



MAR 10 2003

TO: Betty James Duke, Ph.D.
Administrator
Health Resources and Services Administration

FROM: Janet Rehnquist *Janet Rehnquist*
Inspector General

SUBJECT: Pharmaceutical Manufacturers Overcharged 340B-Covered Entities
(A-06-01-00060)

Attached is a copy of our final report providing the results of our self-initiated review of prices charged to 340B-covered entities for prescription drugs.

In written comments, the Health Resources and Services Administration (HRSA) concurred with our recommendation and agreed to take corrective actions. The HRSA comments are included as an appendix to our report.

In accordance with the principles of the Freedom of Information Act, 5 U.S.C. 552, as amended by Public Law 104-231, Office of Inspector General (OIG), Office of Audit Services reports are made available to members of the public to the extent information contained therein is not subject to exemptions in the Act. (See 45 CFR Part 5.) As such, within ten business days after the final report is issued, it will be posted on the OIG web site at <http://oig.hhs.gov/>.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please do not hesitate to call me or Donald L. Dille, Assistant Inspector General for Grants and Internal Activities, at (202) 619-1175, or e-mail at ddille@oig.hhs.gov.

To facilitate identification, please refer to report number A-06-01-00060 in all correspondence relating to this report.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PHARMACEUTICAL
MANUFACTURERS OVERCHARGED
340B-COVERED ENTITIES**




JANET REHNQUIST
Inspector General

MARCH 2003
A-06-01-00060



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TO: Betty James Duke, Ph.D.
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Health Resources and Services Administration

FROM: Janet Rehnquist 
Inspector General

SUBJECT: Pharmaceutical Manufacturers Overcharged 340B-Covered Entities
(A-06-01-00060)

This final report presents the results of our self-initiated review to determine whether pharmaceutical manufacturers were charging 340B-covered entities the correct price for prescription drugs. Specifically, the objectives of our review were to determine:

- (1) whether pharmaceutical manufacturers sold prescription drugs to 340B-covered entities using the correct Medicaid rebate amount; and
- (2) the extent of any overcharges.

We estimated that five manufacturers, makers of the 11 prescription drugs in our review, overcharged 340B-covered entities \$6.1 million for sales occurring during the 1-year period ending September 30, 1999. The overcharges occurred because the drug manufacturers inappropriately excluded sales to health maintenance organization (HMO) repackagers from their best price determinations, thereby increasing the prices charged to 340B entities. We are recommending that the Health Resources and Services Administration (HRSA) require the five drug manufacturers to identify the exact amount of the overcharges for each of the affected 340B-covered entities and apply the overcharge amounts as offsets or credits to each entity's future purchases. In a memorandum dated January 7, 2003, HRSA responded to our November 13, 2002 draft report. The HRSA fully concurred with our recommendation and outlined its implementation plan. The full text of HRSA's comments is included in Appendix A.

BACKGROUND

Statutory Authority and Formula for Determining 340B Drug Prices

Section 602 of the Veterans Health Care Act of 1992 (the Act) enacted section 340B of the Public Health Service Act (PHS Act).¹ Section 340B, "Limitation on Prices of Drugs Purchased by Covered Entities," provides that pharmaceutical manufacturers enter into a pricing agreement with the Secretary of Health and Human Services. In doing so, the

¹ Public Law 102-585, enacted on November 4, 1992.

manufacturers agree to charge a price for certain outpatient drugs that will not exceed an amount determined under a statutory formula. The formula for determining the price for included drugs is based on the Medicaid drug rebate amount.

Under Medicaid provisions,² in order for a pharmaceutical manufacturer's drugs to be eligible for reimbursement under Medicaid, the manufacturer is required to enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the states. Rebates for brand name drugs are calculated using the greater of the following two formulas: subtracting the manufacturer's best price from the average manufacturer price (AMP); **OR**, AMP multiplied by a specified percentage, which was 15.1 percent during the 1-year period ending September 30, 1999. Medicaid provisions specifically require the inclusion of sales to HMOs when manufacturers are determining their best price. Further, there is an additional rebate amount for brand name drugs equal to the amount that AMP increases over and above the consumer price index (CPI).

The HRSA's Role in the 340B Program

The HRSA's Office of Pharmacy Affairs (OPA) is responsible for managing the 340B program. The OPA provides guidance, technical assistance, and liaison services on the drug pricing program to: federal, state, and local government agencies involved in health care, the pharmaceutical industry, and covered entities. To accomplish its mission to promote access to comprehensive pharmacy services by 340B-covered entities, OPA performs a number of activities including: proposing policy guidelines for industry and covered entities; administering agreements with drug manufacturers and working with CMS regarding a manufacturer's continuing Medicaid eligibility; and resolving concerns and disputes between industry and covered entities involving the drug pricing program.

The 340B program allows a large number of "safety net" providers, such as Community and Migrant Health Centers, state AIDS drug assistance programs, and eligible disproportionate share hospitals, to obtain drugs at discount prices.

OBJECTIVES, SCOPE, AND METHODOLOGY

The objectives of our review were to determine: (1) whether pharmaceutical manufacturers sold prescription drugs to 340B-covered entities using the correct Medicaid drug rebate amount; and (2) the extent of any overcharges.

An earlier Office of Inspector General (OIG) report, *Medicaid Drug Rebates--Sales to Repackagers Excluded From Best Price Determination* (A-06-00-00056), issued in March 2001, revealed that 5 manufacturers had inappropriately excluded sales to HMO

² This provision was included in the Omnibus Budget Reconciliation Act of 1990 and is included in Section 1927 of the Social Security Act.

repackagers from their best price determination for 11 drugs³ during the year ending September 30, 1999. Our current review focused on the sales of these same 11 drugs to 340B-covered entities. Because our current review examined the same sales period as the earlier review, we used the information we had already obtained on each manufacturer's best prices, including the prices charged HMO repackagers.

To accomplish our objectives, we obtained information on sales to 340B-covered entities from the 5 manufacturers for the 11 drugs in our review for the year ending September 30, 1999. To compare the prices actually charged by manufacturers to the formula price, we obtained from the CMS Data Center appropriate AMP(s), baseline AMP, and Market Date⁴ for each of the 11 drugs. We also obtained CPI information from the U.S. Department of Labor's Bureau of Labor Statistics. We used this information and the best price information identified in our prior review, which covered the time period for the year ending September 30, 1999, to recalculate the rebate amounts for each drug. This rebate amount was used to calculate the 340B price. For one drug, the amount we calculated resulted in a negative 340B price; therefore, in accordance with current 340B practices, we used one cent for the 340B price.

To determine if manufacturers overcharged covered entities, we reviewed the sales information provided by the manufacturers and compared the prices charged to our calculated 340B price. Finally, we calculated an estimated total difference in cost based on the sales to the 340B-covered entities. Because a timing difference exists between when 340B prices are calculated for a quarter and when the prices are available to covered entities, our calculations are only estimates of the overcharges.

Our review was performed in accordance with generally accepted government auditing standards. Our objectives did not require that we identify or review any internal control systems. We performed our review in our Little Rock, Arkansas field office during the time periods April 2001 to October 2001, and April 2002 to August 2002. We provided a draft report to HRSA on November 13, 2002, and HRSA forwarded its written comments on January 7, 2003.

FINDINGS AND RECOMMENDATIONS

We estimate that 5 manufacturers, makers of the 11 prescription drugs in our review, overcharged 340B-covered entities \$6.1 million for sales occurring during the 1-year period ending September 30, 1999. The overcharges occurred because the drug manufacturers inappropriately excluded sales to HMO repackagers from their best price determinations for the rebate amount calculation, thereby causing an increase to the prices charged to 340B entities.

³ The 5 manufacturers and 11 drugs were identified during our earlier review by: (1) requesting the 53 manufacturers of the top 200 Medicaid-reimbursed brand name drugs to disclose whether their best prices excluded sales to repackagers; and (2) identifying that there were three HMO repackagers purchasing the 11 drugs for their own use (not for resale).

⁴ The Market Date, the date that the drug entered the market, is used with the baseline AMP and CPI to determine the amount, if any, of additional rebate.

Manufacturers are Required to Use Formulas Established in Statutes to Calculate Prescription Drug Prices for Sales to Covered Entities

Section 602 of the PHS Act limits the price of drugs purchased by 340B-covered entities to an amount that is tied to the Medicaid drug rebate program. Specifically, 340B-covered entities, such as state operated drug assistance programs, hemophilia treatment centers, and homeless clinics, can purchase drugs at Medicaid AMP reduced by a rebate percentage. The rebate percentage is defined as the total rebate required under Medicaid divided by AMP.

Best price plays an integral role in the determination of the Medicaid rebate amount. Section 1927(c) of the Social Security Act defines the Medicaid drug rebate amount as the greater of the following two formulas: (1) the difference between AMP and the best price; or, (2) AMP multiplied by a specified percentage, which was 15.1 percent during our review period. Best price is defined as the lowest price available from the manufacturer to any wholesaler, retailer, provider, HMO, nonprofit or governmental entity with the only exclusions being certain government entities. There is an additional rebate, which is equal to the amount that the AMP has increased over and above any increase in the CPI.

The Manufacturers overcharged 340B Entities because their Rebate Calculations did not Include the Amount Charged HMO Repackagers in Best Price Determinations

We estimated that 5 manufacturers, makers of the 11 prescription drugs in our review, overcharged 340B-covered entities \$6.1 million during the 1-year period ending September 30, 1999. The covered entities paid \$13.7 million for the 11 drugs, but should have only paid \$7.6 million if the manufacturers had included sales to HMO repackagers in their best price determinations. The overcharges represented 45 percent of the amount paid by the covered entities. Because a time lag exists between when a 340B price is calculated for a quarter and when it is available to covered entities, our estimate of the overpayment is not an exact amount.

The manufacturers inappropriately excluded the price charged HMO repackagers, **which was the best price**, and consequently resulted in a lower rebate amount. A lower rebate amount results in an increase in the price manufacturers charge 340B entities for the drugs.

In June 1997, CMS issued guidance allowing the exclusion of sales to repackagers from best price; however, sales to HMOs are specifically required to be included in the best price determinations. In July 2000, CMS issued additional guidance to the manufacturers reiterating the statutory requirement that sales to an HMO should be included in best price, regardless of whether the HMO is repackaging the drug.

The following table shows our estimate of the total overcharges to the covered entities. It also illustrates the total sales of the 11 drugs to the covered entities and the number of quarters affected (during the 1-year period October 1, 1998 through September 30, 1999), by manufacturer.

The OIG Estimate of Overcharges

Drug	Manufacturer	Quarters Affected	Total Sales to Covered Entities	Total Overcharges to Covered Entities
1	A	4	\$1,403,333	\$1,387,245
2	A	2	\$ 45,198	\$ 22,599
3	A	1	\$ 21,099	\$ 13,866
4	B	4	\$ 559,957	\$ 281,003
5	B	3	\$ 3,166	\$ 1,724
6	B	4	\$ 4,959	\$ 2,565
7	B	2	\$ 10,391	\$ 5,573
8	C	4	\$1,279,942	\$ 993,215
9	D	4	\$6,868,262	\$ 2,903,871
10	E	1	\$ 855,738	\$ 103,392
11	E	1	\$ 2,616,300	\$ 412,070
Totals			\$13,668,345	\$ 6,127,123

RECOMMENDATION

We recommend that HRSA’s OPA require the five drug manufacturers to identify the exact amount of the overcharges for each of the affected 340B-covered entities and apply the overcharge amounts as offsets or credits to each entity’s future purchases.

HRSA’s Comments

The HRSA responded to our draft report in a memorandum dated January 7, 2003. The HRSA concurred with our recommendation and provided an implementation plan for corrective actions involving the five drug manufacturers. This plan includes determining if overcharges occurred in years outside the scope of our review and whether any other drugs are affected. The full text of HRSA’s comments is included in Appendix A.

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APPENDIX

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, Maryland 20857

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OFFICE OF INSPECTOR GENERAL JAN 7 2003

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TO: Janet Rehnquist
Inspector General

FROM: Administrator

SUBJECT: Office of Inspector General Draft Report "Pharmaceutical Manufacturers Overcharged 340B Covered Entities"
(Code # A-06-01-00060)

Thank you for the opportunity to provide comments on the above subject report. Attached please find HRSA's comments.

Questions may be referred to John Gallicchio on (301) 443-3099.

Betty James Duke
Betty James Duke

Attachment

**Health Resources and Services Administration's Comments on the Office of
Inspector General's Draft Report: "Pharmaceutical Manufacturers
Overcharged 340B Covered Entities"
Code # A-06-01-00060**

Historical Background and General Comments

This report documents that, during FY 1999, certain manufacturers overcharged 340B covered entities \$6.1 million for sales of eleven prescription drugs. This finding builds on an earlier OIG report, *Medicaid Drug Rebates--Sales to Repackagers Excluded From Best Price Determinations* (A-06-00-00056), issued in March 2001. This report established that certain drug manufacturers inappropriately excluded sales to health maintenance organization (HMO) repackagers from their best price determinations, thereby decreasing the rebates paid to Medicaid state agencies. Because the statutory discount on 340B drugs is also dependent on best price, this exclusion has the consequence of increasing the prices charged to 340B covered entities.

The draft report (A-06-01-00060) recommends that the Health Resource and Services Administration (HRSA) require the five drug manufacturers to identify the exact amount of the overcharges for each of the affected 340B-covered entities and apply the overcharge amounts as offsets or credits to each entity's future purchases. We concur with this recommendation and will draft letters to the certain manufacturers to be sent as soon as the draft report is made final and released to the public. To facilitate our implementation, we request that you provide us the names of the drug manufacturers and the eleven drugs examined in these reports.

Implementation process

Based on the findings in the draft report, we plan to notify the drug manufacturers at issue and request them to take the following corrective actions:

- Determine the full extent of the misreporting of best price to CMS. Although the draft report documents the error in FY 1999, it is very likely that other fiscal years are affected as well.
- Determine whether sales to HMO repackagers have been excluded from the best price determinations for other drugs sold to 340B covered entities besides the eleven reviewed by the OIG
- Determine the total overcharge for each of their 340B covered entity customers.
- Develop a refund or credit plan for each of the affected customers.
- Report the results of their corrective actions to the Office of Pharmacy Affairs within 60 days after receiving the letters.