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Good morning Mr. Chairman. I am George Grob, Deputy Inspector General for Evaluation and Inspections, Department of Health and Human Services. I am here today to discuss Medicare payments for prescription drugs.

Medicare pays too much for prescription drugs—more than most other payers. The method it uses to determine the amount to be paid is flawed. In fact, it makes no sense at all. It allows the price to be set arbitrarily by drug manufacturers, not the marketplace. Their published wholesale prices for many drugs are far above what suppliers and physicians actually pay for them. This allows physicians, for example, to make substantial profits from the drugs they administer during the course of treatment in their offices. For the year 2000 we found that Medicare's authorized payments for 24 leading drugs 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. 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. However, 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. This rapid growth illustrates the necessity of ensuring that Medicare pays reasonable prices for the drugs it covers.

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.

Excessive Payments

Over the past 4 years, the Office of Inspector General has produced a number of reports, all of which have reached the conclusion that Medicare and its beneficiaries pay too much for prescription drugs. Although it might be sufficient for me to quote only from our most recent studies, I would like to summarize all of our work here, because it demonstrates the consistency of our findings and the relentless growth of the problem.

A table summarizing the results of our reports is provided on the next page, followed by a more detailed description.

Summary of OIG Medicare Prescription Drug Reports

Year of Report	1997	1998	2000			2001	
Drugs Reviewed	22 drugs	34 drugs	5 ESRD drugs	Albuterol	24 drugs	Albuterol	24 drugs
Year Reviewed	1996	1997	1998	1999	1999	2000	2000
Medicare Expenditures for Reviewed Drugs	$1.5 billion	$2.1 billion	$379 million	$246 million	$3.1 billion	$296 million	$3.7 billion
Excessive Payments Based On: **VA** **Catalogs** **Medicaid**	$447 million	$1 billion	$162 million $42 million	$209 million $120 million	$1.6 billion $761 million $425 million	$264 million $245 million	$1.9 billion $887 million
Beneficiary Share of Excessive Payments	$89 million	$200 million	$32 million $8 million	$42 million $24 million	$320 million $152 million $85 million	$53 million $49 million	$380 million $177 million

Drugs in general

In December 1997, we released a report which compared Medicare payments for 22 drugs to actual wholesale prices available to the physician and supplier communities. These 22 drugs accounted for $1.5 billion of the $2.3 billion in Medicare payments for prescription drugs in 1996. The wholesale prices were computed using catalogs from drug wholesalers and group purchasing organizations which sell drugs to physicians and suppliers.

The report found that Medicare allowances for the 22 drugs exceeded wholesale prices by $447 million in 1996. Medicare paid more than the available wholesale price for all 22 drugs under review. For more than one-third of the drugs, Medicare reimbursement amounts were more than double the wholesale prices available to the physician and supplier community.

We followed up this report in November of 1998 by comparing Medicare allowances for prescription drugs to prices available to the Department of Veterans Affairs (VA) and several other Federal agencies through the Federal Supply Schedule (FSS). (The supply schedule provides agencies lie the VA with a simple process for purchasing commonly-used products in various quantities while still obtaining the discounts associated with

volume buying. Using competitive procedures, contracts are awarded to companies to provide services and supplies at the FSS prices over a given period of time.) This report included 34 drugs which accounted for $2.1 billion of the $2.8 billion in Medicare spending for prescription drugs in 1997.

We found that Medicare and its beneficiaries would have saved $1 billion in 1998 if the allowed amounts for the 34 drugs were equal to prices obtained through the FSS. The potential savings for just one drug, leuprolide acetate, accounted for over $275 million. Medicare paid more than double the VA for 14 of the drugs. Overall, it paid between 15 percent and 1600 percent more than the VA for each of the 34 drugs. The biggest difference was for the drug leucovorin calcium, with a VA price of $1.18 and a Medicare price over $20.

In January of this year, we released another report comparing Medicare reimbursement to prices available to the physician/supplier community, the Department of Veterans Affairs, and Medicaid. This time, we studied the prices for 24 drugs which represented $3.1 billion of the $3.9 billion in Medicare drug expenditures in 1999.

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. For example, Medicare reimburses $43 for 10 mg of the drug doxorubicin, more than four times the wholesale price of $10. The VA pays even less, with a Federal Supply Schedule price of $6.29. 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.

We have recently 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. More conservatively, Medicare and its beneficiaries would save $887 million a year by paying the actual wholesale prices available to physicians and suppliers for these 24 drugs. Beneficiaries would pay over $175 million less in coinsurance if Medicare paid for these drugs based on catalog prices. The potential savings 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 and End Stage Renal Disease (ESRD) Drugs

In addition to our reports summarizing a number of drugs, we have also produced targeted reports on specific nebulizer and end stage renal disease (ESRD) drugs that Medicare covers.

In June 2000, we released a report which looked at Medicare's reimbursement of albuterol, a drug used with a nebulizer to treat asthma, emphysema, and other respiratory problems. Albuterol is one of the top drugs covered by Medicare, with more than $250 million per year in Medicare allowances. This report updated the findings of several of our prior albuterol studies, all of which noted that Medicare's reimbursement amount exceeded prices available through other sources.

We found that Medicare paid nearly double the Medicaid payment amount and almost seven times what the VA pays for one milligram of albuterol. Furthermore, nearly every pharmacy we contacted sold generic

albuterol at prices less than Medicare paid for it. According to our survey results, consumers could go to popular drug stores across the country and buy a monthly supply of albuterol for around $95. For the same monthly supply, Medicare and its beneficiaries would pay a total of $118, with Medicare paying $94 and the beneficiary paying the remaining $24. The VA's entire monthly payment of $17.50 for albuterol is less than just the beneficiary's $24 coinsurance payment under Medicare. We calculated that Medicare could save between $47 million and $209 million per year by setting prices for albuterol equal to those available through these other sources.

Once again, we have recently updated this report with new pricing data. Preliminary findings show that VA prices for albuterol have decreased since last year. 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 *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.

Recently, we have begun to look 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. Our work in this area is continuing.

Also in June 2000, we released a report comparing Medicare payments for ESRD drugs to those of the VA and Medicaid. We focused this inspection on five drugs used by renal dialysis facilities to help treat renal failure. These five drugs accounted for $379 million in total charges to Medicare in 1998.

We found that Medicare paid between 37 percent and 56 percent more than the VA for these drugs. Medicare would have saved up to $162 million in 1998 if they paid the same amount as the VA for the five drugs. Furthermore, Medicare paid between 5 percent and 38 percent more than Medicaid. Medicare would have saved as much as $42 million in 1998 by using Medicaid reimbursement amounts.

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 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 drug product 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 would increase the profit of the suppliers or physicians who purchase the drug because, while not paying the artificially inflated AWP amount, they can bill Medicare for it and get paid at that inflated amount. While the published AWP does not increase the amount the manufacturer receives for each unit of the drug product, it may induce an increase in 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.

For the drug albuterol, the spread is so large and Medicare reimbursement so lucrative that 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 has been reached with one pharmacy that succumbed to this temptation.

Physicians' Concerns

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. We do not think that the decision as to how much Medicare pays for physicians' practice costs should be made by them or by drug manufacturers. The Medicare program or the Congress should have responsibility for this calculation. We certainly do not believe that the basis for their compensation and medical practice expenses should be artificially inflated, misleading, and mis-named average wholesale prices.

The Medicare program already has a procedure for determining and the amount of paying physicians for their practice costs. If the current calculations are incorrect, they should be modified. Physicians deserve fair reimbursement for their valuable services. There is no reason to resort to a make-believe process to accomplish this.

Options for Reforming the Payment System

There are a number of options for revising Medicare's drug reimbursement methodology. We recognize that there may not be one perfect solution to solving all of Medicare's drug pricing issues. However, we believe these options provide reference points for considering how to reform the Medicare drug payment system.

A few general remarks are in order before discussing specific options. First, some of the options offer a way to calculate a base amount for Medicare reimbursement. These include using the Federal Supply Schedule, the average manufacturer's price, or the AWP, for example. For each such option, additional sub-options are possible. One would be to set Medicare prices at a fixed percentage above or below the base. For example, Medicare currently has its payment rate set at 95 percent of AWP. That percentage could be dropped. Alternatively, if the Federal Supply Schedule were used as a base, then Medicare's payment could be set at, say, 105 or 110 percent of this number.

Second, the options are not necessarily exclusive of one another. In the Medicaid program, most States set payment rates at a percentage below AWP, but they also get rebates from manufacturers. The same could be done for Medicare. Another example might be basing Medicare payment rates on average manufacturer prices (AMP) (used for calculating rebates in the Medicaid program), but making upward or downward adjustments on the basis of surveys of amounts paid by of large institutional health care providers such as hospitals or managed care organizations.

Each option has its own advantages and disadvantages. Some things to consider when comparing them are: the cost of gathering data to set the base, the reliability of the data, the time needed to collect and analyze it; how easily it can be gamed or misrepresented.

Logistical considerations are important too, such as: who will collect and analyze data, who will propose the Medicare payment rate, and how often this will be done; how will the underlying data be verified, by whom, and how often; what method will be used to periodically update the payment amounts, and how frequently will this be done.

Finally, some broader principles and concerns need to be addressed, such as: how proprietary data will be protected; the consequences of drug manufacturers, suppliers, wholesalers, and medical care providers not providing the needed data or misrepresenting it; ways to minimize the burden of public reporting associated with data collection; the need for, nature of, and length of a transitional phase in introducing the new payment method; and whether any adjustment is needed in the practice cost component of Medicare's physician payment rate.

Keeping these factors in mind, the following options may be considered for reforming Medicare's drug payment method:

1. Authorize a commission to set payment rates. A commission could be established similar to MEDPAC, which recommends rate increases for Medicare hospital and physician payments and analyzes prices and economic trends. Such a commission could recommend a periodic update of Medicare prices based on a market basket of drugs, including any new drugs. It would be granted authority to require manufacturers to provide them with drug wholesale prices, but would not disclose any of the proprietary data collected from manufacturers.

2. Calculate national estimated acquisition costs based upon the average manufacturer prices (AMP) reported to the Medicaid program. The Centers for Medicare & Medicaid Services (CMS) could calculate reimbursement rates using AMP and send these rates out to the Medicare carriers. Average manufacturer prices are currently reported to CMS under the drug rebate program, and they more accurately reflect the prices paid by drug wholesalers to manufacturers. If this option were used, it would eliminate the need to go to the manufacturers for more pricing information. This option would require legislation to allow Medicare access to AMP data. Prior to this option being implemented, it would be useful to clarify or refine certain definitions. We also believe an initial, intensive effort should be made to audit AMP data reported by manufacturers to validate its accuracy. We estimate that in the year 2000 Medicare and its beneficiaries would have saved $1.4 billion of the $3.7 billion spent on just 24 drugs if reimbursement for the drugs had been based on AMP.

3. Collect more accurate average wholesale prices from drug pricing catalogs or other sources. This option would entail requiring manufacturers or wholesalers to provide their pricing information or catalogues to an appropriate commission or federal agency. Protection of the confidentiality of proprietary data could be guaranteed in the authorizing statute.

4. Increase the discounting of the published AWP. If this option were used, a provision would be needed to prevent manufacturers from just raising AWP by an amount greater than the newly discounted rate.

5. Base payment on physician/supplier acquisition costs. This option would require obtaining invoices of actual payments made. Payment could not be based solely on the listed invoice price as that price often gets discounted by rebates and volume discounts. Net cost would need to be obtained and this might be difficult because many of the manufacturers rebates are not calculated until the end of the year. Additionally, since Medicare would be reimbursing drugs based on cost there would be little incentive to get the best price.

6. Establish manufacturers' rebates similar to those used in the Medicaid program. A Medicare rebate program could be modeled on Medicaid's program. However, if a Medicare rebate program were used in conjunction with, instead of as a replacement for the current AWP system, then the rebates should be based on AWP rather than the AMP used by Medicaid. This would minimize manufacturers' incentives to inflate AWP because rebates would increase as AWP increased.

7. Create a fee schedule for covered drugs based on the Federal Supply Schedule negotiated by the Department of Veterans Affairs. The payment amounts could be set at the Federal Supply Schedule price or that price plus a certain percentage.

8. Use CMS's inherent reasonableness authority. This authority allows CMS to reduce its payment rates if it can be shown that payment amounts are excessive. A recent study by the General Accounting Office (GAO), mandated by the Congress, found this authority to be appropriate, and it supported some recent studies performed by CMS in its proposed used of it. According to the law which mandate the GAO study, the inherent reasonableness authority may be used as soon as CMS promulgates regulations for it.

9. Use competitive bidding. The CMS currently has the authority to demonstrate the efficacy of competitive bidding for medical supplies. The demonstrations have already proven that inhalation drugs can be obtained at prices lower than 95 percent of AWP. A statutory amendment to make general use of this authority might be

appropriate, at least for some categories of drugs, particularly those which are provided by a small number of suppliers or by mail-order firms.

Conclusion

There can be no doubt that Medicare pays too much for prescription drugs. This finding has been confirmed year after year. At the same time, Medicare payments overall, including excessive amounts, are increasing substantially. This adversely affects the Medicare trust fund and Medicare's beneficiaries, who are responsible for 20 percent of the bill. While no payment method will perfectly address all conceivable technical problems, many options are available that are superior to the current payment method, with its misleading nomenclature and artificially inflated prices. Currently, Medicare payments are being set not by the Medicare program but by drug manufacturers and indirectly by health care providers. Until this problem is corrected Medicare and its beneficiaries will unnecessarily pay more and more each year.

I hope this testimony has been constructive in explaining the problem and offering some ideas for its solution.