

Memorandum

Date

DEC 28 1993

From

June Gibbs Brown

Inspector General

Subject

Elimination of the Weighted Average Manufacturer Price Provisions of the Medicaid Outpatient Prescription Drug Rebate Program (A-06-93-00070)

Sine & Brown

Τo

Bruce C. Vladeck Administrator Health Care Financing Administration

Attached are two copies of our final report entitled, "Elimination of the Weighted Average Manufacturer Price Provisions of the Medicaid Drug Rebate Program." The weighted average manufacturer price (WAMP) provisions of the Omnibus Budget Reconciliation Act (OBRA) of 1990 were scheduled to become effective on January 1, 1994. We had underway, prior to the repeal, a review to determine the effect of the WAMP provisions on the drug rebate program and had shared our preliminary results with health policy makers in the Government.

Our analysis showed that: (1) utilization data needed to make WAMP calculations would not be available on a timely basis and (2) WAMP calculations would be unpredictable and could have had a negative impact on Medicaid rebate collections. This would have made it difficult to implement the WAMP provisions and would have provided opportunities for manipulation of drug pricing which would have increased the cost of the Medicaid drug program. In our opinion, the current method which relies on individual drug calculations is an easier and fairer method for computing additional Medicaid rebates. We were unable to actually determine the entire legislative intent for the WAMP provisions and Health Care Financing Administration (HCFA) staff were not able to explain the rationale for the WAMP provisions. In our draft report, we recommended that HCFA support changes in the drug rebate legislation to retain the procedures currently used for computing additional rebates. The WAMP provisions of OBRA 1990 were recently repealed by OBRA 1993. Accordingly, no further action by HCFA is necessary.

The HCFA Administrator responded to our draft report on the problems we saw with the WAMP provisions. The Administrator agreed with the findings and recommendations contained in our draft report and pointed out that HCFA staff worked with both the Office of Inspector General and congressional staff on the WAMP issue. He also pointed out that the WAMP provisions of OBRA 1990 were repealed by OBRA 1993.

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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 Department officials.

To facilitate identification, please refer to Common Identification Number A-06-93-00070 in all correspondence relating to this report.

Attachments

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

ELIMINATION OF THE WEIGHTED AVERAGE MANUFACTURER PRICE PROVISIONS OF THE MEDICAID OUTPATIENT PRESCRIPTION DRUG REBATE PROGRAM



DECEMBER 1993 A-06-93-00070



Memorandum

Date

DEC 2.8 1993

From

June Gibbs Brown June & Brown

Inspector General

Subject

Elimination of the Weighted Average Manufacturer Price Provisions of the Medicaid Outpatient Prescription Drug Rebate Program (A-06-93-00070)

To

Bruce C. Vladeck Administrator Health Care Financing Administration

This report provides you with the final results of our review of the weighted average manufacturer price (WAMP) provisions of the Omnibus Budget Reconciliation Act (OBRA) of 1990 and its impact on the Medicaid outpatient prescription drug rebate program. The WAMP provisions of OBRA 1990, scheduled to become effective on January 1, 1994, were recently repealed by OBRA 1993. We had underway, prior to the repeal, a review to determine the effect of the WAMP provisions on the drug rebate program and had shared our preliminary results with health policy makers in the Government.

Our analysis showed that: (1) utilization data needed to make WAMP calculations would not be available on a timely basis and (2) WAMP calculations would be unpredictable and could have had a negative impact on Medicaid drug rebate collections. This would have made it difficult to implement the WAMP provisions and would have provided opportunities for manipulation of drug pricing which would have increased the cost of the Medicaid drug program. In our opinion, the current method which relies on individual drug calculations is an easier and fairer method for computing additional Medicaid drug rebates. Although we discussed the issue with congressional staff and the Health Care Financing Administration (HCFA) personnel, we could not actually determine the entire legislative intent for the WAMP provisions.

The HCFA Administrator responded to our draft report on the problems we saw with the WAMP provisions. The Administrator agreed with our findings and pointed out that the WAMP provisions were recently repealed by OBRA 1993, which was signed by the President on August 10, 1993. As a result of the repeal of the WAMP provision no further action by HCFA is necessary.

BACKGROUND

On November 5, 1990, the Congress enacted OBRA 1990. 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 1990, 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 (AMP) and best price. Both of these price figures relate to the drug's selling price to the retail customer of the manufacturer. From this information, a unit rebate amount is computed for each drug. Medicaid drug rebate payments are based on a basic unit rebate amount plus, if applicable, an additional unit rebate amount. This report is concerned with the additional rebate amounts that are owed by drug manufacturers to States when manufacturer price increases exceed the rate of inflation.

Currently, AMP is computed quarterly by the individual drug manufacturers by dividing their total retail sales dollar value for each drug type and strength by the number of units sold. That figure is then reported to HCFA. The HCFA then reviews the AMP to determine whether an additional rebate amount is due. This is done by comparing the reported current AMP to the base period AMP which is normally the drug's AMP as of October 1, 1990. If the increase in the AMP exceeds the increase in the Consumer Price Index-Urban (CPI-U) from the base period to the quarter reviewed, the excess percentage is converted to dollars and added to the basic rebate amount in order to arrive at the unit rebate amount. The WAMP provisions of OBRA 1990 would not have affected the computation of the basic unit rebate amount. However, the provision would have significantly changed the additional rebate calculations.

WAMP Calculation

To compute the additional rebate using WAMP, the quantity of each product or item sold to the Medicaid program would have been multiplied by the AMP for each product or item. The result of this calculation is the total dollar sales for the item. These sales amounts would then be added together to arrive at total manufacturer dollar sales. The total sales would be divided by the total Medicaid quantity used to arrive at the WAMP. The result would be a weighted average price for all drugs sold by a manufacturer to Medicaid recipients. This would be done for both a base period and the current period in order to compare the two and determine the average price increase for the current period being measured.

SCOPE

Our audit was performed in accordance with generally accepted government auditing standards. The objective of our audit was to determine the effect of the WAMP provisions on the Medicaid outpatient prescription drug rebate program. To accomplish that objective, we reviewed the provisions of OBRA 1990 that pertained to the program. We held discussions with, and reviewed correspondence from, HCFA's headquarters personnel. Additionally, we reviewed correspondence prepared by a drug manufacturing organization and other correspondence prepared by a drug manufacturer. Further, we constructed computer models which were designed to illustrate the effects of various additional rebate calculations. We did not independently verify any information we obtained from third party sources. Our field work was conducted from March through May of 1993 in our Little Rock, Arkansas field office.

RESULTS OF AUDIT

The WAMP provisions would have been difficult to implement because manufacturers would have to rely upon State supplied Medicaid utilization data which would not have been available on a timely basis. Further, our analysis of two possible calculation options involving the current period weight (based on sales volume) and base period weight showed that WAMP calculations provided opportunities for manipulation of the rebate amounts and could actually have resulted in smaller rebates.

Currently, price increase evaluations are made for each drug. Under WAMP, manufacturers' price increase evaluations would have been made in the aggregate for all drugs sold to Medicaid patients. Accordingly, significant price increases for some individual drug products would be offset against price increases that were less than the CPI-U or price reductions for other drug products. The current system treated drugs individually and did not allow drugs with price increases that were lower than the CPI-U to be offset against those that had price increases in excess of the CPI-U. Also, newly marketed and discontinued products would have been included in the WAMP calculation. This would have distorted any comparisons that were made between the base period and the current period. In our opinion, the current system was easier and fairer for calculating additional Medicaid drug rebates.

UTILIZATION DATA MAY NOT BE AVAILABLE TIMELY FOR WAMP CALCULATIONS

The WAMP provisions would have been difficult to implement because OBRA 1990 required the manufacturers' calculations to be based on State supplied utilization data which would not have been available on a timely basis. Although the

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responsibilities were not detailed in the legislation, we believed drug manufacturers would have been expected to follow current OBRA 1990 requirements for calculating and reporting WAMP. Thus, we would expect manufacturers to be required to calculate and report the base period and current period WAMPs no more than 30 days after the last day of a quarter, which is currently required by OBRA 1990 for AMP calculations and submission of best price data. The AMP and best price data was based on information supplied by the manufacturers. The drug manufacturers had to rely on the States to supply Medicaid utilization data for the current period using the States' billings in order to calculate the WAMPs. The States would also have had to provide Medicaid utilization data in order to construct the base period WAMP (July through September of 1990). Based on our previous audit work in the Medicaid drug rebate program, we had reservations about States' abilities to provide this base period data. Currently, the States are not required to submit Medicaid utilization data to manufacturers until 60 days after the end of the quarter. Also, experience has shown that some States have been extremely slow in submitting utilization data to drug manufacturers. Therefore, we believe that it would be unrealistic to expect States to provide Medicaid utilization data in time for manufacturers to provide current period WAMP calculations to HCFA within 30 days from the end of a quarter.

WAMP CALCULATIONS ARE UNPREDICTABLE AND WOULD HAVE A NEGATIVE IMPACT ON MEDICAID REBATE COLLECTIONS

There were at least two calculation options to consider for the WAMP. These were current period weight and base period weight. Under the current period weight procedure, the current period quantity of drugs utilized by Medicaid patients would have been used to compute both the base period and current period WAMP. The base period weight procedure used base period quantity of drugs used for the base period and current period quantity of drugs used for the current period.

The following paragraph discusses the potential effect of using these calculation options.

The Current Period Weight

Using current period quantity in both the base period and the current period calculations would have solved the problem of discontinued products that distorted the WAMP calculations. For discontinued products, the current period quantity would have been zero and the base period quantity would have also been zero since current period figures would be used. Although the current period weight solves the problem of discontinued products, it would have been

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more costly to the program (that is, result in less rebates) because of the aggregate calculation. The following schedule illustrates this aggregate calculation.

Drug	Base Period AMP	Current Period AMP	Current Period Volume	Total Cost Base Period	Total Cost Current Period	Add'l Rebate After WAMP	Add'l Rebate Before WAMP			
Α	\$1.00	\$1.00	5,000	\$5,000.00	\$5,000.00	(\$400.00)	None			
В	\$1.00 \$1.00		1,000	\$1,000.00	\$1,000.00 (\$80.0		None			
C			2,000	\$4,000.00	\$4,000.00	(\$320.00)	None			
D	,		2,500 \$5,000.		\$5,000.00	(\$400.00)	None			
E	\$3.00	\$3.25	3,000	\$9,000.00	\$9,750.00	\$30.00	\$30 .00			
F	\$3.00	\$3.50	4,000	\$12,000.00	\$14,000.00	\$1,040.00	\$1,040.00			
G	\$4.00	\$4.32	2,200	\$8,800.00	\$9,504.00	\$0.00	None			
Н	\$4.00	\$4.50	1,200	\$4,800.00	\$5,400.00	\$216.00	\$216.00			
Totals			20,900	\$49,600.00	\$53,654.00	\$86.00	\$1,286.00			
	Base WAMP (\$49,600.00 divided by 20,900) \$2.3732 Current WAMP (\$53,654.00 divided by 20,900) \$2.5672									
% CPI-U increase over base year										
Base V	\$2.5631									
Curren	\$0.0041									
Additio	\$86 .00									
				•						

This schedule shows the calculation of the additional rebate using current period quantity (volume) for weighting. In this example, using WAMP would have resulted in an additional rebate that is \$1,200 less (\$1,286 minus \$86) than the current method being used in the Medicaid drug rebate program.

The Base Period Weight

Under this procedure, the base period WAMP would have used base period quantity while the current period WAMP would have used current period quantity. This procedure would have been extremely troublesome because of products that are either newly marketed, or discontinued in the interim between the base period and the current period. In some cases, additional rebates would not have been required even though drug prices may have increased significantly. In other cases, additional rebates would be required even though drug prices were not increased. In our opinion, a base period weight procedure would have provided

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unpredictable and unfair results. The following schedule illustrates the effect of using this procedure when the only change is in quantity.

Drug	Base Period AMP	Current Period AMP	Base Period Volume	Current Period Volume	Total Cost Base Period	Total Cost Current Period
	<u> </u>					
Α	\$1.00	\$1.00	1,000	1,000	\$1,000.00	\$1,000.00
В	\$1.00	\$1.00	5,000	3,000	\$5,000.00	\$3,000.00
С	\$2.00	\$2.00	2,000	2,000	\$4,000.00	\$4,000.00
D	\$2.00	\$2.00	2,500	2,500	\$5,000.00	\$5,000.00
Ε	\$3.00	\$3.00	2,000	3,000	\$6,000.00	\$9,000.00
F	\$3.00	\$3.00	4,000	4,000	\$12,000.00	\$12,000.00
G	\$4.00	\$4.00	2,000	2,200	\$8,000.00	\$8,800.00
Н	\$4.00	\$4.00	1,000	1,200	\$4,000.00	\$4,800.00
Totals			19,500	18,900	\$45,000.00	\$47,600.00
Base W	\$2.3077					
Current	\$2.5185					
% CPI-U	8%					
Base W	\$2.4923					
Current	\$0.0262					
Addition	\$495.38					

In this example (which would be unfair to the manufacturer), an additional rebate would have been owed even though there were no price increases in the eight drugs. The changes in quantity used by Medicaid patients from the base period to the current period resulted in an additional rebate. Yet, the purpose of the Medicaid drug rebate program was to provide a price reduction similar to what was provided to other customers of the drug manufacturers.

CONCLUSIONS AND RECOMMENDATIONS

We believed that the WAMP provisions of OBRA 1990 were not practical, feasible, or workable. We also believed that the WAMP provisions would place the Medicaid drug rebate program in a situation that would reduce the amounts of rebates collected, resulting in a negative impact on the Medicaid drug rebate program. In our draft report, we recommended that HCFA seek changes in the

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drug rebate legislation to retain the current procedures for computing additional rebates. The WAMP provisions of OBRA 1990 were recently repealed by OBRA 1993. Accordingly, no further action by HCFA is necessary.

HCFA'S COMMENTS

In response to our draft report, the HCFA Administrator agreed with the findings and pointed out that the HCFA staff worked with both OIG and congressional staff on the WAMP issue. He also noted that the WAMP provisions of OBRA 1990 were repealed by OBRA 1993, which was signed by the President on August 10, 1993. (See the Appendix to this report for the complete text of the Administrator's comments.)

DEPARTMENT OF HEALTH & HUMAN SERVICES



Memorandum

Date

From

Bruce C. Vladeck

Administrator

SEP 23 1993

Subject

Office of Inspector General (OIG) Draft Management Advisory Report: "Legislative Change Needed for the Additional Rebate Amount Provisions of the Medicaid Outpatient Prescription Drug Rebate Program" (A-06-93-00070)

To

Bryan B. Mitchell Principal Deputy Inspector General

We reviewed the subject draft report which provides results of the initial OIG review of the weighted average manufacturer price (WAMP) provisions of the Omnibus Budget Reconciliation Act of 1990 and its effect on the Medicaid outpatient prescription drug rebate program.

As indicated in your draft report, HCFA staff worked with OIG staff and shared analyses. Prior to receipt of OIG's report, HCFA also worked with Congressional staff on this issue. As a result, the WAMP provisions in section 1927 of the Social Security Act were repealed by the Omnibus Budget Reconciliation Act of 1993. Thus, no further action is necessary on this recommendation.

Thank you for the opportunity to review and comment on this draft report. Please advise us if you would like to discuss our position on the report's recommendation at your earliest convenience.