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Good afternoon, Madam Chairman. I am Robert Vito, Regional Inspector General for Evaluation and Inspections in Philadelphia at the U.S. Department of Health and Human Services' Office of Inspector General (OIG). I appreciate the opportunity to appear before you today to discuss OIG's most recent work regarding Medicare Part B reimbursement for prescription drugs and the average sales prices (ASP) used to set this reimbursement.

In short, the new system appears to have lowered the previously inflated Part B reimbursement amounts and, in turn, reduced overall Medicare expenditures for prescription drugs. Even so, OIG's work has identified a small number of instances in which the reported ASPs, and the resulting Medicare reimbursement amounts, may still be higher than certain other prices in the marketplace. We have also identified an issue with the method CMS uses to calculate reimbursement amounts.

FLAWS IN THE PREVIOUS REIMBURSEMENT SYSTEM

Prior to 2004, Medicare Part B reimbursed for most covered drugs based on the lower of either the billed amount or 95 percent of the average wholesale price (AWP) as published in national pricing compendia. The AWP is not defined by law or regulation, nor is it typically based on actual sales prices. As numerous reports by OIG and the Government Accountability Office have illustrated, the AWP-based reimbursement amounts for most covered drugs were significantly higher than the prices that drug manufacturers, wholesalers, and other similar entities actually charged the physicians and suppliers who purchase these drugs. Consequently, under this flawed system, the Medicare program and its beneficiaries were overpaying by hundreds of millions of dollars per year for prescription drugs.

To help align reimbursement amounts with actual acquisition costs, Congress included in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provisions to reform Part B drug reimbursement. The MMA specified that reimbursement amounts for most outpatient prescription drugs furnished in 2004 be set at 85 percent of the AWP, until a new methodology could be implemented on January 1, 2005. This new methodology based reimbursement amounts on manufacturer-reported ASPs rather than AWPs. Unlike the AWP, an ASP is defined by statute and based on actual sales transactions. The MMA defines an ASP as a manufacturer's sales of a drug to all nonexempt purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume, prompt pay, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those paid

under the Medicaid drug rebate program.[1,2] Under this new methodology, Medicare reimbursement for most Part B drugs is set at 106 percent of the drugs' volume-weighted ASPs.[3]

IMPACT OF ASPS ON MEDICARE REIMBURSEMENT

The Congressional Budget Office estimated that the changes enacted by the MMA would save Medicare almost $16 billion over 10 years by reducing excessive Medicare reimbursement amounts for Part B-covered drugs. Recent data on Medicare reimbursement and expenditures provide evidence confirming that the ASP-based reimbursement system has substantially lowered reimbursement amounts for numerous drugs. For about one-quarter of the drugs covered under Part B, Medicare reimbursement amounts have been reduced by at least 50 percent when compared to pre-MMA levels. For example, in 2003[4] (when reimbursement was set at 95 percent of the AWP), Medicare paid almost $120 for a month's supply of the inhalation drug albuterol; today, Medicare pays $20.[5] For the cancer drug Zoladex, Medicare paid almost $450 per dose in 2003; Medicare currently pays $196 per dose.

The reductions in the reimbursement amounts for individual drugs have had a substantial effect on overall Part B expenditures. Before the MMA was enacted, CMS data indicated that Medicare expenditures for Part B drugs had increased by at least 20 percent annually every year since 1994. By 2004, Medicare was paying almost $11 billion for covered drugs, up from $4 billion just 6 years earlier. Due to changes made by the MMA, this trend has reversed, with Medicare Part B spending close to $1 billion less on covered drugs in 2005 than in 2004. This decrease occurred despite rising utilization for the drugs.

OIG WORK INVOLVING MEDICARE PART B DRUGS

Prior to the passage of the MMA, OIG's primary role in Medicare drug pricing involved identifying and reporting on flaws in the AWP-based system that left the program vulnerable to fraud, waste, and abuse. In more than a dozen reports, we repeatedly found that Medicare paid too much for prescription drugs due to inflated AWPs. In addition, working with our many law-enforcement partners, we assisted in investigations of pricing issues that resulted in significant civil and criminal settlements.

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[1] Section 1847A(c) of the Social Security Act, as added by the MMA.

[2] Pursuant to section 1847A(c)(2) of the Social Security Act, sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" for Medicaid drug rebate purposes.

[3] Although manufacturers submit an ASP and sales volume for each individual drug product they sell, CMS does not establish a reimbursement rate for each specific drug product. CMS uses ASP data for individual drug products to calculate an overall ASP for the procedure code. The ASP for an individual drug product is weighted by the amount of that drug sold during the quarter. This means that the ASP for a drug with a high volume of sales should have greater influence on the reimbursement amount for a procedure code than an ASP for a drug with a low volume of sales.

[4] All data and methods described in the testimony refer to calendar years.

[5] These figures relate only to reimbursement for the drugs themselves. They do not include the dispensing fees paid to the supplier.

The MMA established two mandates for OIG that changed and expanded our role in monitoring Medicare drug pricing. First, the MMA mandated that OIG conduct a study on the adequacy of ASP-based reimbursement amounts for certain cancer drugs. Second, the MMA required OIG to perform an ongoing monitoring function that compares ASPs to other pricing points. As discussed below, we have recently completed studies that address both of these mandates.

OIG WORK REQUIRED BY THE MMA

Adequacy of ASP-Based Reimbursement for Certain Cancer Drugs

The MMA required that OIG conduct a study on the ability of physician practices of different sizes in the specialties of hematology, hematology/oncology, and medical oncology to obtain drugs and biologicals at 106 percent of the ASP. This requirement responded to concerns that the new reimbursement amounts based on ASPs may be lower than the drug acquisition costs for physicians in these specialties. OIG completed this study in September 2005.[6]

We compared the average prices paid by physicians for drugs represented by 39 procedure codes to Medicare reimbursement amounts and concluded that physician practices in the three specialties could generally purchase drugs for the treatment of cancer patients at less than the MMA-established reimbursement rates (i.e., 106 percent of the ASP). Overall, the report found that the average prices paid for 35 of the 39 drugs under review were less than the Medicare reimbursement amounts. Larger physician practices purchased drugs at greater discounts (i.e., at least 15 percent below Medicare reimbursement) for more drugs than smaller practices. In addition, we also estimated that for 35 of the 39 codes, physician practices could purchase drugs for less than the reimbursement amounts during at least half of the months reviewed.

OIG Comparisons of ASPs to Other Pricing Points

The MMA also mandated that OIG conduct studies that determine whether the ASP exceeds certain other prices. Specifically, the MMA required OIG to compare manufacturer-reported ASPs to both average manufacturer prices (AMP)[7] and widely available market prices (WAMP).[8] In certain situations where the ASP of a drug exceeds the AMP or the WAMP by a certain threshold, the MMA gives the Secretary the authority to reduce the reimbursement amount for the drug to either 103 percent of the AMP or 100 percent of the WAMP. Currently, the threshold amount is 5 percent, although the Secretary has the authority to raise or lower this percentage in the future.

[6] "Adequacy of Medicare Part B Drug Reimbursement to Physician Practices for the Treatment of Cancer Patients," A-06-05-00024.

[7] AMPs, also reported by drug manufacturers to CMS, are used in the determination of rebates in the Medicaid program. As defined in section 1927(k)(1) of the Social Security Act, the AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, minus customary prompt pay discounts.

[8] Section 1847A(d)(5) of the Social Security Act generally defines widely available market price to be the price that a prudent physician or supplier would pay for the drug, net of any routinely available price concessions.

- Comparisons of ASPs to AMPs. OIG completed the first of its studies comparing ASPs to AMPs and issued a report earlier this year.[9] We found that in the third quarter of 2004, 51 of the 364 procedure codes (14 percent) included in this review had an ASP that exceeded the AMP by at least 5 percent. If reimbursement amounts for these 51 codes had been lowered to 103 percent of the AMP, Medicare expenditures would have been reduced by an estimated $164 million in 2005.

  In response, CMS stated that the information in the report was helpful in its continuing efforts to monitor payment adequacy under the ASP methodology. However, CMS noted that OIG's review was conducted using data submitted during the initial implementation phase of the ASP methodology. Although CMS acknowledged the Secretary's authority to adjust ASP payment limits when certain conditions are met, it believed that other factors should be considered, including the timing and frequency of pricing comparisons, stabilization of ASP reporting, the effective date and duration of rate substitution, and the accuracy of ASP and AMP data.

  In June 2006, OIG released a second report comparing ASPs to AMPs.[10] We found that for 46 of the 341 procedure codes (13 percent) included in this review, ASPs exceeded AMPs by at least 5 percent in the fourth quarter of 2005.[11] Twenty of these codes were identified in OIG's previous report as having ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2004. If reimbursement amounts for the 46 codes had been based on 103 percent of the AMP, we estimate that Medicare expenditures would have been reduced by $64 million in one year.

- Comparison of ASPs to WAMPs. In addition to the comparisons of ASPs and AMPs, OIG released a report comparing ASPs to WAMPs in June 2006.[12] For this analysis, we specifically selected a purposive sample of nine procedure codes for which we suspected that the ASP might exceed the WAMP by at least 5 percent. The purposive sample was based on the results of the September 2005 OIG report on adequacy of reimbursement for cancer drugs.

  We found that 5 of the 9 procedure codes included in this review met or surpassed the 5-percent threshold defined by the MMA. For these 5 codes, the ASPs exceeded the WAMPs by a range of 17 to 185 percent. We estimate that Medicare expenditures would be reduced by as much as $67 million in 2006 if reimbursement amounts were lowered to the WAMPs for these 5 codes. In

[9] "Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Prices to Average Manufacturer Prices," OEI-03-04-00430, May 2006.

[10] "Comparison of Fourth Quarter 2005 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for the Second Quarter of 2006," OEI-03-06-00370.

[11] Fourth-quarter 2005 ASPs are used to set second-quarter 2006 reimbursement amounts.

[12] "A Comparison of Average Sales Prices to Widely Available Market Prices: Fourth Quarter 2005," OEI-03-05-00340.

addition, the prices that physicians pay for these drugs may be even lower than the WAMPs that were calculated, as all of the responding distributors offered price discounts to physician customers that were not reflected in the calculation of WAMPs.[13]

ADDITIONAL OIG WORK INVOLVING ASP

CMS's Calculation of ASPs

For the most part, the Medicare Part B reimbursement amount for a drug is now based on a volume-weighted ASP that CMS derives from the underlying ASPs for individual drug products reported by manufacturers. In the process of conducting the mandated price comparisons, we identified a problem with the method CMS uses to calculate volume-weighted ASPs. We alerted CMS to the problems with its calculation and issued a report on this subject in February 2006.[14] We found that CMS's method for calculating a volume-weighted ASP is mathematically flawed because CMS does not consistently weight the number of units of a drug that were sold throughout its equation. As a result, many procedure codes have a reimbursement amount that is higher or lower than the amount that would have been calculated if the weighting were applied consistently.

According to OIG's analysis of prices published in the first quarter of 2005, the flawed calculation caused 46 percent of procedure codes to be reimbursed at amounts that were higher than they should have been, resulting in an estimated $115 million in excessive Medicare reimbursements in 2005. For 13 percent of procedure codes, CMS's reimbursement amount was lower than it should have been, representing an estimated $5 million loss to providers in 2005. The flawed calculation did not affect reimbursement amounts for the remaining 41 percent of procedure codes. OIG recommended that CMS change its calculation of volume-weighted ASPs. Although CMS stated that it may consider altering the ASP methodology in the future, the agency has yet to make any changes to its calculation of volume-weighted ASPs.

Drug Manufacturers' Calculations of ASPs

OIG is currently auditing eight drug manufacturers to evaluate their methodologies for calculating ASPs for individual drug products. Several more audits are planned in the near future.

Adequacy of Reimbursement for Intravenous Immune Globulin

This Subcommittee and the House Committee on Energy and Commerce Subcommittee on Health requested that OIG evaluate the current state of pricing and supply for one specific drug, intravenous immune globulin (IVIG). Patient advocacy groups and physicians have repeatedly expressed concerns that, under the ASP-based reimbursement methodology, the cost for physicians to acquire IVIG exceeds Medicare's reimbursement

[13] The most common type of price discount offered to physician customers was a prompt pay discount. Three of the five companies that responded to our request for information offered this type of incentive, with percentage discounts ranging from 1 to 3 percent, depending on the time of payment.

[14] "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs," OEI-03-05-00310.

amount. OIG's work in this area is ongoing. A final report that addresses Medicare reimbursement for IVIG, provides perspectives on the supply and distribution of this unique product, and makes any recommendations that are warranted will be issued in the near future.

Dispensing Fees for Inhalation Drugs

In tandem with the reimbursement reductions resulting from the MMA, CMS raised the dispensing fee paid by Medicare in 2005 for inhalation drugs from $5 to an interim amount of $57 for a 30-day drug supply. It did so based in large part on industry statements claiming that beneficiaries receive numerous, important services from their suppliers. Last year, OIG issued a report that reviewed the nature and extent of dispensing services that Medicare beneficiaries received from inhalation drug suppliers in 2003. OIG found that the most common service beneficiaries received was contact for drug refills. Few beneficiaries received more intensive services such as education, care plan revision, or a respiratory assessment, and 16 percent of beneficiaries received no services at all. The most common way beneficiaries received services was by telephone; only 1 in 10 beneficiaries received a home visit.

CONCLUSION

Prior to the passage of the MMA and the implementation of the new ASP-based methodology, Medicare reimbursed for many prescription drugs at prices that did not reflect actual acquisition costs for physicians and suppliers. Under the new system, there has been a substantial reduction in reimbursement amounts for many high-dollar products, causing the decade-long trend of increasing Part B expenditures for prescription drugs to reverse. Building on OIG's existing work that identified weaknesses in the old system, we have responded to new mandates under the MMA by taking on a more extensive role in helping to ensure the appropriateness of Medicare payments under the new methodology. As a result, OIG has already identified a few instances where the reported ASPs, and the resulting Medicare reimbursement amounts, may still be higher than certain other prices in the marketplace. In addition, OIG has undertaken nonmandated audits and evaluations of issues that we have identified as important to ensuring the integrity of Medicare Part B drug payments, such as the methodology used by CMS to calculate Medicare reimbursement amounts, and the methodologies used by drug manufacturers to calculate ASPs.

It appears that the new ASP methodology represents a marked improvement over the old AWP system. However, like any new reimbursement system, we realize that its implementation must be continually monitored to ensure that payment levels are appropriate. To this end, we are committed through our oversight work to provide CMS and Congress with timely information regarding ASPs and other drug reimbursement issues.

This concludes my testimony, and I welcome your questions.