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MEDICARE PART B DRUGS

Program Payments Should Reflect Market Prices

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Messrs. Chairmen and Members of the Subcommittees:

I am pleased to be here as you discuss the pricing of Medicare's part B-covered prescription drugs. The pricing of these drugs—largely drugs that cannot be administered by patients themselves—has been under scrutiny for several years. Most of the part B drugs with the highest Medicare payments and billing volume fall into three categories: those that are billed for by physicians and typically provided in a physician office setting (such as chemotherapy drugs),[1] those that are billed for by pharmacy suppliers and administered through a durable medical equipment (DME) item (such as a respiratory drug given in conjunction with a nebulizer[2]), and those that are also billed by pharmacy suppliers but are patient-administered and covered explicitly by statute. [3] Studies by the Department of Justice, the Department of Health and Human Services' (HHS) Office of the Inspector General (OIG), and the House Committee on Commerce show that Medicare's payment for these drugs in some cases is significantly higher than the actual costs to the physicians and other providers who bill Medicare for these products.

In September 2000, the Health Care Financing Administration (HCFA)—now the Centers for Medicare and Medicaid Services (CMS)[4]—took steps to reduce Medicare's payment for part B-covered drugs by authorizing Medicare carriers, the contractors that pay part B claims, to use prices obtained in the Justice Department investigations of providers' drug acquisition costs. HCFA retracted this authority in November 2000 following concerns raised by providers. In December 2000, as part of recent Medicare legislation,[5] the Congress asked us to study Medicare's payments for part B-covered drugs and make recommendations for pricing

[1]In the case of chemotherapy drugs, the common practice is for a nurse to provide the services to administer the drug and for the physician to bill Medicare accordingly.

[2]A nebulizer is a device driven by a compressed air machine. It allows the patient to take medicine in the form of a mist (wet aerosol).

[3]Medicare-covered drugs and biologicals that can be self-administered include such drugs as blood clotting factors and some oral drugs used in association with cancer treatment and immunosuppressive therapy.

[4]Our statement refers to HCFA when discussing actions it took under that name.

[5]The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (P.L. 106-554, Appendix F).

methodology refinements. We have reported our findings and made recommendations, as mandated, today.[6]

My remarks today will focus on (1) Medicare payment policies to cover part B-covered drug costs and costs of administering the drugs and (2) key features of other payers' reimbursement policies that suggest opportunities to improve the appropriateness of Medicare's payments. My comments are based primarily on our study of Medicare payments for part B-covered drugs and a forthcoming study of physicians' practice expense payments under Medicare's fee schedule.

In summary, our study shows that Medicare's method for establishing drug payments is flawed. Medicare pays 95 percent of the average wholesale price (AWP), which, despite its name, may be neither an average nor what wholesalers charge. It is a price that manufacturers derive using their own criteria; there are no requirements or conventions that AWP reflect the price of any actual sale of drugs by a manufacturer. Manufacturers report AWPs to organizations that publish them in drug price compendia, and Medicare carriers that pay claims for part B drugs base providers' payments on the published AWPs.

We found that, in 2001, widely available prices at which providers could purchase drugs were substantially below AWP, on which Medicare payments are based. For both physician-billed drugs and pharmacy supplier-billed drugs, Medicare payments often far exceeded widely available prices. Despite concerns about what discounts may be available to smaller-volume purchasers, physicians who billed Medicare for low volumes of drugs reported receiving discounts from AWP, for most drugs, that were similar to or greater than those afforded by the widely available prices we documented.

Physicians and pharmacy suppliers contend that the excess payments for covered drugs are necessary to offset what they claim to be inappropriately low or no Medicare payments for services related to the administration or delivery of these drugs. For administering physician-billed drugs, Medicare makes explicit payments under the physician fee schedule. Our forthcoming review of practice expense payments under the fee schedule will make several points regarding oncologists' payments. It

[6] *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs* (GAO-01-1118, Sept. 21, 2001).

will show that Medicare's payments to these specialists were 8 percent higher than they would have been if the program's prior payment method had remained in place and will show that oncologists' payments relative to their estimated practice expenses were close to the average for all specialists. However, we will also show that HCFA made questionable modifications to its basic method of setting practice expense payments, which resulted in lowering the average fees paid for the administration of drugs by physicians' staffs.

For delivering pharmacy supplier-billed drugs, Medicare's payment policies are uneven. Pharmacy suppliers billing Medicare receive a dispensing fee for one drug type—inhalation therapy drugs—but there are no similar payments for other DME-administered or oral drugs. However, Medicare pays DME suppliers for the rental or purchase of equipment and supplies, and long-standing problems in the program's payments for these items may result in overpayments that implicitly compensate for some service delivery costs not covered.

Other payers and purchasers, such as health plans and the Department of Veterans Affairs (VA), employ different approaches in paying for or purchasing drugs that may be instructive for Medicare. In general, they make use of the leverage from their volume and competition to secure better prices. The federal purchasers, furthermore, use that leverage to secure verifiable data on actual market transactions to establish their price schedules. Private payers' practices—such as negotiating prices that result in selecting certain products or suppliers and arriving at terms without open competition—would not be easily adaptable to Medicare, given the program's size and need to ensure access for providers and beneficiaries. How other federal agencies have exercised their leverage may offer more applicable lessons.

Background

The traditional Medicare program does not have a comprehensive outpatient prescription drug benefit, but under part B (which covers physician and other outpatient services), it covers roughly 450

pharmaceutical products and biologicals.[7] In 1999, spending for Medicare part B-covered prescription drugs totaled almost $4 billion.[8]

Small Number of Products Accounts for Largest Shares of Program Spending and Claims Volume

A small number of products accounts for the majority of Medicare spending and billing volume for part B drugs. In 1999, 35 drugs accounted for 82 percent of Medicare spending and 95 percent of the claims volume for these products.[9] The 35 products included, among others, injectible drugs to treat cancer, inhalation therapy drugs, and oral immunosuppressive drugs (such as those used to treat organ transplant patients).

The physician-billed drugs accounted for the largest share of program spending, while pharmacy supplier-billed drugs constituted the largest share of the billing volume. Three specialties—hematology oncology, medical oncology, and urology—submitted claims for 80 percent of total physician billings for part B drugs. Two inhalation therapy drugs accounted for 88 percent of the Medicare billing volume for pharmacy-supplied drugs administered in a patient's residence.[10]

Medicare Payments for Drugs Are Based on Published AWPs

Medicare's payment for part B-covered drugs is based on the product's AWP, which is a price assigned by the product's manufacturer and may be neither "average" nor "wholesale." Instead, the AWP is often described as a "list price," "sticker price," or "suggested retail price."

The term AWP is not defined in law or regulation, so the manufacturer is free to set an AWP at any level, regardless of the actual price paid by purchasers. Manufacturers periodically report AWPs to publishers of drug pricing data, such as the Medical Economics Company, Inc., which publishes the Red Book, and First Data Bank, which compiles the National Drug Data File. In paying claims, Medicare carriers use published AWPs to

[7]For the remainder of this statement, we will refer to "drugs and biologicals" as "drugs."

[8]Spending is defined as Medicare's total payment, of which Medicare's share is 80 percent and the beneficiaries' share is 20 percent.

[9]Our analysis excluded some high-volume and high-expenditure drugs because of inadequate pricing data. Volume for a drug is measured in terms of the number of units provided. Analyses exclude data on services supplied in Puerto Rico and the U.S. Virgin Islands and exclude payments made on behalf of Railroad Retirement Board beneficiaries.

[10]These two drugs are ipratropium bromide and albuterol (unit dose form).

determine Medicare's payment amount, which is 95 percent of AWP.[11] Thus, given the latitude manufacturers have in setting AWP, these payments may be unrelated to market prices that physicians and suppliers actually pay for the products.

Drug Supply Chain Involves Multiple Parties and Arrangements That Influence the Net Price to the End Purchaser

The actual price that providers pay for Medicare part B drugs is often not transparent. Physicians and suppliers may belong to group purchasing organizations (GPO) that pool the purchasing of multiple entities to negotiate prices with wholesalers or manufacturers. GPOs may negotiate different prices for different purchasers, such as physicians, suppliers, or hospitals. In addition, providers can purchase part B-covered drugs from general or specialty pharmaceutical wholesalers or can have direct purchase agreements with manufacturers.

Certain practices involving these various entities can result in prices paid at the time of sale that do not reflect the final net cost to the purchaser. Manufacturers or wholesalers may offer purchasers rebates based on the volume of products purchased not in a single sale but over a period of time. Manufacturers may also establish "chargeback" arrangements for end purchasers, which result in wholesalers' prices overstating what those purchasers pay. Under these arrangements, the purchaser negotiates a price with the manufacturer that is lower than the price the wholesaler charges for the product. The wholesaler provides the product to the purchaser for the lower negotiated price, and the manufacturer then pays the wholesaler the difference between the wholesale price and the negotiated price.

[11]Technically, the payment equals 95 percent of AWP for the drugs grouped under each HCFA Common Procedure Coding System (HCPCS) code. Individual drugs are identified by the National Drug Code (NDC). NDCs are assigned by the Food and Drug Administration and are the universal product identifiers for drugs for human use. Each NDC specifies a chemical entity, manufacturer, dosage form, strength, and package size. For example, a single drug—marketed by one manufacturer in one form and strength but in three package sizes—would have three NDCs. Because one HCPCS code may have multiple NDCs, the carriers determine the Medicare payment by analyzing multiple NDCs' AWPs. For multisource drugs, the payment allowance is 95 percent of the lower of (1) the median AWP of all generic forms of the drug or (2) the lowest brand name product's AWP.

Medicare's Payment for Part B-Covered Drugs Is Significantly Higher Than Prices Widely Available to Providers

For the part B-covered drugs accounting for the bulk of Medicare spending and claims, Medicare payments in 2001 were almost always considerably higher than wholesalers' prices that were widely available to physicians and suppliers. This was true regardless of whether the drugs had competing products or were available from a single manufacturer. Physicians who billed Medicare for relatively small quantities of these drugs also obtained similar prices.

Wide Disparities Exist Between Drug Acquisition Costs and Medicare Payments

Our study shows that there can be wide disparities between a drug's estimated acquisition cost and Medicare's payment for that drug. Physician-billed drugs account for the bulk of Medicare spending on part B drugs. Of those billed by physicians, drugs used to treat cancer accounted for most of Medicare's expenditures. Specifically:

- Widely available discounts for 17 of the physician-billed drugs we examined averaged between 13 percent and 34 percent less than AWP.
- For two other physician-billed drugs, Dolasetron mesylate and Leucovorin calcium, average discounts were considerably larger—65 percent and 86 percent less than AWP.

The discounts on physician-billed drugs, based on wholesaler and GPO catalogue prices, are notably lower than Medicare's payment, which reflects a discount of 5 percent below AWP. The discounts indicate that Medicare's payments for these drugs were at least $532 million higher than providers' acquisition costs in 2000. Further, the discounts we report may only be the starting point for additional discounts provided to certain purchasers, as chargebacks, rebates, and other discounts may drive down the final sale price.

Concerns have been expressed that small providers either could not or do not obtain such favorable prices. Therefore, we surveyed a sample of physicians who billed Medicare for low volumes of chemotherapy drugs to see if they were able to obtain similar discounts.[12] All of the low-volume purchasers who responded to our survey reported obtaining similar or better discounts than the widely available prices we had documented.

[12]We conducted a telephone survey of a sample of physicians who billed Medicare for a low-volume of cancer treatment drugs in 1999. For more detail, see GAO-01-1118.

More than one-third of these physicians reported belonging to GPOs and obtained the GPOs' substantial discounts, while others said they had contracts with manufacturers and wholesalers.

As with physician-billed drugs, Medicare's payments for pharmacy supplier-billed drugs generally far exceeded the prices available to these suppliers. For the drugs we examined, Medicare's payments were at least $483 million more than what the suppliers paid in 2000. Further, the discounts we report were largest for products that could be obtained from more than one source. Inhalation therapy drugs administered through DME and oral immunosuppressive drugs represent most of the high-expenditure, high-volume drugs billed to Medicare by suppliers. Specifically:

- Two drugs, albuterol and ipratropium bromide, used with DME for respiratory conditions, account for most of the pharmacy-supplied drugs paid for by Medicare. In 2001, they were available to pharmacy suppliers at prices that averaged, respectively, 85 percent and 78 percent less than AWP.
- Other high-volume DME-administered drugs had prices averaging 69 percent and 72 percent less than AWP. These findings are consistent with prior studies of the prices of similar drugs.[13]
- Two of the four high-volume oral immunosuppressives were available from wholesalers with average discounts of 14 percent and 77 percent. Wholesale price information on the other two was not available, but retail prices from online pharmacies were as much as 13 percent and 8 percent below AWP.

Policies to Pay for Related Delivery and Administration Services Vary by Provider

Medicare payment policies for administering or delivering a drug vary, depending on who provides the drug to the patient. Physicians are compensated directly for drug administration through the physician fee schedule. Pharmacy suppliers are compensated for dispensing inhalation therapy drugs used with a nebulizer, which make up the majority of their part B drug claims. No explicit payments are made to pharmacy suppliers for dispensing other drugs, but they may receive payments for equipment and supplies associated with DME-administered drugs. Both physicians and pharmacy suppliers contend that the excess in Medicare's payments

[13] *Medicare Reimbursement of Albuterol* (HHS OIG, OEI-03-00-00311, June 2000) and *Medicare Reimbursement of Prescription Drugs* (HHS OIG, OEI-03-00-00310, Jan. 2001).

for part B-covered drugs compensates for related service costs inadequately reimbursed or not explicitly covered at all.

In prior work on the Medicare physician fee schedule, we concluded that the agency's basic method of computing practice expense payments to physicians was sound.[14] The implementation of this fee schedule, however, has been controversial. The Congress required that payments be budget neutral relative to prior spending. Medicare's physician payments were, in the aggregate, seemingly adequate, as most physicians were participating in Medicare and accepting the program's fees as payment in full. Because of the budget neutrality requirement, if one specialty's fees increased on average, some others would have to decline. Such redistributions have occurred and some are significant.

Oncologists, who represent the majority of physicians billing for drugs, argue that Medicare's payments for administering chemotherapy are inappropriately low and that the excess Medicare drug payments are needed to offset their losses. Yet oncology is one of the specialties to gain under the resource-based physician fee schedule. In our separate study on physicians' practice expenses under Medicare's fee schedule, we will show that payments to oncologists were 8 percent higher than they would have been if the prior charge-based payment method had been maintained; the study will also show that oncologists' payments relative to their estimated practice expenses, which include chemotherapy administration, were close to the average for all specialties.

While oncologists do not appear disadvantaged overall under the fee schedule, adjustments HCFA made to the basic method of computing payments reduced fees for some oncologists' services. In those adjustments, HCFA modified the basic method in computing payments for services delivered without direct physician involvement, like much of chemotherapy administration. The modifications were intended to correct for perceived low payments for these services. While they increased payments for some of these services, they lowered them for many others. Moreover, they increased payments on average for services involving physicians. Oncology payments were particularly affected, as services without physician involvement constitute about one-third of oncologists'

[14]Practice expenses constitute one of three components in Medicare's physician fee schedule. The other two are work and malpractice expenses. For the physician's average fee in 1999, practice expenses accounted for about 42 percent; work, about 55 percent; and malpractice, about 3 percent.

Medicare-billed services, compared to about 5 percent of all physician-billed services. Because of the modifications to the basic method, oncology practice expense payments for nonphysician chemotherapy administration were on average 15 percent lower, while payments for physician-administered services were 1 percent higher, than if HCFA had used the basic method. Across all services, the modifications resulted in oncology practice expense payments that were 6 percent lower.[15] Using the basic method for all services would eliminate these reductions and add about $31 million to oncology payments. Our study will recommend that CMS revert to the use of the basic methodology to determine practice expense payments for all services.

We will also recommend that CMS address a data adjustment it made that affects oncology payments under the new fee schedule. The agency reduced oncology's reported supply expenses to keep from paying twice for drugs that are reimbursed separately by Medicare. Oncologists acknowledge that the supply expense estimate needed to be reduced, but argue that the reduction was too large. We have recommended that the agency develop the appropriate data to more accurately estimate oncology supply expenses. Substituting a supply expense estimate based on a methodology developed by the American Society of Clinical Oncology would raise practice expense payments an additional $20 million,[16] if done in conjunction with our recommendation to use the basic method to calculate payments for all services.

Oncologists have raised concerns about whether the data used to estimate their practice expenses constituted a representative sample of practices surveyed and whether these data reflect current practices in delivering services. How improvements in the data to estimate practice expenses may affect payment levels is uncertain. Payments are based on the differences in expenses of services of one specialty compared to those of others. Some of the data concerns raised by oncologists may apply to other specialties as well, so that additional and more current data may reveal that the relative cost of one service compared to others may have changed only modestly. We are conducting a separate study to determine

[15]The source for these figures is our analysis of 2001 practice expense fees, based on 1999 Medicare utilization.

[16]The source for these figures is our analysis of 2001 practice expense fees, based on 1999 Medicare utilization.

how CMS can improve and update the information used to estimate specialties' practice expenses.

Similar to the physicians who bill for part B drugs, pharmacy suppliers and their representatives contend that the margin on the Medicare drug payment is needed to compensate them for costs not covered by Medicare—that is, the clinical, administrative, and other labor costs associated with delivering the drug. These include costs for billing and collection; facility and employee accreditation; licensing and certifications; and providing printed patient education materials. Medicare pays a dispensing fee of $5.00 for inhalation therapy drugs used with a nebulizer, which are the vast majority of the pharmacy-supplied drugs. This fee was instituted in 1994. It is higher than dispensing fees paid by pharmacy benefit managers, which average around $2.00, and is comparable to many state Medicaid programs, which range from $2.00 to over $6.00. For other pharmacy-supplied drugs, Medicare makes no explicit payment for dispensing the drug.

Besides the profits on the DME-related drugs, pharmacy suppliers may receive additional compensation through the payment for DME and related supplies. Our prior work suggests that, for two reasons, Medicare DME and supply payments may exceed market prices.[17] First, because of an imprecise coding system, Medicare carriers cannot determine from the DME claims they process which specific products the program is paying for. Medicare pays one fee for all products classified under a single billing code, regardless of whether their market prices are greatly below or above that fee.[18] Second, DME fees are often out of line with current market prices. Until recently, DME fees had generally been adjusted only for inflation because the process required to change the fees was lengthy and cumbersome. As a result, payment levels may not reflect changes in technology and other factors that could significantly change market prices.

[17]See *Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies* (GAO/HEHS-98-102, May 12, 1998).

[18]The equipment and supply payment is determined from a DME fee schedule, whose rates are based on a state-specific fee schedule and subject to national minimum and maximum payment limits. Fees are based on average historical supplier charges that are adjusted for inflation over time.

Other Purchasers' Practices Are Instructive for Reforming Medicare's Method of Paying for Part B-Covered Drugs

Private insurers and federal agencies, such as VA, employ different approaches in paying for or purchasing drugs that may provide useful lessons for Medicare. In general, these payers make use of the leverage of their volume and competition to secure better prices. The federal purchasers, furthermore, use that leverage to secure verifiable data on actual market transactions to establish their price schedules. Private payers can negotiate with some suppliers to the exclusion of others and arrive at terms without clear criteria or a transparent process. This practice would not be easily adaptable to Medicare, given the program's size and need to ensure access for providers and beneficiaries. How other federal agencies have exercised their leverage may be more instructive and readily adaptable for Medicare.

VA and certain other government purchasers buy drugs based on actual prices paid by private purchasers—specifically, on the prices that drug manufacturers charge their "most-favored" private customers.[19] In exchange for being able to sell their drugs to state Medicaid programs, manufacturers agree to offer VA and other government purchasers drugs at favorable prices, known as Federal Supply Schedule (FSS) prices. So that VA can determine the most-favored customer price, manufacturers provide information on price discounts and rebates offered to domestic customers and the terms and conditions involved, such as length of contract periods and ordering and delivery practices.[20] (Manufacturers must also be willing to supply similar information to CMS to support the data on the average manufacturer's price, known as AMP, and best price they report for computing any rebates required by the Medicaid program.)

VA has been successful in using competitive bidding to obtain even more favorable prices for certain drugs. Through these competitive bids, VA has obtained national contracts for selected drugs at prices that are even lower than FSS prices. These contracts seek to concentrate the agency's purchase on one drug within therapeutically equivalent categories for the

[19]Under federal procurement regulations, the government seeks to obtain the price is intended to equal or better the price that the manufacturer offers its most-favored nonfederal customer under comparable terms and conditions.

[20]Because the terms and conditions of commercial sales vary, there may be legitimate reasons why the government does not always obtain the most-favored customer price. Hence, under the regulations, VA may accept a higher price if it determines that (1) the price offered to the government is fair and reasonable and (2) awarding the contract is otherwise in the best interest of the government.

agency's national formulary. In 2000, VA contract prices averaged 33 percent lower than corresponding FSS prices.

Medicare's use of competition has been restricted to several limited-scale demonstration projects authorized by the Balanced Budget Act of 1997. In one of these demonstrations under way in San Antonio, Texas, suppliers bid to provide nebulizer drugs, such as albuterol, to Medicare beneficiaries. While Medicare normally allows any qualified provider to participate in the program, under the demonstration only 11 bidders for nebulizer drugs were selected to participate. In exchange for restricting their choice of providers to the 11 selected, beneficiaries are not liable for any differences between what suppliers charge and what Medicare allows. Preliminary CMS information on the San Antonio competitive bidding demonstration suggests no reported problems with access and a savings of about 26 percent realized for the inhalation drugs.

Concluding Observations

Our study on Medicare payments for part B drugs shows that Medicare pays providers much more for these drugs than necessary, given what the providers likely paid to purchase these drugs from manufacturers, wholesalers, or other suppliers. Unlike the market-based fees paid by VA and other federal agencies, Medicare's fees are based on AWP, which is a manufacturer-reported price that is not based on actual transactions between seller and purchaser. Physicians contend that the profits they receive from Medicare's payments for part B drugs are needed to compensate for inappropriately low Medicare fees for most drug administration services. Similarly, the case argued by some pharmacy suppliers for Medicare's high drug payments is that not all of their costs of providing the drugs are covered.

In our view, it should be a principle of Medicare payment policy to pay for each service appropriately and not to rely on overpayments for some services to offset inadequate payments for complementary services. If Medicare were to follow this principle and lessons from other payers in setting fees for part B drugs, it would use information on actual market prices net of rebates and discounts—similar to information currently available to VA and CMS—to establish Medicare payments. It could also determine market-based fees, where appropriate, through a competitive bidding process. Medicare would pay for administration and delivery of these drugs separately, as it does currently for drugs supplied by physicians and for inhalation therapy drugs. As the way drugs are supplied and administered varies, different methods of determining payments would be necessary. Paying for these services explicitly would enable

Medicare to eliminate implicit payments that may have been made through excessive payments for DME and the drugs associated with the DME payment. In our report, we make recommendations reflecting these lessons to revise the program's payment methods.

Messrs. Chairmen, this concludes my statement. I would be happy to answer any questions that you or Subcommittee Members may have.

Contact and Acknowledgments

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