# Memorandum

Date MAR 27 2001

From Michael Mangano
Michael F. Mangano
Acting Inspector General

Subject Medicaid Drug Rebates--Sales to Repackagers Excluded From Best Price Determinations (A-06-00-00056)

To Michael McMullan
Acting Principal Deputy Administrator
Health Care Financing Administration

Attached is our final report on the results of our review of Medicaid rebates--sales to repackagers. The objectives of our review were to determine: (1) whether drug manufacturers were excluding sales to repackagers from their best price determinations and (2) the monetary impact on the Medicaid drug rebate program for excluded sales to health maintenance organization (HMO) repackagers. Although most of the drug manufacturers we reviewed were not excluding sales to repackagers from their best price calculations, the instances of exclusions to HMO repackagers resulted in a significant loss in rebates to the Medicaid program. For the manufacturers of the top 200 Medicaid reimbursed drugs for Fiscal Year (FY) 1999, we found that 7 out of 53 manufacturers excluded sales to 8 repackagers, 3 of which were HMO repackagers. Sales to HMOs are specifically required by statute to be included in a drug manufacturer's best price determination. As a result, Medicaid drug rebates totaling $80.7 million for FY 1999 were lost because sales to HMOs were excluded from the best price determinations.

This review was a follow up to previous work we conducted in response to a congressional inquiry in 1999. In our previous work, we reviewed a limited number of drugs and repackagers for FY 1998, based on information contained in the request. In that review, we found that two of the identified repackagers were HMOs and that they were purchasing drugs significantly below the manufacturers' reported best prices. As a result, Medicaid drug rebates totaling $27.8 million for FY 1998 were lost because sales to HMOs were excluded from best price determinations.

Our two reviews identified over $108 million in lost rebates for FYs 1998 and 1999. Therefore, we recommended that the Health Care Financing Administration (HCFA) require drug manufacturers who excluded sales to HMOs from their best price to repay the lost rebates. Additionally, since current rebate legislation did not specifically provide for the exclusion of sales to repackagers from best price, we recommended that HCFA evaluate its policy guidance relating to the exclusion of sales to other (non-HMO) repackagers from best price determinations, especially where those repackagers used drugs for their own use and

did not resell them. In a memorandum to us dated March 8, 2001, the Acting Deputy Administrator concurred with these recommendations.

We would appreciate your views and the status of any further action taken or contemplated on our recommendations within the next 60 days. If you have any questions, please contact me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits at (410) 786-7104.

To facilitate identification, please refer to Common Identification Number A-06-00-00056 in all correspondence relating to this report.

Attachment

Department of Health and Human Services

# OFFICE OF INSPECTOR GENERAL

# MEDICAID DRUG REBATES--SALES TO REPACKAGERS EXCLUDED FROM BEST PRICE DETERMINATIONS


MARCH 2001
A-06-00-00056

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Acting Inspector General

Subject Medicaid Drug Rebates--Sales to Repackagers Excluded From Best Price Determinations (A-06-00-00056)

To Michael McMullan
Acting Principal Deputy Administrator
Health Care Financing Administration

This final report provides you with the results of our review of Medicaid rebates--sales to repackagers. The objectives of our review were to determine: (1) whether drug manufacturers were excluding sales to repackagers from their best price determinations and (2) the monetary impact on the Medicaid drug rebate program for excluded sales to health maintenance organization (HMO) repackagers. For the manufacturers of the top 200 Medicaid reimbursed drugs for Fiscal Year (FY) 1999, we found that 7 out of 53 manufacturers excluded sales to 8 repackagers, 3 of which were HMOs. Sales to HMOs are specifically required by statute to be included in a drug manufacturer's best price determination. As a result, Medicaid drug rebates totaling $80.7 million for FY 1999 were lost because sales to HMOs were excluded from the best price determinations.

**Over $108 million in Medicaid rebates were lost because sales to HMOs were excluded from drug manufacturers' best price determinations in FY 1998 and FY 1999.**

This review was a follow up to previous work we conducted in response to a congressional inquiry in 1999. In our previous work, we reviewed a limited number of drugs and repackagers for FY 1998, based on information contained in the request. In that review, we found that two of the identified repackagers were HMOs and that they were purchasing drugs significantly below the manufacturers' reported best prices. As a result, Medicaid drug rebates totaling $27.8 million for FY 1998 were lost because sales to HMOs were excluded from best price determinations.

Although most of the drug manufacturers we reviewed were not excluding sales to repackagers from their best price calculations, the instances of exclusions to HMO repackagers resulted in a significant loss in rebates to the Medicaid program. In 1997, the Health Care Financing Administration (HCFA) issued guidance to drug manufacturers that allowed for the exclusion of sales to certain repackagers from best price. The Medicaid drug

rebate statute, however, specifically states that sales to HMOs shall be included in best price computations. During our current work, HCFA issued additional guidance to drug manufacturers which reiterated that sales to HMOs are subject to inclusion in best price calculations regardless of whether the HMO was a repackager. Our two reviews identified over $108 million in lost rebates for FYs 1998 and 1999. Therefore, we recommended that HCFA require drug manufacturers who excluded sales to HMOs from their best price to repay the lost rebates. Additionally, since current rebate legislation did not specifically provide for the exclusion of sales to repackagers from best price, we recommended that HCFA evaluate its policy guidance relating to the exclusion of sales to other (non-HMO) repackagers from best price determinations, especially where those repackagers used drugs for their own use and did not resell them. In a memorandum dated March 8, 2001, HCFA's Acting Deputy Administrator concurred with both of our recommendations. The complete text of the Acting Deputy Administrator's response is included as the Appendix to this report.

## BACKGROUND

The Omnibus Budget Reconciliation Act of 1990 (OBRA 90), which established the Medicaid drug rebate program, defines best price as the lowest price available to any wholesaler, retailer, provider, HMO, nonprofit, or governmental entity with certain exceptions. The exclusion of sales to repackagers from best price was not addressed in OBRA 90 nor was it addressed in rebate agreements between HCFA and the drug manufacturers. In 1997, HCFA issued guidance to drug manufacturers that allowed for the exclusion of sales to certain repackagers from best price. The HCFA issued additional guidance to the manufacturers in July 2000 that reiterated the statutory requirement that sales to HMOs be included in best price regardless of whether the HMO was a repackager.

Medicaid has traditionally represented 11 to 15 percent of the market for prescription drugs. Prior to the passage of OBRA 90, Medicaid took little advantage of its size in the marketplace. However, OBRA 90 allowed Medicaid to take advantage of its purchasing volume by authorizing States to collect rebates from drug manufacturers for drug purchases reimbursed under the Medicaid program. In order for a manufacturer's drugs to be eligible for reimbursement under Medicaid, the manufacturer was required by OBRA 90 to enter into a rebate agreement with HCFA and pay quarterly rebates to the States.

The rebates, for brand name drugs, are based on the difference between an average manufacturer's price (AMP) - the manufacturer's average selling price - and a manufacturer's lowest or best price thereby affording Medicaid access to a manufacturer's best price. The AMP is defined in the rebate agreement between HCFA and the manufacturers to mean the average price paid by wholesalers for drugs distributed to the retail pharmacy class of trade. The definition also specifically excludes direct sales to hospitals, HMOs, and wholesalers where the drug was relabeled or repackaged under that wholesalers national drug code. Therefore, AMP is based on sales to the higher paying

retail sector and does not include sales to customers that traditionally pay lower prices than the retail sector. Best price is defined by OBRA 90 to mean the lowest price available to any wholesaler, retailer, provider, HMO, nonprofit, or governmental entity with the only exclusions being certain government entities. The definition of best price thus specifically includes certain entities that are excluded from AMP, including HMOs.

The HCFA periodically provides guidance to drug manufacturers concerning drug rebates through program releases. In Release No. 29, HCFA advised that sales to certain repackagers or relabelers should be excluded from best price as well as AMP. While sales to certain relabelers or repackagers are specifically excluded in the definition of AMP, these sales are not, however, mentioned in the definition of best price. Further, OBRA 90 specifically requires sales to HMOs to be included in the computation of best price. The HCFA issued Release No. 47 in July 2000 after it was alerted to a situation where drug sales to an HMO were omitted from a manufacturer's best price calculation because that purchaser was a repackager. In Release No. 47, HCFA reiterated that the statute requires sales to an HMO to be included in best price regardless of whether the HMO was repackaging the drug.

**Objective, Scope, and Methodology**

Our review was performed in accordance with generally accepted government auditing standards. The objectives of this review were to determine whether drug manufacturers were excluding sales to repackagers from manufacturers' best price determinations and to determine the monetary impact on the Medicaid drug rebate program for excluded sales to HMO repackagers. To accomplish our objective, we identified manufacturers of the top 200 brand name drugs, in terms of Medicaid reimbursement, for the year ended September 30, 1999. We requested, from each of these manufacturers, information about any sales to drug repackagers that were excluded from their best price calculation for the same year. We also contacted the repackagers for every excluded sale and determined whether the drugs were repackaged for resale or for the repackager's own use.

In order to determine the impact of manufacturers excluding sales to repackagers from best price, we recalculated the rebates for any sale to a repackager that was at a price below the reported best price. However, we only recalculated the rebate for excluded sales to repackagers that were HMOs. We obtained AMP, best price, baseline AMP, and drug utilization data from the HCFA Data Center. Additionally, HCFA provided the listing of the top 200 Medicaid reimbursed brand name drugs for the year ended September 30, 1999.

## RESULTS OF REVIEW

For manufacturers of the top 200 Medicaid prescription drugs for FY 1999, we found that 46 of 53 drug manufacturers reviewed did not exclude sales to repackagers from their best price. However, we did find that seven manufacturers reported that they had excluded sales

to repackagers from their best price for some drug products. The seven drug manufacturers excluded sales to eight different drug repackagers from their best price. Three of the repackagers indicated that they repackaged the drugs for resale while the other five repackaged for their own use. Three of those five repackagers were HMOs.

**Financial Impact of Excluded Sales For FY 1999**

We identified 30 excluded sales to HMOs at prices that were all significantly below the reported best price for the drugs. In some instances the sales to the HMOs were at prices as much as 75 percent below the reported best price. The prices for the 14 excluded sales to non-HMO repackagers ranged from 46 percent below best price to 194 percent above best price.

We recalculated the rebates for excluded sales made to repackagers that were HMOs. As a result of these sales being excluded from best price, the Medicaid drug rebate program lost $80.7 million for the year ended September 30, 1999. The loss in rebates was attributable to 11 drugs sold to 3 different HMOs. The following table shows that if sales to these HMO repackagers had been included in best price, rebates for some drugs would have more than doubled.

| DRUG | MANUFACTURER | LOST REBATES* | ACTUAL REBATES* | QUARTERS AFFECTED |
|---|---|---|---|---|
| 1 | A | $16,977 | $16,486 | 4 |
| 2 | A | $817 | $757 | 2 |
| 3 | A | $502 | $221 | 1 |
| 4 | B | $4,855 | $5,388 | 4 |
| 5 | B | $3,689 | $4,110 | 4 |
| 6 | B | $1,076 | $1,207 | 3 |
| 7 | B | $135 | $144 | 2 |
| 8 | C | $7,897 | $11,672 | 4 |
| 9 | D | $36,396 | $30,695 | 4 |
| 10 | E | $6,048 | $10,264 | 1 |
| 11 | E | $2,273 | $3,301 | 1 |
| TOTALS | | $80,665 | $84,245 | |

*Amounts in thousands

**Previous Review in Response to a Congressional Inquiry**

In 1999, we received a congressional inquiry which in part requested that the Office of Inspector General determine whether drug manufacturers were using repackagers to manipulate drug pricing in order to avoid offering Medicaid the best price as required by OBRA 90. This inquiry identified a limited number of manufacturers, drugs, and repackagers for us to review. In responding to this request, we did not find that most manufacturers were avoiding the best price provisions of OBRA 90 by selling to repackagers. However, we did find that for FY 1998, two repackagers were HMOs and they purchased one drug at an average of 34.3 percent below the reported best price.

Because sales to these HMO repackagers had been excluded from the best prices, about $27.8 million in rebates were lost for FY 1998 - representing a 125 percent increase in rebates for this drug. As a result of our findings in responding to this inquiry, we initiated the current review to follow-up on these issues.

**Guidance Provided by HCFA**

The OBRA 90 specifically requires sales to HMOs to be included when manufacturers determine their best prices. The guidance given to drug manufacturers in Release No. 29 allowed for the exclusion from best price of sales to certain drug repackagers. In July 2000, HCFA issued Release No. 47 in which it advised that sales to an HMO should be included in best price regardless of whether the HMO was repackaging the drug.

**Conclusion and Recommendations**

While most of the drug manufacturers that we reviewed were not excluding sales to repackagers from their best price, the instances of exclusions resulted in a significant loss in rebates to the Medicaid program. Our reviews have identified over $108 million in lost rebates for 2 FYs related to excluded sales to HMO repackagers. Therefore, we recommended that HCFA:

- require drug manufacturers who excluded sales to HMOs from their best price determination to repay the lost rebates; and

- evaluate the policy guidance relating to the exclusion of sales to other (non-HMO) repackagers from best price determinations, especially where those repackagers used the drugs for their own use and did not resell them.

**HCFA's Response**

In a memorandum dated March 8, 2001, HCFA's Acting Deputy Administrator responded to the recommendations in our draft report. Regarding our recommendation that drug

manufacturers that excluded HMO sales from their best price determinations be required to repay the lost rebates, HCFA concurred. The Acting Deputy Administrator advised us that HCFA recently issued policy guidance clarifying that sales to repackagers, which were also HMOs, must be included in best price determination. Additionally, she responded that HCFA intends to issue policy guidance to the manufacturers in the near future addressing the problem of underpayment of rebates for past periods. Further, the Acting Deputy Administrator concurred with our recommendation that HCFA evaluate the policy relating to the exclusion of sales to other (non-HMO) repackagers from best price determinations, especially where those repackagers purchased the drugs for their own use and did not resell them.

See the Appendix to this report for the full text of the Acting Deputy Administrator's comments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

**DATE:** MAR - 8 2001

**TO:** Michael F. Mangano
Acting Inspector General

**FROM:** Michael McMullan
Acting Deputy Administrator

**SUBJECT:** Office of the Inspector General (OIG) Draft Report: "Medicaid Drug Rebates--Sales to Repackagers Excluded From Best Price Determinations," (A-06-00-00056)

Thank you for the opportunity to review and comment on the above draft report. The objectives of the review were to determine: (1) whether drug manufacturers were excluding sales to repackagers from their best price determination and; (2) the monetary impact on the Medicaid drug rebate program for excluded sales to health maintenance organization (HMO) repackagers.

Under the Medicaid drug rebate program, manufacturers are required to report their statutorily defined lowest or best price at which the drug was sold. In turn, this price is used in the calculation of the rebate. In 1999, Medicaid expenditures for drugs were $17 billion before rebates and rebates from manufacturers were $3.3 billion.

Although most of the drug manufacturers included in the review were not excluding sales to repackagers from their best price calculations, those few instances of the exclusions to HMO repackagers resulted in significant loss in rebates to the Medicaid program. Sales to HMOs are specifically required by statute to be included in a drug manufacturer's best price determination. As a result, Medicaid drug rebates totaling $80.7 million for Fiscal Year 1999 were lost because sales to HMOs were excluded from the best price determinations.

Our specific comments are as follows:

OIG Recommendation:
HCFA should require drug manufacturers who excluded sales to HMOs from their best price determination to repay the lost rebates.

HCFA Response:
We concur. We recently issued policy guidance clarifying that sales to repackagers, which were also HMOs, must be included in best price determination. We intend to issue

policy guidance to the manufacturers in the near future addressing the underpayment of rebates for past periods based on the exclusion of best price to repackagers, which are also HMOs.

OIG Recommendation:

HCFA should evaluate the policy guidance relating to the exclusion of sales to other (non-HMO) repackagers from best price determination, especially where those repackagers used the drugs for their own use and did not resell them.

HCFA Response:
We concur. We are re-examining our current policy to assure that we have made it clear that manufacturers have not inappropriately excluded other prices from best price, as required by section 1927 of the Act.

Attachment

**Technical Comment:**

Page 2, fourth paragraph, third sentence should read: The definition also specifically excludes *direct* sales to hospitals, HMOs, and wholesalers where the drug was relabeled or repackaged under that wholesalers national drug code.