross sales approach could affect the AMPs provided to the Medicaid program if the manufacturers' gross sales figures included sales at varying prices. For illustration purposes, assume that this manufacturer sold 10,000 units of a given product: 3,000 units to wholesaler A at $10 per unit, 3,000 units to wholesaler B at $8 per unit, and 4,000 units to wholesaler C at $6 per unit. The gross AMP should be $7.80 computed as follows:

	UNITS SOLD	UNIT PRICE	SALES	
WHOLESALER A	3,000	$10.00	$30,000	$10.00
WHOLESALER B	3,000	$8.00	$24,000	$8.00
WHOLESALER C	4,000	$6.00	$24,000	$6.00
Gross Sales	10,000		$78,000	$7.80

For this manufacturer the gross AMP would be $7.80. If we assume that retail sales were made by only one of the three wholesalers, the AMP for actual sales to retailers could range from $6 per unit (all retail sales made by wholesaler C) to $10 per unit (all retail sales made by wholesaler A). The gross sales AMP would be accurate only if retail sales were proportionately distributed by all wholesalers.

Net Sales To Wholesalers. Two of the four manufacturers "estimated" the amount of drugs sold to the retail pharmacy class of trade. These manufacturers adjusted their wholesaler sales figures for the nonretail sales by subtracting the chargeback sales and sales returns. The chargeback sales were included and removed from the wholesaler sales figures at net selling prices. Sales returns were valued at the selling price that was in effect when the products were returned. The wholesalers' net sales figure was then combined with any direct sales made by the manufacturer to retail pharmacies to determine total sales to the retail pharmacy class of trade. This method assumes that all sales by the wholesaler, after adjustments for charge-backs, would be for the retail pharmacy class of trade. Under the system used by the manufacturer to determine nonretail drug sales, only those specific drugs sold to buying groups under contract with the manufacturer would be considered.



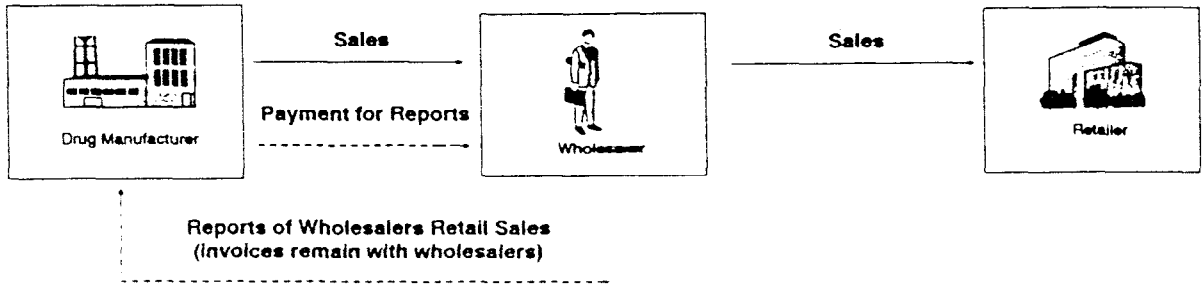
One of these manufacturers did not have detailed records available to support: (1) merchandise issued to wholesalers for replacement of old merchandise at retailers and (2) credits for outdated merchandise returned by retailers through the wholesaler. As a result, we could not reconcile the net sales units sold. The net sales units are used by the manufacturer to calculate

Base AMP, AMP, and best price. Officials of this manufacturer believed that these items would be offsetting over a period of time and suggested that these be eliminated from the pricing calculations.

Our concern with the net sales method is that not all nonretail sales by the wholesalers are necessarily made through chargebacks. Some nonretail sales may be made outside of the chargeback arrangements. Additionally, not all drugs sold to wholesalers are distributed to retailers, but may remain in wholesaler inventory. In our discussions with representatives of these two manufacturers, they advised us that they receive no feedback from their wholesalers on what portion of the drugs are actually sold to the retail pharmacy class of trade.

This methodology increased the AMPs and rebate payments for these manufacturers because they have removed from the total product sales universe the chargeback sales which are made at prices that are normally lower than retail prices. However, we have no assurance that the AMPs are representative of those for the retail class of trade. Additionally, the manufacturers have incurred higher administrative costs in capturing the chargeback sales figures by product to use in computing the AMPs.

Specific Identification Of Retail Sales. The fourth manufacturer identified the sales of its products to the retail pharmacy class of trade. This manufacturer could not, however, provide us with adequate documentation to support the retail sales figures. Retail pharmacy sales at this manufacturer are made through both wholesalers and its own direct sales. The sales by wholesalers to retailers is reported monthly to the manufacturer by product on magnetic tape. The manufacturer does not receive a copy of the wholesalers' sales invoices. We consider the sales invoice to be the basic record of sale and should be required as proof of sale for audit purposes. Approximately 94 percent of this particular manufacturer's sales of our sampled drugs is to wholesalers who, in turn, sell to retailers (pharmacies). The manufacturer combines the wholesalers' retail sales information with its own direct sales to retailers to calculate its quarterly retail pharmacy class of trade AMP.



Officials at this manufacturer agreed with our interpretation that the sales invoice was needed for proof of the sale. The manufacturer requested that its wholesalers provide invoices on a sample of 185 sales transactions made through the wholesalers, but the wholesalers declined to provide the invoices. Because of the problem in obtaining sales invoices, we have no assurance that the sales transactions we tested were accurate. The manufacturer did provide sales invoices supporting each transaction sampled from their direct sales to the retail pharmacy class of trade.

This specific identification method provides the more accurate AMP of the four manufacturers for sales to the retail class of trade. While this manufacturer incurred significant administrative costs in capturing the specific sales data from wholesalers on the retail class of trade, it was advantageous for this manufacturer to use this method. This manufacturer will have the lowest AMP because about 94 percent of the wholesalers' sales of its products for our sampled items are to retail buying groups at reduced prices. (This may be an anomaly; we would assume that chargeback sales are not normally made for the retail class of trade.)

Overall Impact of Various Methods

As shown throughout this report, AMPs, rebate payments, and manufacturers' costs can be affected by the various calculation methods. Generally, the use of a gross sales price, which is the same for all wholesalers or catalog price for AMP, will be beneficial to the Federal Government and the States because it will result in a higher rebate payment. It will also be easier and less costly for the manufacturers. Conversely, specific identification of sales to the retail pharmacy class of trade is more accurate but more costly for the manufacturers.

The manufacturers' use of various methods for computing AMP has occurred because HCFA has not provided adequate instructions to the manufacturers. The HCFA has expressed its intent to have a uniform computation method as shown by the March 21, 1991 directive in which HCFA stated that it should ensure that AMP is computed consistently across the board. However, we believe that HCFA should further study this matter.

GUIDANCE NEEDED ON ACCESS AND RETENTION OF RECORDS

Our on-site review at the three drug manufacturers disclosed varying policies regarding access to their records and with their record retention policies. One manufacturer did not provide us with free and unrestricted access to its records supporting AMP and best price calculations. The second manufacturer provided us access to records, but did not retain records in support of its calculations of sales units returned. This manufacturer also advised us of its intention to retain records for only five quarters. The third manufacturer did not have invoices in support of the sale of its drug products to

retailers. As a result, we believe that uniform records access and retention policies are needed in order to ensure the proper provision of records for those agencies with oversight responsibilities for the rebate program.

Restricted Access To Records

One manufacturer restricted our access to the records which supported its AMP and best price calculations. The manufacturer interpreted the access provisions of OBRA '90 to mean that we could only view its records. We were not allowed to obtain, remove or photocopy records because of the manufacturer's concerns regarding the proprietary nature of its AMP and best price calculations. At the conclusion of our site work at this manufacturer, and after a negotiation process, we were given copies of vendor invoices for sales transactions selected for our sample. The manufacturer, however, deleted its name, the wholesalers' (customers') names, the product names, and the national drug code references. As a result, these records were of no value to us for purposes of an audit since we have no assurance that they support the sales transactions we tested.

Records Retention Period

The records retention policy was different at each of the three manufacturers we visited. For example, the records retention policy at one manufacturer required that all records supporting the Base AMP, AMP, and best price calculations be maintained in a controlled access on-site area for a 3-year period. After 3 years, the records would be transferred to a warehouse for storage until destroyed.

Another manufacturer did not have a policy for the retention of pricing data used to compute Medicaid drug rebate amounts. Officials at this manufacturer expressed concern regarding the cost of maintaining documents either in paper form or on magnetic tape for each transaction. These officials suggested that a reasonable retention period would be five calendar quarters.

The third manufacturer had no established policy for retaining records supporting its computations of drug prices used to calculate rebates made under the Medicaid drug rebate program. The retention policy at this manufacturer for its basic business records is 7 years. With regard to the records needed for our review of Medicaid drug rebates for the quarter ended March 31, 1991, we found that in some instances the manufacturer had to create these records from its "live" customer data files but with great difficulty because the data changes on a daily basis.

The issues concerning access to and retention of records required to audit drug rebate pricing calculations at the manufacturers were discussed with HCFA's policy staff. Currently, HCFA is considering a proposal to change the Medicaid drug rebate

regulations by requiring a record retention period of 5 years. The sales by large drug manufacturers result in the creation of millions of records over a 5-year period. As a result, we believe that HCFA's proposed change in the regulations would be a tremendous financial burden for the drug manufacturers.

We believe that a 3-year period is a reasonable period to require manufacturers to retain rebate records, unless they are specifically instructed by a Federal oversight agency to retain them for a longer period. This is consistent with other Medicaid retention requirements.

RECOMMENDATIONS

We recommend that HCFA: (1) survey other manufacturers to identify the various calculation methods used to determine AMP, (2) develop and disseminate to interested parties a more specific policy based on the survey results for calculating AMP which would protect the interests of the Government and which would be equitable to the manufacturers, (3) establish requirements which provide for unrestricted access by Federal oversight agencies to manufacturers' records which pertain to the drug rebate program, and (4) establish requirements which direct drug manufacturers to retain rebate records for a period of 3 years.

HCFA'S COMMENTS

In a memorandum, dated September 3, 1992, HCFA commented on the findings contained in our draft report. The HCFA did not concur with our recommendations regarding the calculation of AMP and took the position that the drug rebate law and the rebate agreement have already established a methodology for computing AMP. The HCFA stated that it has undertaken numerous activities to assure uniform and correct AMP calculations and that:

- HCFA staff have responded to many requests for the proper method of computing AMP;
- with this guidance, manufacturers have submitted hundreds of corrections to earlier data, and as a result, manufacturers have been able to correctly compute AMP;
- HCFA intends to clarify the AMP definition in the drug rebate regulation; and
- HCFA encourages the OIG to reexamine the accuracy of AMP data.

The HCFA agreed that the OIG and other oversight authorities should not only have access to drug manufacturers' records, but should also be allowed to photocopy the appropriate records as necessary to conduct audits. However, HCFA added that it must consider the very stringent confidentiality provisions regarding the protection of manufacturers' pricing information.

The HCFA also stated that it is in the process of proposing a regulatory requirement for a 3-year retention period for rebate records.

See Appendix A for the complete text of the Acting Administrator's comments.

OIG'S RESPONSE

The HCFA's comments were generally not responsive to our recommendations concerning manufacturers' AMP calculations. The HCFA disagreed with our recommendations for developing a more specific policy for calculating AMP because it stated that the drug rebate law and the rebate agreement have already established a methodology for computing AMP. We disagree. The rebate law and agreement defined AMP but did not provide a specific written methodology for computing AMP.

Although HCFA stated that it has given manufacturers guidance on the proper method for calculating AMP which has resulted in many corrections, it did not provide us with any written documentation which further defines how AMP should be computed.

The thrust of our report was that HCFA, at a minimum, did not: (1) specify how to identify retail sales, (2) address chargebacks, and (3) specify how to handle sales returns. As a result, HCFA's comments were not responsive to these three important areas. The HCFA's statement that it intends to clarify its description of AMP in a future regulation is contradictory because this indicates that HCFA recognizes that a problem continues to exist. Further, HCFA did not specify what clarification it intended to describe in the regulation.

Concerning access to manufacturers' records by oversight agencies, we could not determine HCFA's position. The HCFA stated that it concurs in part, with our recommendation but stated that it must consider the very stringent confidentiality provisions regarding protection of manufacturers' pricing information. Since both OBRA '90 legislation and internal OIG policy require the safeguarding of proprietary data, we believe HCFA must specify that manufacturers provide oversight agencies with unrestricted access to manufacturers' rebate records.

We are in full agreement with HCFA's intentions to require a 3-year retention period. Our final report was revised to recommend a 3-year retention period.

The HCFA suggested that we reexamine the accuracy of AMP data. However, the OIG plans no future audits of drug manufacturers' AMP data, at least until such time as the HCFA develops more specific written policies for calculating AMP and for providing unrestricted access to records. When this is done, the OIG will have criteria needed to effectively audit AMP and manufacturers will be aware that they must provide unrestricted access to their records.

OTHER MATTERS

During the course of our review, all of the manufacturers advised us that there were significant rebate amounts in dispute between the manufacturers and the States. Section V of the rebate agreements permit the manufacturers to withhold payments to States in instances where the manufacturers believe the State Medicaid agencies' utilization information is erroneous.

Our review has shown that the amounts and percentages of rebate billings that are in dispute are significant for three of the four manufacturers reviewed. Also, the manufacturers advised us that the disputed amounts were unlikely to be resolved because there was no formal resolution process established by HCFA. The following schedule shows the amounts in dispute by manufacturer.

TOTAL AMOUNT MANUFACTURER	TOTAL AMOUNT BILLED	IN DISPUTE	PERCENTAGE IN DISPUTE
A	Amounts are not available		
B	$8,691,750	$1,683,691	19%[1]
C	$1,639,942	$ 721,968	44%
D	$8,759,697	$2,795,483	32%

[1] The amounts and percentages for this manufacturer do not consider those instances where rebates were paid to a State which did not bill a specific dollar amount but provided units of drugs sold. Additionally, these figures cover only 14 States.

We believe that this condition could seriously impair the rebate program. It appears that the manufacturers and States may be at an impasse regarding the disputes. We will be conducting audits to identify the extent, cause, and ways to reduce the amounts in dispute.

APPENDIX

HCFA's Comments to Draft Report

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Memorandum

Date SEP 3 1992

From William Toby, Jr.
Acting Administrator

Subject Office of the Inspector General (OIG) Draft Management Advisory Report: "Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program," A-06-91-00092

To Byran B. Mitchell
Principal Deputy Inspector General

We have reviewed the subject draft management advisory report which concerns drug manufacturers' calculation of the average manufacturer price (AMP). The Health Care Financing Administration (HCFA) uses the AMP, the best price drug data, and the Consumer Price Index-Urban (CPI-U) to determine the unit rebate amount for each drug which is payable to States by drug manufacturers.

OIG found major variations in the methods used by drug manufacturers to calculate the AMP, in the drug manufacturers' policies with regard to OIG's right of access to company records, and in the length of time Medicaid drug rebate records are retained. OIG recommends that HCFA:

- o survey drug manufacturers to identify the various calculation methods used to determine AMP;
- o develop and disseminate to interested parties a more specific policy, based on that survey;
- o establish requirements which provide for unrestricted access by Federal oversight agencies to manufacturers' records which pertain to the drug rebate program; and
- o establish requirements which direct drug manufacturers to retain rebate records for a period of 2 years.

HCFA does not concur with the first two recommendations. We partially concur with the third and fourth recommendations. Our specific comments are attached for your consideration.

HCFA's Comments to Draft Report

Page 2 - Inspector General

Thank you for the opportunity to review and comment on this draft management advisory report. Please advise us if you agree with our position on the report's recommendations at your earliest convenience.

Attachment

Comments of the Health Care Financing Administration (HCFA) on the Office of the Inspector General (OIG) Draft Management Advisory Report - "Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program," A-06-91-00092

Recommendation 1

HCFA should survey other drug manufacturers to identify the various calculation methods used to determine the average manufacturer price (AMP).

HCFA Response

HCFA does not concur with this recommendation. The drug rebate law and the rebate agreement have already established a methodology for computing the AMP. We believe that it would be inappropriate to use a survey of drug manufacturers to identify various calculation methods since HCFA has undertaken numerous activities since the enactment of this legislation to assure uniform and correct AMP calculations.

As we expected, there were numerous questions on the correct calculation of AMP in the early stages of the implementation of the Medicaid drug rebate program and, as expected, some manufacturers incorrectly computed AMP. In fact, this was part of our reasoning in asking OIG to look at these calculations by manufacturers.

In conjunction with the HCFA-requested OIG review, HCFA staff have spent many hours calling manufacturers and answering questions on the proper calculation of AMP. In addition, HCFA staff have responded to many written requests for the proper method of computing AMP. With this guidance, manufacturers have submitted hundreds of corrections to earlier data. As a result of these efforts, manufacturers have increasingly been able to correctly compute AMP.

Further, we intend to clarify the AMP definition in the drug rebate regulation. We encourage OIG to reexamine the accuracy of the AMP data.

Recommendation 2

HCFA should develop and disseminate to interested parties a more specific policy based on the survey results for calculating AMP which would protect the interests of the Government and which would be equitable to the manufacturers.

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HCFA Response

HCFA does not concur with the recommendation. Since we do not believe HCFA should survey manufacturers to develop legislatively-required policy, we do not concur with developing policy on the results of such a survey. HCFA will further clarify our description of AMP in a future regulation. We believe our current policies on the calculation of AMP protect the interests of the Government since in no instance did OIG find an AMP that was lower than that which should have been properly calculated.

Recommendation 3

HCFA should establish requirements which provide for unrestricted access by Federal oversight agencies to drug manufacturers' records which pertain to the drug rebate program.

HCFA Response

HCFA concurs, in part, with this recommendation. We agree that OIG and other oversight authorities should not only have access to drug manufacturers' records, but should also be allowed to photocopy the appropriate records as necessary to conduct audits. We believe that it was the intent of the legislation to allow access to those records in order to verify the pricing data used by the drug manufacturers. However, we must consider the very stringent confidentiality provisions regarding the protection of manufacturers' pricing information. We will carefully consider these issues as we develop revisions to the Medicaid drug rebate agreement.

Recommendation 4

HCFA should establish requirements which direct drug manufacturers to retain rebate records for a period of 2 years.

HCFA Response

HCFA partially concurs with this recommendation. We are in the process of proposing regulations which include a requirement that drug manufacturers maintain Medicaid drug rebate records for 3 years. We believe that a 3-year period is preferable to the 2-year period proposed by OIG, because it is more consistent with the requirements for retention of other State Medicaid records.

HCFA's Comments to Draft Report

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Additional Comments

HCFA has taken steps to better disseminate information to manufacturers, States, and other interested parties involved in the Medicaid drug rebate program. Recently, it was decided during a resolution conference between OIG and HCFA, that HCFA will provide professional pharmacy organizations with the same informational releases we provide to States.