United States Government Accountability Office
Washington, DC 20548

October 31, 2005

The Honorable Charles E. Grassley
Chairman
The Honorable Max Baucus
Ranking Minority Member
Committee on Finance
United States Senate

The Honorable Joe Barton
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Honorable William M. Thomas
Chairman
The Honorable Charles B. Rangel
Ranking Minority Member
Committee on Ways and Means
House of Representatives

Subject: *Medicare: Comments on CMS Proposed 2006 Rates for Specified Covered Outpatient Drugs and Radiopharmaceuticals Used in Hospitals*

On July 25, 2005, the Centers for Medicare & Medicaid Services (CMS) in the Department of Health and Human Services (HHS) published its notice of proposed rulemaking (NPRM) entitled "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates."[1] As part of these changes, CMS is proposing Medicare payment rates for certain hospital outpatient drugs—classified for payment purposes as specified covered outpatient drugs (SCOD). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) defined a SCOD as a drug or radiopharmaceutical used in hospital outpatient departments, covered by Medicare, and paid for individually rather than as part of a payment group with other services.[2]

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[1]70 Fed. Reg. 42,674.

[2]Pub. L. No. 108-173, sec. 621(a), § 1833(t)(14)(B), 117 Stat. 2066, 2307—08 (to be codified at 42 U.S.C. § 1395*l*(t)(14)(B)).

With regard to SCODs, the MMA directed CMS to set 2006 payment rates equal to hospitals' average acquisition costs—the cost to hospitals of acquiring a product, net of rebates.[3] In several related requirements, the MMA directed us to provide information on SCOD costs and CMS's proposed rates.[4] First, we were required to conduct a survey of hospitals to obtain data on their acquisition costs of 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. We provided information from this survey in two reports[5]—one on drugs and biologicals, and another on radiopharmaceuticals.[6] These reports presented systematic information on hospitals' purchase prices of SCODs and limited information on rebates. Second, we were required to evaluate CMS's proposed rates for SCODs and comment on their appropriateness in light of the survey of SCOD prices we conducted.[7]

In response to the second requirement, this report assesses the appropriateness of the Medicare payment rates that CMS has proposed for SCODs, taking into account the purchase prices obtained from the MMA-mandated survey we conducted in 2004 and 2005. Specifically, this report focuses on the appropriateness of CMS's proposed 2006 hospital outpatient rates for (1) drug SCODs and (2) radiopharmaceutical SCODs. To conduct this assessment, we examined the information CMS provided in the proposed rule on the data sources and methodology used to set the 2006 rates, analyzed this information in light of our survey of hospitals' purchase prices, and

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[3]Specifically, the MMA required that payment rates equal the average acquisition costs as determined by the Secretary of Health and Human Services, unless hospital acquisition cost data are not available. If such data are not available, the law permitted payment rates to equal one of several amounts, including average sales price, as calculated and adjusted by the Secretary. MMA 117 Stat. 2307.

[4]MMA 117 Stat. 2308—09. The law also required the Medicare Payment Advisory Commission (MedPAC) to report on overhead and related expenses (such as pharmacy services and handling costs) and authorized the Secretary of Health and Human Services to adjust the SCOD rates for these costs. MMA 117 Stat. 2309. See ch. 6, "Payment for pharmacy handling costs in hospital outpatient departments," in MedPAC's mandated report, *Issues in a Modernized Medicare Program* (Washington, D.C.: June 2005).

[5]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).

[6]In this report, the term drugs refers to both drugs and biologicals. Biologicals are products derived from living sources, including humans, animals, and microorganisms. Radiopharmaceuticals are radioactive substances used for diagnostic or therapeutic purposes.

[7]The MMA also required us to report on differences in SCOD acquisition costs by type of hospital and recommend future data collection methods, taking into account our experience. We will address these issues in a future report.

convened an expert panel to review our findings.[8] Consistent with the MMA, we did not study the issue of hospitals' handling costs for SCODs and do not address these costs in this report. We performed our work according to generally accepted government auditing standards from July through October 2005.

Results in Brief

We consider CMS's selection of a data source—average sales price (ASP)—for use in setting Medicare's hospital outpatient rates for drug SCODs to be practical, given available alternatives, but we consider CMS's proposed 2006 rates for drug SCODs to be excessive.

CMS proposes to base its 2006 drug SCOD rates on manufacturers' ASP data, setting rates at ASP+6 percent. ASP is a composite measure of the average price of a SCOD—net of discounts, rebates, and other price concessions—paid by all purchasers, not just hospitals. Manufacturers report this information quarterly. In our view, ASP is a practical data source, providing the most timely publicly available data on prices of drug SCODs. However, we have two concerns about setting the proposed drug SCOD rates:

- As a composite measure, ASP is a black box, lacking the detail CMS needs to validate the reasonableness of the data underlying the reported prices. Without a breakdown of price data showing rebates and other components as well as average prices by purchaser type, CMS cannot ensure that ASPs accurately reflect average acquisition costs by hospital purchasers alone.

- CMS does not provide a convincing rationale for proposing a rate 6 percent higher than ASP. CMS's analysis indicates that ASP+6 percent will exceed hospitals' acquisition costs. CMS states that the prices reported in our survey—that is, the average prices hospitals paid for drug SCODs (which do not net out rebates received at a later time)—equal ASP+3 percent. Logically, acquisition costs, which do net out rebates from purchase prices, would equal an amount less than ASP+3 percent. Therefore, our survey data and CMS's analysis of these data indicate that a rate set at or above ASP+3 percent is not appropriate, given that it would exceed the hospitals' average acquisition cost.

Similarly, we are concerned that CMS's proposed 2006 rates for radiopharmaceutical SCODs will, on average, exceed hospitals' acquisition costs. CMS chose to use cost estimates developed from hospital charges rather than survey data on the prices hospitals reported paying for radiopharmaceuticals. However, as we have previously

[8]The panelists were Joseph P. Newhouse, John D. MacArthur Professor of Health Policy and Management, Harvard University; Robert A. Berenson, Senior Fellow, Urban Institute; Ernst R. Berndt, Professor of Applied Economics, Sloan School of Management, Massachusetts Institute of Technology; Andrea G. Hershey, Clinical Coordinator and Pharmacy Residency Program Director, Union Memorial Hospital (Baltimore, Md.); and Richard L. Valliant, Senior Research Scientist, University of Michigan.

reported,[9] the methodology for estimating costs from charges results in significant imprecision. CMS states that it intends to set rates for radiopharmaceutical SCODs that are consistent with previous years' payment rates, even though the MMA does not establish such a criterion. ASPs are not available for radiopharmaceuticals for 2006 rate setting, but CMS plans to get this information from manufacturers for future years' rates.

In light of our assessment that CMS's proposed rates are higher than can be justified, we are recommending that the Secretary of Health and Human Services reconsider the level at which HHS has proposed to set drug SCOD rates, reconsider its reliance on charge-based cost estimates in setting radiopharmaceutical SCOD rates, and collect more detailed information on ASPs. In written comments on a draft of this report, CMS stated that it is considering our recommendations as it prepares the final rule on the OPPS for 2006.

Background

The relationship of SCODs to the outpatient prospective payment system (OPPS) and the distinctions among acquisition costs, prices, and related terms provide a context for interpreting CMS's proposed 2006 rates for SCODs and the agency's discussion of these rates in the NPRM.

Hospital Outpatient Payment System and SCODs

The recent history of Medicare's rate setting for hospital outpatient department services forms a backdrop for our comments on the proposed SCOD payment rates. Specifically, CMS uses OPPS to pay hospitals for services that Medicare beneficiaries receive as part of their treatment in hospital outpatient departments. Under OPPS, Medicare pays hospitals predetermined rates for most services.

When OPPS was first developed as required by the Balanced Budget Act of 1997,[10] the OPPS rates for hospital outpatient services, drugs, and radiopharmaceuticals were based on hospitals' 1996 median costs. However, these rates prompted concerns that payments to hospitals would not reflect the costs of newly introduced pharmaceutical products used to treat, for example, cancer, rare blood disorders, and other serious conditions. In turn, congressional concerns were raised that beneficiaries might lose access to some of these products if hospitals avoided providing them because of a perceived shortfall in payments. In response to these concerns, the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 authorized pass-through payments, which were a way to temporarily augment the OPPS payments for newly introduced pharmaceutical products first used after 1996.[11] The MMA modified this payment method for some of these pharmaceutical

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[9]GAO, *Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services*, GAO-04-772 (Washington, D.C.: Sept. 17, 2004).
[10]Pub. L. No. 105-33, § 4523, 111 Stat. 251, 445—50.

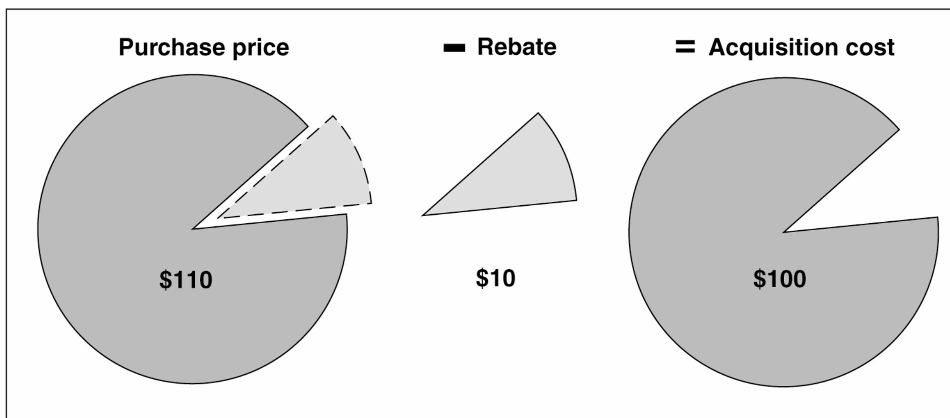
[11]Pub. L. No. 106-113, app. F, § 201(b), 113 Stat. 1501A-321, 1501A-337—1501A-339.

products.[12] As part of the modification, the MMA defined the new SCOD payment category, which includes many of these newly introduced pharmaceutical products.

Acquisition Costs, Purchase Prices, Discounts, and Rebates

Hospital acquisition costs—the level at which CMS is directed to set payment rates for SCODs—cannot be directly observed from price data alone. Hospitals can buy pharmaceutical products directly from manufacturers or from other vendors, namely wholesalers and distributors.[13] Hospitals may receive discounts or rebates or both. Discounts are price concessions given by manufacturers or wholesalers that are reflected in the purchase price—the price hospitals pay at the time of delivery. Rebates are price concessions given to hospitals by manufacturers subsequent to receipt of the product. The acquisition cost to hospitals is the difference between the purchase price paid at the time of a product's delivery and any rebates given by the manufacturer after hospitals receive the product. (See fig. 1.) As a result of rebates, a hospital's acquisition cost for a product may be lower than the purchase price.

Figure 1: Relationship of Purchase Prices, Rebates, and Acquisition Costs



Source: GAO analysis.

Note: Numbers are hypothetical.

Both discounts and rebates depend on a hospital's purchasing patterns. Manufacturers' discounts and rebates may be based on a hospital's purchase volume of a drug or on its market share—the percentage of a certain type of drug bought from a single manufacturer. In some cases, rebates are based on a purchaser's volume or market share 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 as bandages and surgical gloves. Hospitals can also receive "prompt pay" discounts when they pay in advance or within a prescribed time period.[14]

[12]MMA 117 Stat. 2307—10.

[13]Wholesalers and distributors perform related functions, and the two terms are often used interchangeably. We refer to both wholesalers and distributors as wholesalers.

[14]Conversely, vendors can charge markups when hospitals do not pay within an agreed-upon time period.

In contrast to purchase price and acquisition cost, which are common business and economic terms, ASP is a price measure established in law and used by CMS. This price measure is used to set payment rates for drugs administered in physician offices and covered under part B of Medicare. CMS instructs pharmaceutical manufacturers to report ASP data to CMS within 30 days after the end of each quarter. The MMA defined ASP as the average sales price for all U.S. purchasers[15] of a drug, net of volume, prompt pay, and cash discounts; free goods contingent on a purchase requirement; and charge-backs and rebates.[16]

CMS's Proposed Rule to Pay for SCOD Products in 2006

Under the MMA, payment for SCODs in 2006 is required to be equal to the average acquisition cost for the drug as determined by the Secretary of Health and Human Services, taking into account the hospital acquisition cost survey data we collected in 2004 and 2005.[17]

CMS has issued an NPRM that, along with other matters relating to the OPPS, describes the way it proposes to implement the MMA requirements on SCOD payment rates. CMS will receive comments from interested organizations and individuals, consider these comments, and publish a final rule—which may differ in some particulars from the proposed rule—later in 2005. To establish the proposed rates, CMS made two primary decisions for both drug SCODs and radiopharmaceutical SCODs: the data source to use and the level at which the rates should be set.

Data for Drug SCODs

CMS considered three possible data sources—purchase prices from our survey, Medicare charges, and ASP; it selected ASP. The NPRM noted two problems with the purchase price data: (1) prices could have increased since the end of the time period for which they were collected—July 2003 through June 2004—and (2) the data did not take into account rebates and similar price concessions. The problem cited with the Medicare charge data was that charges include both acquisition costs and handling costs. Because of the inclusion of handling costs, CMS concluded that Medicare charges were not an acceptable proxy for acquisition costs. The NPRM

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[15]MMA 117 Stat. 2240—41. Certain prices, including prices paid by federal purchasers and prices for drugs furnished under the Medicare prescription drug discount card program, are excluded. In the future, prices for drugs furnished under Medicare part D, the prescription drug benefit, will also be excluded.

[16]A charge-back is a payment by a manufacturer to a wholesaler that is made when the wholesaler's price to a hospital is lower than the price the wholesaler initially paid the manufacturer. Charge-back arrangements occur when hospitals have negotiated lower prices from the manufacturer, often through a group purchasing organization. All but Medicaid rebates are deducted in the manufacturer's calculation of ASP. Under the Medicaid program, manufacturers are required to pay rebates to states for prescription drugs covered by state Medicaid programs.

[17]MMA 117 Stat. 2307.

stated that ASP-based payment rates served as the best proxy for average acquisition costs because the manufacturers' sales prices from the last quarter of 2004 provided the most recent data available.

Rates for Drug SCODs

CMS considered setting the rates at three levels: ASP+3 percent, ASP+6 percent, and ASP+8 percent; it selected ASP+6 percent.[18] CMS considered ASP+3 percent because, on average, it was equal to the purchase price obtained from our survey. It considered ASP+8 percent because, on average, it was equal to an estimate of cost based on charges.[19] CMS did not use either of these options because of its concerns about using the purchase prices from our survey and the charges from Medicare claims as data sources. CMS arrived at a hospital drug SCOD rate of ASP+6 percent by eliminating the other two options. The NPRM mentioned that ASP+6 percent is also the rate that Medicare pays physicians for drugs.

Data for Radiopharmaceutical SCODs

CMS considered two data sources for radiopharmaceutical rates: survey results on purchase prices and Medicare charges; it selected Medicare charges.[20] ASP was not an option because ASP has not been collected for radiopharmaceuticals. (For payment rates in 2007 and future years, CMS plans to collect ASP for radiopharmaceuticals.) CMS elected not to use the survey results on purchase prices because, in comparing the purchase prices of the nine radiopharmaceuticals in the GAO data to CMS's 2005 payment rates, it found that "the GAO purchase prices were substantially lower for several of these agents." Similarly, the Medicare charge data yielded estimated costs lower than the 2005 payment rates. CMS selected the Medicare charge data, noting that charges are believed to cover both acquisition costs and handling costs, so these data could be used to set a payment rate that covered both.

Rates for Radiopharmaceutical SCODs

Having selected the charge data, CMS had only one option: to use the charges to estimate costs for setting radiopharmaceutical SCOD rates. For each radiopharmaceutical SCOD, it proposed adjusting the hospital charges to a hospital-specific estimate of costs. These estimates of cost would include both acquisition costs and handling costs. CMS stated that it intended to maintain consistency whenever possible between the payment rates in 2005 and 2006, because such "rapid

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[18] 70 Fed. Reg. 42,724—27.

[19] To estimate the cost of a SCOD, CMS multiplied hospital charges for the SCOD by a ratio of hospital costs to hospital charges.

[20] 70 Fed. Reg. 42,727—28.

reductions" could adversely affect beneficiary access to services utilizing radiopharmaceuticals.[21]

Adjustments to Rates for Overhead

Under the MMA, the Medicare Payment Advisory Commission (MedPAC) was required to report on adjusting SCOD payments to take account of overhead and related expenses, such as pharmacy services and handling costs, and the Secretary may adjust payment rates to take into account MedPAC's recommendations.[22] For drugs, the proposed regulation provides for increasing the payment for drug acquisition costs by 2 percent of ASP to cover overhead and handling, resulting in a total payment for drugs of ASP+6 percent+2 percent. According to CMS, costs calculated from charges equal ASP+8 percent. Since it has determined that acquisition costs are equal to ASP+6 percent, and since pharmacy overhead costs are built into the charges, CMS concluded that the difference between charge-based costs (equal to ASP+8 percent) and acquisition costs (which CMS states equal ASP+6 percent) is the overhead adjustment. Consequently, it proposed to set the overhead adjustment at 2 percent of ASP.

For radiopharmaceuticals, CMS has chosen to use charge-based costs. Since these costs appear to include overhead, CMS concluded that no further adjustment for overhead is required.

See table 1 for a summary of the proposed rule for drug and radiopharmaceutical SCODs.

Table 1: CMS's Proposed Rule for Drug and Radiopharmaceutical SCODs

	Alternatives that CMS considered (*CMS decision in italics*)
Drug SCODs	
• Data source	*ASP* Purchase prices[a] Cost estimated from claims data
• Rates	ASP+3 percent *ASP+6 percent* [b] ASP+8 percent
Radiopharmaceutical SCODs	
• Data source	Purchase prices[a] *Cost estimated from claims data*
• Rates	Average purchase price *Cost estimated from charges*[c]

Source: GAO analysis of CMS proposed rule.

[a]Calculated by GAO from its hospital survey data.

[b]CMS also proposed an additional 2 percent of ASP to cover hospitals' overhead and handling costs for drug SCODs.

[c]The rate includes hospitals' overhead and handling costs.

[21]CMS gave no indication of the magnitude of any such reductions.

[22]70 Fed. Reg. 42,728-29. For MedPAC's report and recommendations, see *Issues in a Modernized Medicare Program*, ch. 6.

ASP Is Reasonable as Data Source for Setting Rates, but ASP+6 Percent Is Excessive Relative to Hospitals' Acquisition Costs

The results from our survey of hospitals' purchases of drug SCODs suggest that the data source on which CMS proposes to base its rate-setting is reasonable, but the proposed rate is too high. For several practical reasons, ASP is an acceptable data source for setting drug SCOD rates, given the challenges of collecting drug price data. However, without more information on the data used to construct ASP, CMS cannot determine if this blend of average prices paid by all U.S. purchasers—not just hospitals—measures the prices paid by hospitals alone with sufficient accuracy. In addition, CMS's proposal to set the 2006 payment rate 6 percent above ASP is excessive and inconsistent with setting payment rates equal to acquisition costs.

ASP Practical as Data Source, but Accuracy Could Be Affected by Certain Information Gaps

CMS's decision to use ASP data is practical for four reasons. First, ASP at least roughly approximates hospital acquisition costs of drug SCODs.[23] Second, the use of ASP does not entail data collection start-up costs for CMS or manufacturers, as CMS uses an ASP-based methodology to pay for drugs in the physician office setting. Third, ASP is the most recent publicly available price information: it is based on data submitted by manufacturers 30 days after the close of each quarter. In contrast, an alternative method to ASP—conducting surveys of hospitals—would likely be costly, present challenges to hospitals' information system capabilities, and require a lengthy period for data collection and processing.[24] Fourth, ASP takes account of rebates, which we found were difficult for hospitals to report, and therefore we did not deduct them from our estimates.

Notwithstanding these advantages, information gaps remain that render ASP a "black box" in terms of its constituent components. For example, in reporting ASP data to CMS, manufacturers do not break out ASP price components, such as rebates and other price concessions.[25] CMS instructs manufacturers to deduct components such as rebates in calculating ASP, but lacking a price breakdown—or an independent

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[23]Because purchase price is the largest component of acquisition costs, and purchase cost is equal to ASP+3 percent, it follows that ASP roughly approximates acquisition costs. Purchase price is highly correlated with ASP for drug SCODs (r = .9978).

[24]For example, our methodology, consistent with statutory requirements, entailed considerable start-up and logistical costs as well as a substantial period for data collection. The MMA required that we obtain price information from hospitals, not manufacturers, and that the sample of hospitals be "large." Our survey included over 1,000 hospitals with a wide range of capabilities to provide needed data promptly. Fielding the survey required a commitment of substantial resources. In addition, hospitals had to expend considerable effort to identify, compile, and transmit purchase price data, making the potential for frequent data collection through hospital surveys problematic.

[25]The only information regarding price that CMS requires is the product's ASP. Nonprice information that manufacturers must report consists of the manufacturer's name, the product's National Drug Code, and the number of units.

source of price and rebate data—the agency cannot assess whether rebates and other components were appropriately excluded or whether the amount of any exclusions was plausible. In addition, information about the basis on which manufacturers calculate rebates would be useful. Collecting price breakdowns and related information would allow CMS to assess the reasonableness of the data underlying the reported prices.

In addition, because ASP is an average of prices paid for a product by all U.S. purchasers, it lacks sufficient detail for estimating acquisition costs of hospitals in particular. ASP data are not compiled by purchaser type—such as hospital outpatient department, physician office, retail pharmacy, or wholesaler. Thus, ASP does not permit CMS to distinguish between prices paid by hospitals and those paid by other end purchasers. The net effect of averaging all sales into one price is to weaken ASP as an accurate indicator of acquisition costs for hospitals alone.

Rationale Unconvincing for CMS's Proposed Rates, Which Would Pay Hospitals More Than Their Acquisition Costs

CMS proposes to set payments for drug SCODs at ASP+6 percent, but the questions that arise from setting rates at this level are not answered by the agency's analysis. As CMS notes, the MMA requires that the agency's determination of average acquisition costs take into account our mandated survey of prices hospitals paid for SCOD products. According to CMS, our survey's purchase prices on average equal ASP+3 percent,[26] and we and CMS agree that these purchase prices do not account for any after-purchase rebates that would lower the product's actual cost to the hospital. Logically, then, for payment rates to equal acquisition costs, CMS would need to set rates lower than ASP+3 percent, taking our survey data into account. We could not determine how much lower the rates should be set, as neither we nor CMS were able to systematically quantify the magnitude of rebates or other price concessions as a percentage of a product's purchase price or ASP. In effect, ASP+3 percent is the upper bound of acquisition costs—that is, acquisition costs should be less than ASP+3 percent. Consistent with our reasoning, CMS notes that "Inclusion of these 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."

Nevertheless, CMS did not propose to set rates at less than ASP+3 percent. It suggests that SCOD prices may have increased from the June 30, 2004, end point of the time period for which hospitals submitted survey data. However, neither data from our survey of purchase prices nor CMS's quarterly ASP data support the agency's concerns about potential drug price increases. Specifically:

- Between the first and last quarters for which we collected survey data, purchase prices for drug SCODs decreased slightly—falling by about 1 percent, on average.

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[26]Our purchase prices do not uniformly equal ASP+3 percent. For example, for several drug SCODs, the purchase price is approximately equal to ASP.

- CMS found that, between the fourth quarter of 2004 and the first quarter of 2005, ASP declined, on average, by 2 percent. CMS officials also told us that, between the third and fourth quarters of 2004, the trend in the average ASP for drug SCODs was relatively flat or slightly downward.

The lack of evidence for SCOD drug price inflation—coupled with CMS's calculation that hospitals' acquisition costs on average are lower than purchase prices (equivalent to ASP+3 percent)—show that a rate for SCOD drugs of ASP+6 percent would be too high. In the NPRM, CMS notes that it proposes to pay for drug SCODs at the payment rates used for drugs used in physician offices and suggests that a "consistency of drug pricing between physician offices and hospital outpatient departments" would be desirable. However, CMS does not show evidence that acquisition costs are similar for the two provider types.

CMS's Estimates of Hospitals' Costs for Radiopharmaceuticals Do Not Utilize Available Data on Actual Prices Paid and May Be Excessive

CMS's proposed rates for radiopharmaceutical SCODs are cost estimates based on charges and, although ASP data are not available for radiopharmaceuticals, do not utilize available survey data on actual prices paid for these products. In addition, the proposed rates may be excessive.

Historically, CMS has not directed manufacturers to report ASPs for radiopharmaceuticals. Lacking these data, CMS proposes to set 2006 rates for radiopharmaceutical products equal to its estimates of the costs to hospitals of acquiring and handling these products. To obtain these cost estimates, CMS converts charges to costs using a ratio that applies to all of a hospital's expenses and is not specific to radiopharmaceuticals. In calculating this ratio, CMS will use the most recent data available on costs, which likely will be for 2004.

CMS contends that its estimated costs are the best available proxy for the average acquisition cost of a radiopharmaceutical and include its handling cost. It states that hospitals' different purchasing, preparation, and handling practices for radiopharmaceuticals are reflected in hospitals' charges, which can be converted to costs using hospital-specific cost-to-charge ratios. In the absence of actual transaction data, this method would be reasonable though imperfect. At best this method is subject to significant imprecision. The charge-setting methodologies of hospitals and departments within hospitals vary considerably, whereas CMS's cost-to-charge calculations assume uniformity.[27] In contrast, we collected transaction data for our recent reports.[28] Our survey data included purchase prices on nine key radiopharmaceutical SCODs—accounting for over 90 percent of Medicare spending

[27]See GAO, *Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services*, GAO-04-772 (Washington, D.C.: Sept. 17, 2004).

[28]GAO-05-581R and GAO-05-733R.

on all radiopharmaceutical SCODs. These purchase prices are averages of the actual prices that hospitals paid. As a result, the average purchase prices approximate hospitals' acquisition costs more closely than the charge-based estimates CMS has proposed. Unlike purchase prices for drugs, purchase prices for most radiopharmaceuticals are likely to be equivalent to acquisition costs, as rebates are not commonly paid for radiopharmaceuticals. Regarding the radiopharmaceutical SCODs for which purchase price data are not available and which account for less than 10 percent of Medicare spending on radiopharmaceutical SCODs, CMS's proposed charge-based method of estimating costs is reasonable in setting 2006 rates.

CMS does not rely on the purchase prices from our survey in setting rates for radiopharmaceutical SCODs. It contends that the average purchase prices developed from our survey for some radiopharmaceutical SCODs are not suitable because these prices were substantially lower than CMS's payment rates for these SCODs in 2005.[29] However, this relationship to payment rates is also true for CMS's estimated costs of radiopharmaceutical SCODs, based on charges found in hospital claims data—the method selected in CMS's proposed rule. CMS states that it wants to maintain consistency between 2005 and 2006 payment rates and is concerned that "rapid reductions" in payment rates could adversely affect access to radiopharmaceuticals. As with purchase prices, CMS also found that for several radiopharmaceuticals its estimated costs based on charges were lower than CMS's 2005 payment rates. However, CMS did not explain why, despite their similar relationship to the payment rates, the estimated costs from claims data were preferable to the actual purchase prices for key radiopharmaceutical SCODs.

Nonetheless, maintaining consistency with 2005 rates is a questionable goal, since the MMA directed CMS to pay SCODs an amount equal to acquisition costs and did not mention other goals. Moreover, this relationship suggests that some of CMS's 2005 payment rates were excessive relative to the actual costs hospitals incurred to acquire these products, thereby refuting CMS's contention that "rapid reductions" in 2006 payment rates (based on average purchase price) could reduce beneficiary access to services using radiopharmaceuticals. Furthermore, in light of the tendency CMS noted for 2005 rates to exceed purchase prices, we are concerned that payment rates for radiopharmaceutical SCODs for 2006 may also be too high.

Conclusions

Overall, we have two concerns about CMS's proposed 2006 rates for drug SCODs:

- First, ASP is a black box, which does not permit CMS to ensure the reasonableness of the data underlying the drug SCOD rates. While CMS's selection of ASP as a data source for drug SCODs is reasonable, given the alternatives, additional information to validate ASP is needed to assess the accuracy of these data in approximating hospitals' acquisition costs. A

[29]For two of the radiopharmaceuticals in our survey, CMS payment rates were lower than purchase prices.

breakdown of ASP by hospitals and other purchaser types would enable CMS to determine if ASP—a blend of prices paid by wholesalers and various end purchasers—closely approximates the prices paid by hospitals alone. A separate breakdown of ASP by rebates and other components would enable CMS to assess whether the magnitudes of the various components are reasonable and to confirm that they are taken into account appropriately in calculating ASPs.

- Second, the proposed rates for drug SCODs are too high because their level exceeds hospitals' acquisition costs. To approximate hospitals' acquisition costs, average purchase prices—estimated by CMS to equal ASP+3 percent—would need to be reduced by some unknown magnitude to account for rebates. Instead, CMS's proposed rate—ASP+6 percent—is higher than the average purchase price, for reasons that CMS does not convincingly explain.

For setting radiopharmaceutical SCOD rates, CMS proposes to rely on charge-based estimates of cost, which are likely to be inaccurate measures of acquisition costs, and dismisses available purchase price data, which cover products accounting for more than 90 percent of Medicare's expenditures for hospital outpatient radiopharmaceuticals. CMS's proposed 2006 rates for radiopharmaceutical SCODs are likely to exceed hospitals' acquisition costs. CMS relies on cost estimates rather than available data on actual purchase prices. CMS declined to use our purchase prices for the proposed 2006 radiopharmaceutical SCOD rates because it found that our prices were substantially lower than CMS's 2005 payment rates. However, the fact that 2005 payment rates were higher—or lower—than the purchase prices hospitals paid for key radiopharmaceutical SCODs only reveals weaknesses in the payment rates.

Paying hospitals' acquisition costs and no more should be the aim that drives CMS's rate-setting calculations for SCODs. For drug SCODs, CMS proposes rates that are too high, while for radiopharmaceutical SCODs, the agency has declined to set rates equal to an available measure of acquisition costs.

Recommendations for Executive Action

We recommend that, to better approximate hospitals' acquisition costs of SCODs, the Secretary of Health and Human Services take three actions:

- Reconsider the level of proposed payment rates for drug SCODs, in relation to survey data on average purchase price, the role of rebates in determining acquisition costs, and the desirability of setting payment rates for SCODs at average acquisition costs.

- Reconsider the decision to base payment rates for radiopharmaceutical SCODs exclusively on estimated costs, in light of the availability of data on actual prices paid for key radiopharmaceuticals.

- Collect information on ASP components and ASP by purchaser type to validate the reasonableness of reported ASPs as a measure of hospital acquisition costs.

Agency Comments and Our Evaluation

In written comments on a draft of this report, CMS summarized our analyses of its proposed method and payment rates for SCODs. (We reprinted CMS's comments in enclosure I of this report.) CMS stated that it is considering our recommendations as it prepares the final rule on the OPPS for 2006. In particular, CMS expressed appreciation for our analysis of the data sources it considered in the NPRM and noted our concern that because of information gaps, CMS cannot ensure that ASPs accurately reflect hospitals' acquisition costs. CMS affirmed its commitment to ensuring that SCOD payment rates equal hospitals' average acquisition costs, as required by law, and cited our finding that ASP+3 percent should be a ceiling on payment rates. However, our finding was that ASP+3 percent is the upper bound on acquisition costs; therefore we have revised our report to clarify that payment rates should be *less* than the ceiling. With respect to radiopharmaceutical SCODs, CMS expressed appreciation for our analysis and noted our concern that CMS's proposed charge-based rates would overpay hospitals for these products. CMS also noted our recommendation to collect additional information on ASP to validate the reasonableness of reported ASPs, saying that it would consider the feasibility of the recommendation.

Our recommendations seek to ensure that the payment rates Medicare sets for SCODs equal hospitals' average acquisition costs and that these average costs are measured as accurately as possible. We reiterate the importance of taking our recommendations into account in preparing the final rule.

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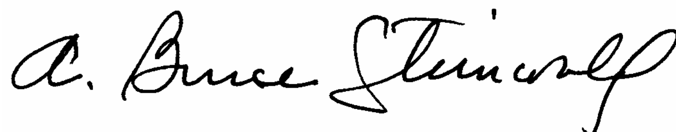
We are sending copies of this report to the Secretary of Health and Human Services and the Administrator of CMS. The report is available at no charge on GAO's Web site at http://www.gao.gov. We will also make copies available to others on request. If you or your staff have any questions about this report, please contact me at (202) 512-7119 or steinwalda@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in enclosure II.



A. Bruce Steinwald
Director, Health Care

Enclosures – 2

Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

OCT 21 2005

Mr. A. Bruce Steinwald
Director, Health Care
U.S. Government Accountability Office
Washington, DC 20548

Dear Mr. Steinwald:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO's) draft correspondence entitled, "MEDICARE: Comments on CMS Proposed 2006 Rates for Specified Covered Outpatient Drugs and Radiopharmaceuticals Used in Hospitals" (GAO-06-17R). These comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

for Daniel R. Levinson
Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft correspondence in our capacity as the Department's designated focal point and coordinator for U.S. Government Accountability Office reports. OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

HHS COMMENTS ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT CORRESPONDENCE ENTITLED, "MEDICARE: COMMENTS ON CMS PROPOSED 2006 RATES FOR SPECIFIED COVERED OUTPATIENT DRUGS AND RADIOPHARMACEUTICALS USED IN HOSPITALS" (GAO-06-17R)

The Department of Health and Human Services (HHS) appreciates the opportunity to comment on the U.S. Government Accountability Office's (GAO) draft correspondence.

General Comments

The draft correspondence summarizes GAO's position regarding the proposed payment rates for Specified Covered Outpatient Drugs (SCODs) and radiopharmaceuticals included in the calendar year (CY) 2006 Outpatient Prospective Payment System (OPPS) Proposed Rule.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) instructed the Centers for Medicare & Medicaid Services (CMS) to pay hospitals for outpatient drugs based on average acquisition cost beginning in 2006. Also in the MMA was a provision requiring GAO to conduct a survey in 2004 and 2005 on hospital acquisition cost of drugs in the outpatient department and to share the results with CMS.

In the OPPS proposed rule, CMS proposed basing average acquisition cost on average sales price (ASP) data already collected by CMS. CMS included GAO's findings on hospital acquisition costs in our analysis of the three proposed payment rate options: ASP + 3 percent, ASP + 6 percent, and ASP + 8 percent. As radiopharmaceuticals were not required to report ASP data in 2005, CMS proposed to base payment on hospital charges adjusted to cost using hospital-specific, department-specific cost-to-charge (CCR) ratios.

In general, GAO supports CMS's proposal to pay acquisition costs based upon ASP methodology and includes further analysis of the three proposed payment rates for SCODs discussed in the OPPS rule. In addition, GAO analyzes the proposed payment rate for radiopharmaceuticals and offers alternative suggestions for CMS to consider for all drugs and radiopharmaceuticals.

The GAO analysis notes several reservations to CMS's proposal to set SCOD payment rates at ASP + 6 percent and the payment of radiopharmaceutical agents at hospital charges adjusted to costs.

CMS is committed to ensuring that in 2006 hospitals are paid for SCODs and radiopharmaceuticals at average hospital acquisition cost as required by the MMA. We appreciate the effort that went into this report and are considering GAO's recommendations as we prepare our final rule on the OPPS for CY 2006. We look forward to working with GAO on this and other pertinent issues addressed in this report.

GAO Recommendation #1

Reconsider the level of proposed payment rates for drug SCODs in relation to survey data on average purchase price, the role of rebates in determining acquisition costs, and the desirability of setting payment rates for SCODs at average acquisition costs.

HHS Response

CMS is committed to ensuring that in 2006 hospitals are paid for SCODs at average hospital acquisition cost as required by the MMA.

In this draft correspondence, GAO generally supports CMS's proposal to base SCOD payments on the ASP methodology because of its ability to quickly reflect market trends and its ability to account for hospital rebates, but cautions that information gaps may decrease the accuracy of ASP rates. GAO suggests ASP + 3 percent as a payment ceiling instead of CMS's proposed ASP + 6 percent payment rate for SCODs.

We appreciate GAO's analysis of the data sources that we considered when developing our proposed rule. We are considering GAO's recommendations as we prepare our final rule on the OPPS for calendar year 2006.

GAO Recommendation #2

Reconsider the decision to base payment rates for radiopharmaceutical SCODs exclusively on estimated costs, in light of the availability of data on actual prices paid for key radiopharmaceuticals.

HHS Response

Unlike SCODs, radiopharmaceuticals were not subject to ASP reporting requirements in 2005, and therefore payments must be based on an alternative methodology that accounts for the cost of the materials and their preparation.

GAO presents an analysis regarding radiopharmaceutical costs and outlines the alternative payment method that they suggest CMS adopt for these products in 2006. GAO offers analysis that indicates that CMS's proposed payment rate of hospital charges reduced to cost would overpay hospitals for these agents.

Again, CMS appreciates GAO's analysis, and the recommendation will be considered as we prepare our upcoming OPPS final rule.

GAO Recommendation #3

Collect information on ASP components and ASP by purchaser type to validate the reasonableness of reported ASPs as a measure of hospital acquisition costs.

HHS Response

We note the GAO's recommendations for better understanding the relationship between ASP and hospital acquisition costs and will consider the feasibility of the recommendation.

GAO Contact and Staff Acknowledgments

GAO Contact

A. Bruce Steinwald, (202) 512-7119 or steinwalda@gao.gov

Acknowledgments

Jon Ratner, Assistant Director; Hannah Fein; Dae Park; Phyllis Thorburn; Thomas Walke; and Craig Winslow contributed to this report.

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