Good morning, Mr. Chairman. I am Janet Rehnquist, Inspector General for the Department of Health and Human Services. I appreciate the opportunity to appear before you today regarding the important issue of Medicare reimbursement for prescription drugs.

We have consistently found that Medicare pays too much for prescription drugs—more than most other payers. For example, we found that Medicare's authorized payments for 24 leading drugs in the year 2000 were $887 million more than actual wholesale prices available to physicians and suppliers and $1.9 billion more than prices available through the Federal Supply Schedule. We believe that this has occurred because Medicare's reimbursement methodology is flawed. Until the system is changed, Medicare and its beneficiaries will continue to pay excessive amounts for prescription drugs, and the amount of excessive payments will increase every year.

Medicare Coverage and Payments for Prescription Drugs

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. In general, Medicare reimburses physicians and suppliers for 95 percent of the average wholesale price (AWP) published by the drug manufacturers. Of this amount, Medicare beneficiaries are responsible for a 20 percent coinsurance payment.

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 2000, it paid $5 billion. Between 1999 and 2000 alone, payments increased by $1 billion.

Excessive Payments

Since 1997, the Office of Inspector General has produced a number of reports, all of which have concluded that Medicare and its beneficiaries pay too much for prescription drugs. Today I am issuing three new reports. Two of these are related to Medicare payments for the drugs albuterol and ipratropium bromide. The third focuses on Medicaid reimbursement for generic drugs. It shows that the Medicaid program faces the same kinds of problems as Medicare when paying for prescription drugs.

The following summarizes the results of our many reports on Medicare payments for prescription drugs.

Medicare Reimbursement for Prescription Drugs. In a January 2001 report, 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.

In June 2001, we updated the findings of this report with more current drug pricing information. We found that Medicare would have saved $1.9 billion of the $3.7 billion it spent for 24 drugs in 2000 if the drugs were reimbursed at prices available to the VA. Over $380 million of this savings would directly impact 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. 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. Beneficiaries would pay over $175 million less in coinsurance if Medicare paid for these drugs based on catalog prices. The potential total savings available to both Medicare and its beneficiaries is probably higher, assuming data for all Medicare drugs is similar to that for the 24 we analyzed.

Nebulizer Drugs. In June 2000, 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 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 for around $52. 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.

In a report that we are releasing today, we show that the VA price for albuterol has continued to decrease. 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. In 2000, published wholesale acquisition costs for albuterol ranged from $0.09 to $0.18 per mg. These wholesale acquisition costs were provided by manufacturers to drug compendiums such as the *Red Book*. The Medicare reimbursement rate of $0.47 per mg was anywhere from three to five times the wholesale acquisition costs reported by manufacturers.

Also in this report, we looked at who actually supplies albuterol to Medicare beneficiaries. We found that Medicare reimbursed more than 6,500 pharmaceutical suppliers for albuterol claims in 2000. However, less than 3 percent of these suppliers (184) accounted for approximately 80 percent of albuterol reimbursement. Each of these suppliers had over $150,000 in paid Medicare claims for albuterol last year. Thirty-four of these suppliers were each responsible for more than $1 million in Medicare reimbursement for albuterol in 2000, with five having between $11 million and $35 million in reimbursement. Thus, the vast majority of the albuterol supplied to Medicare beneficiaries was provided by suppliers that purchase and bill for a large quantity of the product. We believe that suppliers that purchase albuterol in such large quantities are likely to receive volume discounts similar to those provided to the VA and other large purchasers.

We are releasing a separate report today in which we 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. Furthermore, we found that less than 1 percent of the 5,652 pharmaceutical suppliers that were reimbursed by Medicare for ipratropium bromide accounted for the majority of the drug's reimbursement that year. Each of these high-volume suppliers provided home-delivery/mail-order services to Medicare beneficiaries.

Flawed Payment Method

Our reports have shown time after time that Medicare pays too much for drugs. Why does Medicare pay so much? We believe that it is because Medicare's payment methodology is fundamentally flawed. By statutory requirement, Medicare's payment for a drug is equal to 95 percent of the drug's average wholesale price (AWP). However, the AWPs which Medicare uses are not really wholesale prices.

For the most part, AWPs are reported by manufacturers to companies that compile drug pricing data, such as First DataBank and Medical Economics, which publishes the *Red Book.* As our reports have indicated, the published AWPs that Medicare uses to establish drug prices bear little or no resemblance to actual wholesale prices available to physicians, suppliers, and large government purchasers.

Aside from the obvious problem of inflated AWPs resulting in inappropriate Medicare payments, the use of AWP also has other potential adverse implications. 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" serves as an inducement for suppliers or physicians to use one brand of the drug over another. Thus, publishing an artificially high AWP is 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, it does increase the manufacturer's market share because of the higher profits made by physicians and suppliers. This in turn increases the profits of the drug company. All of this occurs at the expense of the Medicare program and its beneficiaries.

Recent Settlements

Recent settlements further illustrate some of the problems associated with Medicare's current reimbursement methodology. Because 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 AWPs were also associated with recent settlements involving Bayer Corporation and TAP Pharmaceutical.

Bayer Corporation. In January of 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 AWPs 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 sale 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, travel and entertainment, and other items to induce them to purchase Lupron. In addition, TAP allegedly set and reported AWPs 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.

Medicaid Drugs

Although Medicare is the primary focus of my testimony today, problems resulting from the publication of misleading AWPs have also plagued the Medicaid program because the payment methods based on AWPs are fundamentally flawed. This is illustrated by a report we are releasing today related to Medicaid drug reimbursement. As a follow-up to our previous work, we conducted a nationwide review of pharmacy acquisition costs for generic drugs reimbursed under the Medicaid prescription drug program. 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 this review was to develop an estimate of the discount below AWP at which pharmacies purchase generic drugs.

We obtained pricing information from 217 pharmacies in 8 States, which resulted in an analysis of 8,728 invoice prices for 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. We estimated that the actual generic drug acquisition cost was a national average of 65.93 percent below AWP. Our previous estimate, based on calendar year 1994 pricing data, showed a discount of 42.45 percent below AWP for generic drugs. As a result, this review showed

an increase of 55.31 percent in the average discount below AWP for generic drugs from 1994 to 1999.

Unlike brand name drugs for which Medicaid reimbursement is based predominately on a discounted AWP, reimbursement for generic drugs can be limited by Federal upper limit amounts. Taking the discounts below AWP, as well as those generic drugs for which upper limits could be applied, we calculated that as much as $470 million could have been saved for the 200 generic drugs with the greatest amount of Medicaid reimbursements in CY 1999, if reimbursement had been based on the discount percentages below AWP as identified in this report. Accordingly, 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 generic drug products, which we identified as being 65.93 percent below AWP.

Similarly, in August 2001 we issued a report on pharmacy acquisition costs for brand name drugs reimbursed under the Medicaid prescription drug program. The objective of the review was to develop an estimate of the discount below AWP at which pharmacies purchase brand name drugs. We estimated that nationally, pharmacy actual acquisition cost was an average of 21.84 percent below AWP. Our previous estimate, based on CY 1994 pricing data, showed a discount of 18.30 percent below AWP for brand name drugs. Therefore, this review showed that from 1994 to 1999 there was an increase of 19.3 percent in the average discount below AWP for brand name drugs. We estimated that the Medicaid program could have saved as much as $1.08 billion if reimbursement had been based on a 21.84 percent average discount below AWP.

Correcting the Current Payment System

I believe a number of factors need to be considered when deciding how to correct Medicare's reimbursement method for prescription drugs. These factors provide a basis for considering how to change the Medicare drug payment system.

Market Prices. A drug reimbursement system should be based on real prices available in the marketplace. Physicians and suppliers 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.

Data Availability and Reliability. We need a practical way to obtain data which can be used to set reimbursement. Further, there needs to be confidence that the data are reliable and cannot be misrepresented.

Periodic Updates. Reimbursement needs to be periodically updated to reflect market changes. This will also impact how monitoring is conducted to ensure that access problems do not occur, and how payment revisions are made if this does occur or if individual payments continue to be inflated.

Proprietary Information. We need to consider how to protect proprietary data.

Physician Practice Costs. Finally, we recognize that some physician groups have raised concerns about Medicare's attempts to lower reimbursement for prescription drugs. For example, some oncologists have stated that Medicare does not adequately reimburse physicians for the practice costs associated with providing treatment to cancer patients. 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. The Medicare program already has a procedure for determining the amount physicians should be reimbursed for their practice costs. If the current calculations are incorrect, they should be modified. Physicians deserve fair reimbursement for their valuable services.

Conclusion

Our reports, including the ones that I am releasing today, contain numerous options to reform Medicare's drug pricing method. Each has its own advantages and disadvantages. We recognize that there may not be one perfect solution to solving all of Medicare's drug pricing issues. We hope that these are helpful as the Congress and the Administration move forward to address this pressing problem.

Mr. Chairman, this concludes my testimony. I appreciate the opportunity to address this important issue with you today. 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. The payment system is based on the AWP, a list price reported by the drug manufacturers that is neither average nor wholesale and bears little or no resemblance to the actual wholesale prices available to physicians and suppliers who participate in the Medicare program. Until this problem is corrected, Medicare and its beneficiaries will unnecessarily pay more and more each year. I welcome your questions.