ONE HUNDRED SIXTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6143

MAJORITY (202) 225–5074
MINORITY (202) 225–5051
TTY (202) 225–6852

February 16, 2000

The Honorable Donna E. Shalala
Secretary
U.S. Department of Health and Human Services
Washington, DC 20201

Dear Secretary Shalala:

I am writing to bring your attention to the apparent manipulation of drug prices by manufacturers seeking to avoid offering Medicaid the "best price" rebates required by law. This drug price manipulation appears to be costing taxpayers tens of millions of dollars -- if not more -- each year.

Under the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), states paying for prescription drugs for low-income persons covered by Medicaid are entitled to rebates from the manufacturers of the drugs. These rebates were designed to ensure that state Medicaid programs obtain drugs at the same "best prices" that drug companies offer their most favored private sector customers, such as health maintenance organizations.

Last year, I received allegations that drug manufacturers are circumventing the requirements of this law. According to these allegations, the drug companies sell their drugs at ultra-low prices to favored customers, such as HMOs, who repackage the drugs with their own labels. The drug manufacturers take the position that these favored customers are buying the drugs as "repackagers," not as HMOs, and thus are not covered by the Medicaid "best price" provisions.

At my request, the Inspector General of the Department of Health and Human Services, June Gibbs Brown, reviewed these allegations. The Inspector General looked at a small sample of drugs and found that "some repackagers did purchase drugs at prices lower than best price." Specifically, she found that two HMOs were able to purchase one drug at "prices considerably below (34.3%) the reported best price for that drug."

The budgetary implications of these practices are significant. The Inspector General found that for just one drug, the "repackaging" strategy cost state and federal taxpayers over $25 million in one year. Moreover, the Inspector General found that when drugs are bought by repackagers who resell the drugs to doctors, the rebate obligations may be avoided altogether.

The following discussion provides additional detail about this apparent abuse of the Medicaid drug pricing system. This matter deserves immediate investigation and, I believe, vigorous efforts to enforce the law and recoup funds owed to the taxpayers.

I. Medicaid Drug Pricing Requirements

As you know, the Medicaid program was created to provide health care coverage for low-income families with dependent children and low-income elderly and disabled individuals. This program is jointly funded by the federal government and the states, with each state administering its own program under broad federal guidelines. On average, the federal government provides approximately 57% of the funding for state Medicaid programs.[1]

Every state provides Medicaid recipients with a prescription drug benefit. In most cases, the state allows the beneficiary to get his or her prescription filled at a local pharmacy and requires the beneficiary to pay at most a minimal co-payment. The pharmacy is then reimbursed for the prescription by the state Medicaid program. According to the Health Care Financing Administration's own data, Medicaid payments for outpatient prescription drugs totaled $16.6 billion in fiscal year 1999, and accounted for 13% to 15% of the overall domestic market for these drugs.[2]

To reduce drug costs, OBRA 90 established the Medicaid rebate program for outpatient prescription drugs. Under this program, as you know, drug manufacturers who want their products covered by Medicaid agree to pay a rebate to state Medicaid agencies for drugs purchased by Medicaid patients. To date, the rebate program has resulted in billions of dollars in rebate payments to the states.[3]

Under OBRA 90, the rebate owed to state Medicaid programs is based upon the "best price" that drug manufacturers offer their most favored customers. Under the law, the rebate is equal to the difference between the "average manufacturer price" (AMP), which is defined as the price paid "by wholesalers for drugs distributed to the retail class of trade,"[4] and the "best price" offered by the manufacturer, which is defined as the "lowest price available from the

---

[1]According to the Health Care Financing Administration, the federal share of the Medicaid program was 56.7% in fiscal year 1999.

[2]Health Care Financing Administration, Office of Legislative Affairs (Jan. 21, 2000).

[3]*How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*, Congressional Budget Office (Jan. 1995).

[4]42 U.S.C. §1396r-8(k)(1)

manufacturer ... to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity within the United States."[5] The law further states that the "best price ... shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package."[6] If the "best price" is greater than 84.9% of the AMP, the manufacturer must pay a minimum rebate of 15.1% of the AMP. A second rebate, equal to the increase in the AMP above the annual rate of inflation, ensures that prices do not rise for the government faster than the rate of inflation.

The rebate is calculated by the Health Care Financing Administration (HCFA) based on drug utilization statistics compiled by the states. Each time a pharmacy dispenses a prescription to a Medicaid beneficiary, the pharmacy reports the National Drug Code (NDC) for the drug to the state. The NDC identifies the manufacturer or repackager, chemical compound, dosage, and package size. The pharmacy is reimbursed by the state for the prescription, and the state receives a rebate from the drug manufacturer.

Although the rebate program has saved taxpayers billions of dollars, the size of the rebate per prescription has declined since the passage of OBRA 90. The most detailed analysis of this issue was prepared by the Congressional Budget Office in 1995. CBO found that "best price" discounts have decreased from an average of more than 36% in 1991 to 19% in 1994.[7]

There have been two different theories about the decline in the size of the "best price" discount and the Medicaid rebate. One theory is that drug companies have less incentive to discount drugs for favored customers because that discount would also apply to the Medicaid market. The other theory is that the drug companies have found one or more ways to circumvent the drug pricing requirements. Under this view, the discounts to favored customers have not necessarily diminished; rather, they are showing up in ways that are designed to thwart Medicaid requirements.

The evidence investigated by my staff and reviewed by the Inspector General provides support for the latter view. As described below, it appears that at least some drug manufacturers have found mechanisms for selling drugs at ultra-low prices to some customers without extending these best price discounts to the Medicaid program. Moreover, it also appears that some drugs are being sold to Medicaid beneficiaries without any rebates at all being paid to the states.

---

[5] 42 U.S.C. §1396r-8(c)(1)(C)(i)

[6] 42 U.S.C. §1396r-8(c)(1)(C)(ii)(II)

[7] *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*, Congressional Budget Office (Jan. 1995).

II. Allegations of a "Repackaging" Scheme

In 1999, I received allegations that drug companies may be using drug repackaging to avoid Medicaid requirements. Under this alleged scheme, the manufacturer sells finished drugs to HMOs or other favored customers in a form that allows the favored customer to repackage the drugs. This repackaging can be as simple as just relabeling the product or putting pills bought in bulk from the manufacturer into bottles for dispensing to patients. The manufacturer then deliberately fails to report the transaction price to HCFA. Although the "best price" provisions of OBRA 90 expressly state that the best price includes "the lowest price available from the manufacturer ... to any ... health maintenance organization," the manufacturer apparently takes the position that sales to HMOs who "repackage" or "relabel" drugs are not covered by this literal language.

According to the allegations, the manufacturer uses this repackaging or relabeling scheme to segment the market so that its best customers get a lower price than is available to Medicaid -- even if the repackaged or relabeled drug is identical to the original drug in all respects. In effect, the manufacturer is manipulating its drug pricing to reduce the size of its drug rebates, thereby violating both the intent and language of the "best price" provisions of OBRA 90.[8]

During our initial investigation, my staff learned that since passage of the Medicaid rebate in 1990, there has been a substantial growth in drug repackaging. In fact, Professor Stephen Schondelmeyer of the University of Minnesota calculated that the number of repackaged drugs has grown from 791 in January 1990 -- before the rebate program took effect -- to 17,231 in January 2000.[9]

My staff then reviewed a select group of drugs with high Medicaid sales and found these drugs are in fact sold to a substantial number of repackagers. For example, according to FDA records, six of the ten prescription drugs with the highest Medicaid reimbursements in fiscal year

---

[8]This use of repackaging or relabeling to segment the market and manipulate drug pricing can be distinguished from sales by a manufacturer to a traditional repackager that repackages or relabels drugs for resale to other consumers. When a repackager resells the drugs, it may be appropriate to treat the repackager as the drug's "manufacturer" and hold the repackager responsible for offering the drug to the Medicaid program at the repackager's "best price." *See* Health Care Financing Administration, Attachment to Medicaid Drug Rebate Program Release No. 29 (June 1997). The situation is fundamentally different, however, when the repackager is buying drugs for its own use, as is the case with HMOs that act as repackagers. In this situation, the manufacturer's transaction with the so-called "repackager" is functionally equivalent to the transactions that OBRA 90 intended to include in the determination of "best price."

[9]Personal communications between House Government Reform Committee minority staff and Professor Stephen Schondelmeyer.

1998 are registered under 56 separate NDCs by 17 different repackagers. Many of these repackagers purchase drugs for resale to physicians who dispense their own drugs. But some are traditional favored customers of drug manufacturers. For example, two of the repackagers my staff identified were HMOs. The drugs sold by the repackagers are not generally available through retail pharmacies.

These circumstances suggested that there could be merit to the allegations of drug pricing manipulation. However, my staff was not able to determine whether manipulation was actually occurring because neither the Medicaid "best prices" nor the prices at which manufacturers sell to repackagers are publicly available. For this reason, I wrote the Inspector General on April 19, 1999, to request her assistance. Specifically, I requested that she investigate "whether drug manufacturers have been manipulating drug pricing in order to avoid offering Medicaid the "best prices."[10]

III. The Inspector General's Findings Regarding Repackaging by Favored Customers

Based on the evidence we had accumulated, the Inspector General agreed that "drug manufacturers could easily be gaming the rebate system."[11] The Inspector General conducted a limited review of 12 drugs identified in my letter as having high Medicaid reimbursements and a large number of repackagers. The Inspector General then obtained and reviewed confidential pricing information about these drugs from the drug manufacturers and repackagers.

The Inspector General's review found that "some repackagers did purchase drugs at prices lower than best price."[12] According to the Inspector General, "[t]he repackagers that purchased drugs at less than the best price were health maintenance organizations (HMO)."[13] Specifically, the Inspector General found that the HMOs acting as repackagers were able to purchase one of the drugs "at prices considerably below (34.3%) the reported best price for that drug."[14]

The Inspector General found that if sales to these HMOs were included in the "best price" calculation, rebates to the Medicaid program would have increased substantially. According to the Inspector General, if the "best price" rebate for the drug had been based on the price at which

---

[10]Letter from Rep. Henry A. Waxman to Department of Health and Human Services Inspector General June Gibbs Brown (Apr. 19, 1999).

[11]Letter from Department of Health and Human Services Inspector General June Gibbs Brown to Rep. Henry A. Waxman (Nov. 22, 1999). A copy of this letter is enclosed.

[12]*Id.*

[13]*Id.*

[14]*Id.*

the drug was sold to the HMOs, the rebate would have increased by $27.8 million in fiscal year 1998 alone -- a 125% increase in the rebate for that drug.

Because of the small sample size, the Inspector General wrote that her auditors "were unable to determine how many HMOs are repackaging drugs nor how frequently the HMO repackagers are purchasing drugs at prices below best price."[15] She did conclude, however, that "[c]learly, the exclusion of sales to repackagers from the best price provision of OBRA 90 provides drug manufacturers the opportunity to sell to favored customers without offering that price to Medicaid."[16]

IV. The Inspector General's Findings Regarding Repackaging for Doctor-Dispensed Medications

During the review, the Inspector General also found that state Medicaid programs may not be receiving rebates for drugs resold by repackagers to physicians for direct physician-to-patient dispensing.

According to the Inspector General, eight repackagers that account for many of the repackaged drugs "are repackaging for physician dispensing."[17] They do this by "repackaging drugs into commonly dispensed package sizes so that physicians can dispense the drugs by simply handing the patient a prepackaged product."[18]

The Inspector General found that unlike the HMOs, these repackagers generally did not buy drugs directly from the drug manufacturer. Instead, they normally bought their drugs through traditional drug wholesalers, often at prices above "best prices." In addition, the Inspector General found that the drug manufacturers were often unaware of the purchases by these repackagers and were unlikely to be the cause of their growth. Nevertheless, the Inspector General found that their activities appeared to be depriving state Medicaid programs of rebates from drug manufacturers.

The Inspector General found that when physicians dispense drugs to Medicaid-eligible patients, they receive reimbursement from Medicaid for the drugs' costs, but do not always identify the specific NDCs for the drugs depending on state requirements. According to the Inspector General, there was no Medicaid utilization shown for the repackaged drugs because the

---

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

physicians can bill for the drugs through a form that did not capture the NDCs. Without the NDCs, the Inspector General reported, "the manufacturers were not readily identified" and therefore "no Medicaid rebates have been collected."[19] The Inspector General wrote that she was considering conducting an audit to identify and collect those rebates.

V. Conclusion

It appears that manufacturers of brand-name prescription drugs are avoiding Medicaid "best price" requirements by offering ultra-low prices to favored customers like HMOs that repackage or relabel drugs. This practice is apparently costing state and federal taxpayers tens of millions of dollars -- if not more -- in lost rebates each year. Additional rebates may be lost when drug repackagers resell drugs to physicians for direct physician-to-patient dispensing.

These actions -- if true -- appear to violate both the intent and the literal language of OBRA 90. I urge you to fully investigate this matter and to take all necessary action to recoup any lost rebates. I also urge you to take appropriate enforcement action to sanction any companies found to be illegally circumventing Medicaid laws.

Thank you, in advance, for your prompt attention to this matter.

Sincerely,

Henry A. Waxman
Ranking Minority Member

Enclosure

---

[19] *Id.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

NOV 22 1999

The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
B350-A Rayburn House Office Building
Washington, DC 20515-6143

Dear Mr. Waxman:

This is in response to your letter requesting that the Office of Inspector General determine whether drug manufacturers are using repackagers to manipulate drug pricing in order to avoid offering Medicaid the best price as required under the Omnibus Budget Reconciliation Act of 1990 (OBRA 90). You also requested that we determine whether drug manufacturers are marketing existing drugs under new national drug codes (NDC) in order to circumvent the inflation adjustment rebate also required under OBRA 90. Your letter provided evidence that the number of drug repackagers and repackaged drugs had grown exponentially since the enactment of OBRA 90 and that certain repackagers appeared to be the types of entities that are most likely to get favored drugs prices.

We met with members of your staff concerning these matters and agreed that, based on the information your staff had accumulated, drug manufacturers could easily be gaming the rebate system. We limited this review to the 12 drugs you identified in your letter. After obtaining and reviewing documentation from drug manufacturers and repackagers, we were unable to determine how frequently drug manufacturers are avoiding the best price provision of OBRA 90 by selling to repackages. Some repackagers did purchase drugs at prices lower than best price. Most repackagers were purchasing drugs from wholesalers without the manufacturers' knowledge and at prices substantially higher than best price. The repackagers that purchased drugs at less than the best price were health maintenance organizations (HMO).

HMOs Can Purchase Below Best Price

Your request identified two repackagers that are HMOs. Each HMO was listed as a repackager of two drugs (one of the drugs was repackaged by both HMOs, therefore a total of three drugs were repackaged). According to the manufacturers, both HMOs were able to purchase one drug at prices considerably below (34.3 percent) the reported best price for that drug. Another drug was purchased at an average price of 8.1 percent above best price. The manufacturer of the third drug indicated that it did not sell that drug to the HMO. Therefore, if the HMO purchased that drug, it would have been through a wholesaler and at a price substantially higher than best price.

If sales to repackagers were included in the best price, rebates would have increased by $27.8 million for the drug which was purchased at 34.3 percent below best price. The $27.8 million figure is for the year ending September 30, 1998, and would represent a 125 percent increase in rebates for the drug. Total Medicaid reimbursement for the drug was $112 million for that same time period.

We limited our review to the 12 drugs and the repackagers listed in your letter and do not know how many HMOs are repackaging drugs nor how frequently the HMO repackagers are purchasing drugs at prices below best price. Clearly, the exclusion of sales to repackagers from the best price provisions of OBRA 90 provides drug manufacturers the opportunity to sell to favored customers without offering that price to Medicaid.

Growth in the Number of Repackagers

There is no disputing that the number of repackagers has increased significantly since the passage of OBRA 90. We do not believe that this increase is attributable to a concerted effort by manufacturers to avoid the best price provisions of OBRA 90, but is related to changes in the marketing of drugs. Eight repackagers account for almost every repackaged drug listed in the Red Book (a pharmaceutical industry reference source) and we believe that these repackagers are responsible for the huge increase in repackaged drugs. All eight repackagers are repackaging for physician dispensing. Specifically, these repackagers repackage drugs into commonly dispensed package sizes so that physicians can dispense the drugs by simply handing the patient a prepackaged product. Today's computer technology has made the dispensing and labeling of drugs very practical in physician offices.

In most cases the repackagers for physician dispensing were purchasing drugs from wholesalers rather than from manufacturers and at prices much higher than best price. And, in most instances, the manufacturers were not aware that the repackagers were purchasing their drugs. One repackager that marketed drugs to physician offices told us that it made very little profit on repackaging since it purchased at wholesale prices, but that its profit came from software sold to physicians. Another repackager had an internet web site which indicated that it repackaged for physician dispensing. It even had a page on its web site where a physician could calculate expected profits from dispensing directly to the patient rather than writing a prescription for the patient.

There was no Medicaid utilization shown for the repackaged drugs because the physicians billed for the drugs through a form that did not capture the NDCs. Without the NDCs the manufacturers were not readily identified, therefore no Medicaid rebates have been collected. In that regard, we are considering conducting an audit to identify and collect those rebates.

Inflation Rebate Concerns

You requested that we determine whether drug manufacturers are marketing existing drugs under new NDCs in order to circumvent the inflation adjustment rebate that is required under OBRA 90. The additional rebate that results from the inflation adjustment is the amount by which current average manufacturer price (AMP) for a drug exceeds the base AMP indexed to the consumer price index for urban consumers (CPI-U).

We analyzed the 1000 brand name drugs with the highest Medicaid reimbursement for the year ended September 30, 1998. We identified 615 drugs that had entered the market after the passage of OBRA 90. Of those 615 drugs, we identified 175 for which there were earlier versions of the drug and, therefore, for which the potential exists that the manufacturer had changed the drug in order to restart the indexing for the inflation rebate. About one third of the changes to the drugs were changes in product forms (such as tablet to capsule, capsule to liquid, or extended release) and another third of the changes were changes in the strength of the drug. The rest of the changes were to both the form and strength. The Food and Drug Administration advised us that a drug manufacturer could obtain a new NDC for any change to the drug, including something as minor as a change in color.

The potential exists for manufacturers to be gaming the inflation rebate for these 175 drugs. One solution would be to decrease the base AMP for any new version of a drug by an amount equal to the percentage increase above the CPI-U for the earliest version of the drug. This would, of course, require a legislative change. We are considering conducting a study to determine the impact of such a change.

We appreciated the opportunity to respond to your concerns regarding drug repackaging and the inflation adjustment rebate. Should you have any questions or comments regarding these matters, please contact Helen Albert at 202-260-8610.

Sincerely,

June Gibbs Brown

June Gibbs Brown
Inspector General