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MEDICARE PART B DRUGS

CMS Data Source for Setting Payments Is Practical but Concerns Remain

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GAO-06-971T

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Highlights

Highlights of GAO-06-971T, a testimony before the Subcommittee on Health, Committee on Ways and Means, House of Representatives

Why GAO Did This Study

In 2005, the Centers for Medicare & Medicaid Services (CMS), as required by law, began paying for physician-administered Part B drugs using information on the drugs' average sales price (ASP). Subsequently, CMS selected ASP as the basis to pay for a subset of Part B drugs provided at hospital outpatient departments. To calculate ASP, CMS uses price data submitted quarterly by manufacturers. GAO was asked to discuss its work on Medicare payment rates for Part B drugs. This testimony is based on several GAO products:

- *Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS*, GAO-06-372, Apr. 28, 2006.
- *Medicare: Comments on CMS Proposed 2006 Rates for Specified Covered Outpatient Drugs and Radiopharmaceuticals Used in Hospitals*, GAO-06-17R, Oct. 31, 2005.
- *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs*, GAO-01-1118, Sept. 21, 2001.

Specifically, GAO's statement discusses (1) ASP as a practical and timely data source for use in setting Medicare Part B drug payment rates and (2) components of ASP that are currently unknown and implications for Medicare rate-setting.

www.gao.gov/cgi-bin/getrpt?GAO-06-971T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact A. Bruce Steinwald at (202) 512-7101 or steinwalda@gao.gov.

What GAO Found

In summary, using an ASP-based method to set payment rates for Part B drugs is a practical approach compared with methods based on alternative data sources, for several reasons. First, ASP is based on actual transactions and is a better proxy for providers' acquisition costs than average wholesale price or providers' charges included on claims for payment, neither of which is based on transaction data. Second, ASPs, which manufacturers update quarterly, offer information that is relatively timely for rate-setting purposes. In comparison, rates for other Medicare payment systems are based on data that may be at least 2 years old. Finally, using manufacturers as the data source for prices is preferable to collecting such data from health care providers, as the manufacturers have data systems in place to track prices, whereas health care providers generally do not have systems designed for that purpose.

CMS lacks certain information about the composition of ASP that prompted GAO, in commenting on CMS's 2006 proposed payment rates for a subset of Part B drugs, to call ASP "a black box." Significantly, CMS lacks sufficient information on how manufacturers allocate rebates to individual drugs sold in combination with other drugs or other products; this is important, as CMS does not have the detail it needs to validate the reasonableness of the data underlying the reported prices. In addition, CMS does not instruct manufacturers to provide a breakdown of price and volume data by purchaser type—that is, by physicians, hospitals, other health providers, and wholesalers, which purchase drugs for resale to health care providers. As a result, CMS cannot determine how well average price data represent acquisition costs for different purchaser types. In particular, to the extent that some of the sales are to wholesalers that subsequently mark up the manufacturer's price in their sales to providers, the ASP's representation of providers' acquisition costs is weakened. Additionally, a sufficient empirical foundation does not exist for setting the payment rate for Medicare Part B drugs at 6 percent above ASP, further complicating efforts to determine the appropriateness of the rate. Given these information gaps, CMS is not well-positioned to validate the accuracy or appropriateness of its ASP-based payment rates.

Madam Chairman and Members of the Subcommittee:

I am pleased to be here as you discuss Medicare's method of paying for outpatient drugs covered under the program's Part B, the part of Medicare that covers a broad range of medical services, including physician, laboratory, and hospital outpatient department (HOPD) services and durable medical equipment (DME). Part B-covered drugs are typically administered by a physician or other medical professional rather than by patients themselves. In contrast, drugs covered under the new prescription drug benefit, known as Part D, are generally self-administered by patients.[1] In 2005, Medicare paid more than $9 billion for Part B drugs furnished in conjunction with physician services, HOPD services, dialysis services, and services performed using DME, such as nebulizers.[2, 3]

Until 2005, Medicare's method of paying physicians for Part B drugs was based on the drug's average wholesale price (AWP), which, despite its name, was neither an average nor what wholesalers charged.[4] It was a price that manufacturers derived using their own criteria; there were no requirements or conventions that AWP reflect the price of an actual sale of drugs by a manufacturer.[5] An analysis we conducted in 2001 on Part B drug prices found that Medicare's AWP-based payments often far exceeded market prices that were widely available to health care providers.[6]

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated that, beginning in 2005, payments for physician-administered drugs be based on the drug's average sales price (ASP)—that

[1]Medicare Part A covers inpatient hospital services; Medicare Part C, known as Medicare Advantage, covers beneficiaries enrolled in managed care plans.

[2]In this testimony, we will refer to physicians, hospital outpatient services, dialysis services, and durable medical equipment suppliers collectively as providers.

[3]A nebulizer is a device driven by a compressed air machine. It allows the patient to inhale medicine in the form of a mist.

[4]Until 2004, Medicare paid physicians 95 percent of AWP. Legislation changed Medicare's payment to 85 percent of AWP in 2004.

[5]Manufacturers reported AWPs to organizations that published them in drug price compendia, and the Medicare claims administration contractors that pay claims for Part B drugs based physicians' payments on the published AWPs.

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

is, an average, calculated from price and volume data reported by drug manufacturers, of sales to all U.S. purchasers.[7] The law directed that ASPs be net of rebates and other price concessions and that 2005 payments to physicians for these drugs be set at 106 percent of ASP.[8]

The MMA took a different approach to setting rates for a subset of Medicare Part B drugs delivered in the HOPD setting. Prior to the MMA, Medicare paid HOPDs for Part B drugs based on hospitals' 1996 median costs for these drugs. In response to concerns that payments would not reflect the cost of newly introduced pharmaceutical products—such as those used to treat cancer or rare blood disorders—1999 legislation authorized augmented payments for these drugs on a temporary basis.[9] Subsequently, the MMA defined a new payment category for these drugs called specified covered outpatient drugs (SCOD). The MMA required the Centers for Medicare & Medicaid Services (CMS) in the Department of Health and Human Services (HHS) to set rates for this subset of Part B drugs. Specifically, it directed CMS to set 2006 payment rates for SCOD products equal to hospitals' average acquisition costs—the cost to hospitals of acquiring a product, net of rebates. Subsequently, CMS selected ASP as the basis to pay for SCODs provided at HOPDs.

In several related requirements, the MMA directed us to provide information on SCOD costs and CMS's proposed rates. Among them was a requirement to conduct a survey of a large sample of hospitals to obtain data on their acquisition costs for SCODs and provide information based on these data to the Secretary of Health and Human Services for his consideration in setting 2006 Medicare payment rates.[10] We were also required to evaluate CMS's proposed rates for SCODs, comment on their

[7]Certain prices were excluded, including prices paid to federal purchasers and prices for drugs furnished under the Part D program.

[8]The term rebates refers to price concessions given to purchasers by manufacturers subsequent to receipt of the product.

[9]See the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113, app. F, § 201 (b), 113 Stat. 1501A-321, 1501A-337—1501A-339.

[10]We provided information from this survey in two reports—one on drugs and another on radiopharmaceuticals. See GAO, *Medicare: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate Setting*, GAO-05-581R (Washington, D.C.: June 30, 2005), and GAO, *Medicare: Radiopharmaceutical Purchase Prices for CMS Consideration in Hospital Outpatient Rate Setting*, GAO-05-733R (Washington, D.C.: July 14, 2005). The Secretary of HHS considered the price data we provided but elected not to use these data as the basis for 2006 rates.

appropriateness in light of the survey we conducted, and advise on future data collection efforts by CMS based on our survey experience.[11] We issued reports in 2005 and 2006 in response to these requirements, and my remarks about ASP are based on that work. Specifically, my remarks today will focus on (1) ASP as a practical and timely data source for use in setting Medicare Part B drug payment rates and (2) components of ASP that are currently unknown and implications for Medicare rate-setting. Our work was conducted in accordance with generally accepted government auditing standards.

In summary, using an ASP-based method to set payment rates for Part B drugs is a practical approach compared with methods based on alternative data sources, for several reasons. First, ASP is based on actual transactions and is a better proxy for health care providers' acquisition costs than AWP or health care providers' charges included on claims for payment, neither of which is based on transaction data. Second, ASPs, which manufacturers update quarterly, offer information that is relatively timely for rate-setting purposes. In comparison, rates for other Medicare payment systems are based on data that may be at least 2 years old. Finally, using manufacturers as the data source for prices is preferable to collecting such data from health care providers, as the manufacturers have data systems in place to track prices, whereas health care providers generally do not have systems designed for that purpose.

Despite these advantages, CMS lacks certain information about the composition of ASP that prompted us, in our report commenting on CMS's proposed 2006 SCOD rates, to call ASP "a black box."[12] Significantly, CMS lacks sufficient information on how manufacturers allocate rebates to individual drugs sold in combination with other drugs or other products; this is important, as CMS does not have the detail it needs to validate the reasonableness of the data underlying the reported prices. In addition, CMS does not instruct manufacturers to provide a breakdown of price and volume data by purchaser type—that is, by physicians, hospitals, other health care providers, and wholesalers, which purchase drugs for resale to

[11]We provided our comments on the proposed rates in GAO, *Medicare: Comments on CMS Proposed 2006 Rates for Specified Covered Outpatient Drugs and Radiopharmaceuticals Used in Hospitals*, GAO-06-17R (Washington, D.C.: Oct. 31, 2005). We provided information on our data collection experience in GAO, *Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS*, GAO-06-372 (Washington, D.C.: Apr. 28, 2006).

[12]GAO-06-17R.

health care providers. As a result, CMS cannot determine how well average price data represent acquisition costs for different purchaser types. In particular, to the extent that some of the sales are to wholesalers that may subsequently mark up the manufacturer's price in their sales to health care providers, the ASP's representation of providers' acquisition costs is weakened. Additionally, a sufficient empirical foundation does not exist for setting the payment rate for Medicare Part B drugs at 6 percent above ASP, further complicating efforts to determine the appropriateness of the rate. Given these information gaps, CMS is not well-positioned to validate the accuracy or appropriateness of its ASP-based payment rates.

Background

CMS calculates payment rates for each Part B drug with information on price data that manufacturers report quarterly to the agency. In reporting their price data to CMS, manufacturers are required to account for price concessions, such as discounts and rebates, which can affect the amount health care providers actually pay for a drug.

ASP Is a Price Measure Established in Law and Calculated with Manufacturers' Data

The MMA defined ASP as the average sales price for all U.S. purchasers of a drug, net of volume, prompt pay, and cash discounts; charge-backs and rebates. Certain prices, including prices paid by federal purchasers, are excluded, as are prices for drugs furnished under Medicare Part D. CMS instructs pharmaceutical manufacturers to report data to CMS—within 30 days after the end of each quarter—on the average sale price for each Part B drug sold by the manufacturer. For drugs sold at different strengths and package sizes, manufacturers are required to report price and volume data for each product, after accounting for price concessions. CMS then aggregates the manufacturer-reported ASPs to calculate a national ASP for each drug category.[13]

Varying Payment Arrangements Affect the Price Purchasers Pay at the Time of Sale

Common drug purchasing arrangements can substantially affect the amount health care providers actually pay for a drug. Physicians and hospitals may belong to group purchasing organizations (GPO) that negotiate prices with wholesalers or manufacturers on behalf of GPO members. GPOs may negotiate different prices for different purchasers,

[13]Manufacturers' reported price data are based on the Food and Drug Administration's (FDA) system of National Drug Codes, while the ASP that CMS calculates for each drug is based on the agency's Healthcare Common Procedure Coding System, which uses categories that are broader than the FDA's coding system.

such as physicians, suppliers of DME, or hospitals. In addition, health care providers can purchase covered outpatient drugs from general or specialty pharmaceutical wholesalers or can have direct purchase agreements with manufacturers. In these arrangements, providers may benefit from discounts, rebates, and charge-backs that reduce the actual costs providers incur. Discounts are applied at the time of purchase, while rebates are paid by manufacturers some time after the purchase. Rebates may be based on the number of several different products purchased over an extended period of time. Under a charge-back arrangement, the provider negotiates a price with the manufacturer that is lower than the price the wholesaler normally charges for the product, and the provider pays the wholesaler the negotiated price. The manufacturer then pays the wholesaler the difference between the wholesale price and the price negotiated between the manufacturer and the provider.

ASP Is a Practical Payment Approach, Given the Limitations of Other Data Sources Available for Rate-Setting

Using an ASP-based method to set prices for Medicare Part B drugs is a practical approach compared with alternative data sources for several reasons. First, unlike AWP, ASP is based on actual transactions, making it a useful proxy for health care providers' acquisition costs. Whereas AWPs were list prices developed by manufacturers and not required to be related to market prices that health care providers paid for products, ASPs are based on actual sales to purchasers. For similar reasons, payments based on ASPs are preferable to those based on providers' charges, as charges are made up of costs and mark-ups, and mark-ups vary widely across providers, making estimates of the average costs of drugs across all providers wide-ranging and insufficiently precise. In addition, basing payments on charges does not offer any incentives for health care providers to minimize their acquisition costs.

Second, ASPs offer relatively timely information for rate-setting purposes. Manufacturers have 30 days following the completion of each quarter to report new price data to CMS. Before the end of the quarter in which manufacturers report prices, CMS posts the updated Part B drug payment rates, to take effect the first day of the next quarter. Thus, the rates set are based on data from manufacturers that are, on average, about 6 months old. In comparison, rates for other Medicare payment systems are based on data that may be at least 2 years old.

Third, acquiring price data from manufacturers is preferable to surveying health care providers, as the manufacturers have data systems in place that track prices, whereas the latter generally do not have systems designed for that purpose. In our survey of 1,157 hospitals, we found that

providing data on drug acquisition costs made substantial demands on hospitals' information systems and staff. In some cases, hospitals had to collect the data manually, provide us with copies of paper invoices, or develop new data processing to retrieve the detailed price data needed from their automated information systems.[14] Hospital officials told us that, to submit the required price data, they had to divert staff from their normal duties, thereby incurring additional staff and contractor costs. Officials told us their data collection difficulties were particularly pronounced regarding information on manufacturers' rebates, which affect a drug's net acquisition cost.[15] In addition, we incurred considerable costs as data collectors, signaling the difficulties that CMS would face should it implement similar surveys of hospitals in the future.

CMS Lacks Information on ASP Necessary to Monitor Payment Rate Accuracy and Appropriateness

Despite its practicality as a data source, ASP remains a "black box." That is, CMS lacks detailed information about the components of manufacturers' reported price data—namely, methods manufacturers use to allocate rebates to individual drugs and the sales prices paid by type of purchaser. Furthermore, for all but SCODs provided in the HOPD setting, no empirical support exists for setting rates at 6 percent above ASP, and questions remain about setting SCOD payment rates at ASP+6 percent. These information gaps make it difficult to ensure that manufacturers' reported price data are accurate and that Medicare's ASP rates developed from this information are appropriate.

Significantly, CMS has little information about the method a manufacturer uses to allocate rebates when calculating an ASP for a drug sold with other products. Unlike discounts, which are deducted at the point of purchase, rebates are price concessions given by manufacturers subsequent to the purchaser's receipt of the product. In our survey of hospitals' purchase prices for SCODs, we found that hospitals received rebate payments following the receipt of some of their drug purchases but often could not determine rebate amounts. Calculating a rebate amount is complicated by the fact that, in some cases, rebates are based on a purchaser's volume of a set, or bundle, of products defined by the manufacturer. This bundle may include more than one drug or a mixture of drugs and other products, such

[14]The burden was more taxing for some hospitals than for others. Many hospitals were able to rely on price data downloaded from their drug wholesalers' information systems.

[15]Typically, hospitals did not systematically track all manufacturers' rebates on drug purchases, although nearly 60 percent of hospitals reported receiving one or more rebates.

as bandages and surgical gloves. Given the variation in manufacturers' purchasing and rebate arrangements, the allocation of rebates for a product is not likely to be the same across all manufacturers. CMS does not specifically instruct manufacturers to provide information on their rebate allocation methods when they report ASPs. As a result, CMS lacks the detail it needs to validate the reasonableness of the data underlying the reported prices.

In addition, CMS does not require manufacturers to report details on price data by purchaser type. Because a manufacturer's ASP is a composite figure representing prices paid by various purchasers, including both health care providers and wholesalers, CMS cannot distinguish prices paid by purchaser type—for example, hospitals compared with other institutional providers, physicians, and wholesalers. In particular, to the extent that some of the sales are to wholesalers that may subsequently mark up the manufacturer's price in their sales to health care providers, the ASP's representation of providers' acquisition costs is weakened. Thus, distinguishing prices by purchaser type is important, as a central tenet of Medicare payment policy is to pay enough to ensure beneficiary access to services while paying pay no more than the cost of providing a service incurred by an efficient provider. In our 2005 report on Medicare's proposed 2006 SCOD payment rates, we recommended that CMS collect information on price data by purchaser type to validate the reasonableness of ASP as a measure of hospital acquisition costs.[16]

Better information on manufacturers' reported prices—for example, the extent to which a provider type's acquisition costs vary from the CMS-calculated ASP—would help CMS set rates as accurately as possible. For most types of providers of Medicare Part B drugs—physicians, dialysis facilities, and DME suppliers—no empirical support exists for setting rates at 6 percent above ASP. In the case of HOPDs, a rationale exists based on an independent data source—our survey of hospital prices—but the process of developing rates for SCODs was not simple. In commenting on CMS's proposed 2006 rates to pay for SCODs, we raised questions about CMS's rationale for proposing rates that were set at 6 percent above ASP.[17] CMS stated in its notice of proposed rulemaking that purchase prices reported in our survey for the top 53 hospital outpatient drugs, ranked by

[16]GAO-06-17R.

[17]GAO-06-17R.

expenditures,[18] equaled ASP+3 percent on average, and these purchase prices did not account for rebates that would have lowered the product's actual cost to the hospital.[19] We noted that, logically, for payment rates to equal acquisition costs, CMS would need to set rates lower than ASP+3 percent, taking our survey data into account. In effect, ASP+3 percent was the upper bound of acquisition costs. Consistent with our reasoning, CMS stated in its notice of proposed rulemaking that "Inclusion of … rebates and price concessions in the GAO data would decrease the GAO prices relative to the ASP prices, suggesting that ASP+6 percent may be an overestimate of hospitals' average acquisition costs." In its final rule establishing SCOD payment rates, CMS determined that our survey's purchase prices equaled ASP+4 percent, on average, based on an analysis of data more recent than CMS had first used to determine the value of our purchase prices. CMS set the rate in the final rule at ASP+6 percent, stating that this rate covered both acquisition costs and handling costs.[20] We have not evaluated the reasonableness of the payment rate established in the final rule.

Lacking detail on the components of ASP, CMS is not well-positioned to confirm ASP's accuracy. In addition, CMS has no procedures to validate the data it obtains from manufacturers by an independent source. In our 2006 report on lessons learned from our hospital survey,[21] we noted several options available to CMS to confirm the appropriateness of its rates as approximating health care providers' drug acquisition costs. Specifically, we noted that CMS could, on an occasional basis, conduct a survey of providers, similar to ours but streamlined in design; audit manufacturers' price submissions; or examine proprietary data the agency considers reliable for validation purposes. HHS agreed to consider our recommendation, stating that it would continue to analyze the best approach for setting payment rates for drugs.

[18]These drugs accounted for 95 percent of Medicare spending on all SCODs in the first 9 months of 2004.

[19]The purchase prices hospitals reported to us took account of discounts but not rebates.

[20]Handling costs include providers' expenses associated with storing, preparing, and disposing of drugs.

[21]GAO-06-372.

Concluding Observations

Because ASP is based on actual transaction data, is relatively timely, and is administratively efficient for CMS and health care providers, we affirm the practicality of the ASP-based method for setting Part B drug payment rates. However, we remain concerned that CMS does not have sufficient information about ASP to ensure the accuracy and appropriateness of the rates. To verify the accuracy of price data that manufacturers submit to the agency, details are needed—such as how manufacturers account for rebates and other price concessions and how they identify the purchase prices of products acquired through wholesalers. Equally important is the ability to evaluate the appropriateness of Medicare's ASP-based rate for all providers of Part B drugs over time. As we recommended in our April 2006 report, CMS should, on an occasional basis, validate ASP against an independent source of price data to ensure the appropriateness of ASP-based rates.

Madam Chairman, this concludes my prepared statement. I will be happy to answer any questions you or the other Subcommittee Members may have.

Contact and Staff Acknowledgments

For further information regarding this testimony, please contact A. Bruce Steinwald at (202) 512-7101 or steinwalda@gao.gov. Phyllis Thorburn, Assistant Director; Hannah Fein; and Jenny Grover contributed to this statement. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement.

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