

Good morning, Madam Chairman. I am George Reeb, Assistant Inspector General for the Centers for Medicare and Medicaid Audits within the Department of Health and Human Services. I am accompanied by Robert Vito, Regional Inspector General for Evaluation and Inspections, Philadelphia. We appreciate the opportunity to appear before you today regarding the important issue of Medicare payments for currently covered prescription drugs. I am here to describe the findings of several Office of Inspector General (OIG) reports showing that Medicare and Medicaid pay too much for prescription drugs. This occurs largely because of the use of the average wholesale price (AWP) as the basis for calculating reimbursements to physicians and suppliers, including pharmacies. We have consistently found that the AWP's which Medicare and Medicaid use are not really wholesale prices. I will also describe settlements of two cases which included the issue of manufacturers' use of the AWP as a marketing tool, at unnecessarily high costs to taxpayers and beneficiaries.

## Background

For the most part, AWP's (which are not clearly defined by law or regulation) are compiled in drug compendia such as Medical Economics' *Red Book*. As our reports have indicated, the published AWP's that Medicare and Medicaid use to establish drug reimbursement bear little or no resemblance to actual wholesale prices available to physicians, suppliers, and large government purchasers.

In general, Medicare reimburses physicians and suppliers at the published AWP less a discount of 5 percent (i.e., 95 percent of the AWP). Of this amount, Medicare beneficiaries are responsible for a 20 percent coinsurance payment. Similarly, most state Medicaid agencies reimburse pharmacies based on the AWP of a drug less a discount which averages about 10.3 percent nationally. Federal regulations require that each State's reimbursement for a brand name or certain other drugs not exceed, in the aggregate, the lower of estimated acquisition costs or the providers' usual and customary charge to the public for the drug.<sup>1</sup> Some states require a small copayment for each prescription filled by a pharmacy.

The current cost to Medicare and Medicaid for currently covered drugs is in the billions. Medicare's total payments for prescription drugs have risen steadily over the past decade. In 1992, Medicare paid about \$700 million for prescription drugs; by 2001, it paid \$6.5 billion. Between 2000 and 2001 alone, payments increased by \$1.5 billion. Unlike Medicare which currently covers a narrow range of drugs, Medicaid covers most outpatient prescription drugs. Medicaid payments for

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<sup>1</sup> Medicaid regulations limit reimbursement of multiple source (generic) drugs to federal upper limit amounts (FUL) if at least three generic equivalents are available. The FULs restrict the amount that Medicaid can reimburse for drugs that have available generic equivalents (42 CFR 447.332). The FULs are established by the Centers for Medicare & Medicaid Services.

prescription drugs totaled almost \$24 billion in FY 2001. Our reports, which I am summarizing in this testimony, have shown time after time that Medicare and Medicaid pay too much for drugs .

## **Medicare Pays Too Much – OIG Reports**

Medicare's coverage of outpatient drugs is limited primarily to drugs used in dialysis, organ transplantation, and cancer treatment. Medicare also covers certain vaccines and drugs used with durable medical equipment such as infusion pumps and nebulizers. Physicians and suppliers purchase these drugs, administer or provide them to Medicare beneficiaries, and then submit a bill to Medicare for reimbursement. Medicare's current payment methodology for prescription drugs adversely affects the Medicare trust fund and Medicare's beneficiaries, who are responsible for 20 percent of the allowed amounts.

Over the past 5 years, the OIG has issued a number of reports, all of which have reached the conclusion that Medicare and its beneficiaries pay too much for prescription drugs. For example, we studied the prices for 24 Medicare covered drugs (\$3.1 billion of the \$3.9 billion in Medicare drug expenditures in 1999) comparing Medicare reimbursement to prices available to the physician/supplier community, the Department of Veterans Affairs, and Medicaid. We found that Medicare and its beneficiaries would have saved \$1.6 billion for these 24 drugs by paying the VA's Federal Supply Schedule price. For half of the drugs, Medicare paid more than double the VA price. The savings would have been \$761 million a year by paying the actual wholesale prices available to physicians and suppliers. For every drug in our review, Medicare paid more than the wholesale price available to physicians and suppliers and the VA Federal Supply Schedule price. We also found that Medicare would have saved over \$425 million or almost 15 percent a year for the 24 drugs by obtaining rebates similar to the Medicaid program.

Subsequently, we updated the findings of this report with more current drug pricing information and estimated that, of the \$3.7 billion Medicare spent for 24 drugs in 2000, the program would have saved \$1.9 billion if the drugs had been reimbursed at prices available to the VA. Over \$380 million of this savings would have directly impacted Medicare beneficiaries in the form of reduced coinsurance payments. In some cases, the VA price for a drug was less than the amount a Medicare beneficiary would pay in coinsurance. Further, we estimated that, if Medicare paid the actual wholesale prices available to physicians and suppliers for these 24 drugs, the program and its beneficiaries would save \$887 million a year. If Medicare paid for these drugs based on catalog prices, beneficiaries would pay over \$175 million less in coinsurance. The potential total savings available to both Medicare and its beneficiaries is probably higher than our estimates, assuming data for all Medicare drugs is similar to that for the 24 we analyzed.

In other reviews, we reported that Medicare pays nearly double the Medicaid price and almost seven times more than the VA for one milligram of albuterol, a drug used with a nebulizer to treat asthma, emphysema, and other respiratory problems. Nearly every chain pharmacy we contacted sold generic albuterol at prices less than Medicare paid for it. According to our survey results, any consumer could buy a monthly supply of albuterol from Internet pharmacies for around \$63. For the same monthly supply, Medicare and its beneficiaries would pay \$120, \$96 from Medicare and \$24 from the beneficiary. The VA's entire monthly payment of \$17.50 for albuterol is less than just the beneficiary's \$24 coinsurance payment under Medicare. The VA price for albuterol has fallen by

more than 50 percent over the last 3 years, from \$0.11 per mg in 1998 to \$0.05 per mg in 2001. During the same time period, Medicare's reimbursement amount (based on reported average wholesale prices) has remained constant at \$0.47 per mg.

We also found that Medicare and its beneficiaries would save \$279 million a year if ipratropium bromide were reimbursed at the median price paid by the VA. The VA's purchase price has decreased considerably over the last 3 years, from \$1.29 per mg in 1998 to \$0.66 per mg in 2001. In contrast, the Medicare reimbursement amount has remained constant at \$3.34 per mg. We also found that Medicare would save between \$223 million and \$262 million a year if ipratropium bromide were reimbursed at prices available to wholesalers and suppliers. The median catalog price available to suppliers was \$0.82 per mg, the median supplier invoice price was \$1.18 per mg, and the median wholesale acquisition cost reported by manufacturers was \$1.20 per mg.

Aside from the obvious problem that AWP's can be arbitrarily inflated, resulting in inappropriate Medicare payments, the use of AWP as a basis for reimbursement in Medicare has other potential adverse side-effects. For instance, because physicians and suppliers get to keep the difference between the actual price they pay for the drug and 95 percent of its AWP, this "spread" can serve as an inducement for suppliers or physicians to use one brand of the drug over another. Thus, publishing an artificially high AWP can be used as a marketing device to increase a drug company's market share. Such a tactic increases the profit of the suppliers or physicians who purchase the drug because, while not paying the artificially inflated AWP amount, they are reimbursed based on that inflated amount. While inflating the published AWP does not increase the amount the manufacturer receives for each unit of the drug product, the higher profits available to physicians and suppliers may lead them to purchase one brand of drug over another, thereby increasing a manufacturer's market share. This in turn increases the profits of the drug company. All of this occurs at the expense of the Medicare program and its beneficiaries.

### **Medicaid Pays Too Much – OIG Reports**

Although this hearing pertains to Medicare, I would like to mention our work in the Medicaid program because it confirms that the average wholesale price (AWP) is not a realistic basis for drug reimbursements. Our Medicaid work also serves as a red flag that, if Medicare is expanded to cover more prescription drugs, particularly those that beneficiaries can obtain from pharmacies, it would be unwise for Medicare to reimburse pharmacies at Medicare's current rate of AWP minus 5 percent (i.e., 95 percent of AWP).

In Medicaid, we found there is a significant difference between pharmacy acquisition costs for both brand and generic drugs and the basis for most states reimbursement for drugs—the average wholesale price (AWP). We believe if states would reimburse pharmacies for Medicaid patient prescriptions more in line with the actual acquisition costs of the drugs, substantial savings could be realized by the Medicaid program.

As a follow-up to our previous work, we conducted nationwide reviews of pharmacy acquisition costs for both brand name and generic drugs reimbursed under the Medicaid prescription drug program during Calendar Year (CY) 1999. Since most states use AWP minus a percentage discount, which varies by state, as a basis for reimbursing pharmacies for drug prescriptions, the objective of

these reviews were to develop an estimate of the discount below AWP at which pharmacies purchase brand and generic drugs.

We obtained pricing information from 217 pharmacies in 8 states, which resulted in an analysis of thousands of invoice prices that included both brand and generic drug products. We compared each invoice drug price to AWP for that drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. Our estimates were that pharmacy acquisition costs for brand name drugs in 1999 was an average of 21.84 percent below AWP and for generic drugs an average of 65.93 percent below AWP. These estimates were both higher than our previous 1994 studies of 18.30 for brands and 42.45 for generics.

In each of these reports, we recommended that the Centers for Medicare & Medicaid Services (CMS) require the states to bring pharmacy reimbursement more in line with the actual acquisition cost of both brand and generic drug products.

In response to comments made by both state Medicaid officials and industry representatives, we further analyzed the results of our studies of CY 1999 expenditures. This additional information was a breakdown of discount percentages for various brand and generic drug categories from single source innovator through drugs with and without federal upper limits. Based on the results of our additional analyses, if states continue to reimburse for drugs based on AWP, we recommended that CMS encourage the states to consider using a multi-tiered reimbursement methodology. These tiers should be oriented to the significant differences in pharmacy acquisition costs depending on the drug's category of brand, generic, subject to federal upper limits, etc. The current method used by most states for reimbursing for brand name drugs and non-federal upper limit multiple source drugs using a single percentage discount does not consider these large differentials found during our additional analysis.

The discount percentages in this report ranged from 17.2 to 72.1 percent below AWP. These percentages do not consider discounts available to most pharmacies such as volume discounts, prompt pay discounts, and related rebates. The Medicaid program, unlike the Medicare program, includes a rebate component that is based, in part, on the average manufacturers' price (AMP). However, our report does not address the disconnect caused by basing Medicaid reimbursements on AWP while basing rebates on the AMP. That practice could result in higher cost and lower rebates for the States under Medicaid. In an earlier report we recommended tying the rebate to the AWP rather than the AMP.

## **Recent Settlements**

Recent settlements further illustrate some of the problems associated with Medicare's current reimbursement methodology. Because of the price spread is so large and Medicare reimbursement so lucrative for the drug albuterol, some mail-order pharmacies have been tempted to capitalize on the difference by making illegal kickback payments to durable medical equipment suppliers for patient referrals. A civil settlement totaling \$10 million was reached with one pharmacy that engaged in this conduct. Issues of inflated AWP's were also associated with recent settlements involving Bayer Corporation and TAP Pharmaceutical Products Inc.

***Bayer Corporation.*** In January 2001, the United States settled a qui tam False Claims Act case with the Bayer Corporation, a major pharmaceutical manufacturer. Under the terms of a settlement negotiated by a team of federal and state law enforcement officials, Bayer agreed to pay \$14 million in order to resolve its liability to the Medicaid program. This case was investigated and handled by a team of federal and state representatives—including the OIG, representatives of the Medicaid Fraud Control Units of four states and the Texas Attorney General’s Office, the United States Attorney’s Office for the Southern District of Florida, and the Department of Justice.

Through this settlement, Bayer resolved its liability under the False Claims Act and the Medicaid Rebate Statute for its conduct in connection with six of its drugs between January 1993 and August 1999. Although Bayer did not admit liability, the United States alleged that Bayer: 1) knowingly set and reported AWP’s for these drugs at levels far higher than the actual acquisition cost of the majority of its customers and caused those customers to receive excess Medicaid reimbursement, 2) made misrepresentations to the Medicaid programs of certain states, and 3) knowingly misreported and underpaid its Medicaid rebates for the drugs.

***TAP Pharmaceutical Products, Inc.*** In October of last year, the United States announced a major global health care fraud settlement with TAP Pharmaceutical Products Inc. (“TAP”). TAP agreed to pay a total of \$875 million to resolve its liability, the largest health care fraud settlement ever. TAP also agreed to plead guilty to violating federal law governing the use of drug samples. The investigation centered on TAP’s sales and marketing efforts to physicians who used TAP’s prostate cancer drug, Lupron. The company routinely provided free samples of Lupron to physicians, expecting that those physicians would bill the free samples to the patients and Medicare. TAP also allegedly paid kickbacks to physicians, HMOs, and others in the form of grants, debt forgiveness, travel, and entertainment, and other items to induce them to purchase Lupron. In addition, TAP allegedly set and reported AWP’s for Lupron at levels far higher than the actual acquisition cost of the majority of its customers and caused those customers to receive excess reimbursement from Medicare and Medicaid. TAP also allegedly underpaid rebate amounts due to the states under the Medicaid Rebate Statute.

## **Conclusion**

A drug reimbursement system should be based on real prices available in the marketplace. Physicians and suppliers, including pharmacies, should be fairly reimbursed and at levels that ensure that the drugs are accessible. If reimbursement is set too low, some beneficiaries may not be able to obtain needed prescription drugs. We recognize that some physician groups have raised concerns about Medicare’s attempts to lower reimbursement for prescription drugs. Specifically, these physician groups say that overpayments for prescription drugs simply make up for inadequate payments for their practice costs. We agree that physicians need to be properly reimbursed for patient care. However, we do not believe that the payment of artificially inflated drug prices is an appropriate mechanism to compensate them.

This concludes my testimony. I appreciate the opportunity to address this important issue with you today. I welcome your questions.

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