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Report to Congressional Committees

April 2006

MEDICARE HOSPITAL PHARMACEUTICALS

Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS

GAO-06-372

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GAO Accountability · Integrity · Reliability

Highlights

Highlights of GAO-06-372, a report to congressional committees

Why GAO Did This Study

In 2003, the Medicare Modernization Act required the Centers for Medicare & Medicaid Services (CMS) to establish payment rates for a set of new pharmaceutical products—drugs and radiopharmaceuticals—provided to beneficiaries in a hospital outpatient setting. These products were classified for payment purposes as specified covered outpatient drugs (SCOD). The legislation directed CMS to set 2006 Medicare payment rates for SCODs equal to hospitals' average acquisition costs and included requirements for GAO. As directed, GAO surveyed hospitals and issued two reports, providing information to use in setting 2006 SCOD rates. To address other requirements in the law, this report analyzes SCOD price variation across hospitals, advises CMS on future surveys it might undertake, and examines both lessons from the GAO survey and future challenges facing CMS.

What GAO Recommends

GAO recommends that the Secretary of Health and Human Services seek to ensure that CMS's SCOD payment rates are based on sufficiently reliable data by (1) validating data collected on drug prices and (2) basing payment rates for each radiopharmaceutical SCOD on the price of a ready-to-use unit dose. Although expressing some reservations, particularly concerning the burden of data collection, HHS agreed to consider GAO's recommendations.

www.gao.gov/cgi-bin/getrpt?GAO-06-372.

To view the full product, including the scope and methodology, click on the link above. For more information, contact A. Bruce Steinwald at (202) 512-7119 or steinwalda@gao.gov.

What GAO Found

Analyzing pharmaceutical price data collected from its 2004 survey of hospitals, GAO found that prices hospitals paid for SCOD products varied across hospitals. Certain factors—namely, whether the hospital had a major teaching program or not, was in an urban or rural area, and had a large or small hospital outpatient department—were associated with whether hospitals paid higher or lower prices for SCOD products. Major teaching hospitals paid prices that were an estimated 3.2 percent lower than those paid by nonteaching hospitals for drug SCODs; rural hospitals paid prices an estimated 4.4 percent higher than those paid by urban hospitals for radiopharmaceutical SCODs; and large hospitals paid prices an estimated 1.4 percent lower than those paid by small hospitals for drug SCODs and 3.1 percent lower for radiopharmaceutical SCODs. Combining these factors, GAO found that large, urban, major teaching hospitals—compared with other hospitals—generally paid lower prices, on average, for all SCOD products.

From conducting its hospital survey, GAO learned a key lesson that CMS could use in the future: such a survey would not be practical for collecting the data needed to set and update SCOD rates routinely but would be useful for validating, on occasion, CMS's rate-setting data. GAO's survey produced accurate hospital drug price data, but it also created a considerable burden for hospitals as the data suppliers and considerable costs for GAO as the data collector. Nonetheless, the benefit of collecting actual prices paid by hospitals could make such surveys advantageous for occasionally validating CMS's proxy for SCODs' average acquisition costs--the average sales price (ASP) data that manufacturers report.

CMS will face important challenges as it seeks to obtain accurate data on hospitals' acquisition costs for drug and radiopharmaceutical SCODs.

- Regarding drugs, CMS lacks the detail on manufacturers' ASP data needed to determine if rates developed from these data are appropriate for hospitals. Manufacturers report ASP as a single price paid by all purchasers, making it impossible to distinguish the price paid by hospitals alone. CMS instructs manufacturers to report ASP net of rebates but does not specify how to allocate individual product rebates when several products are purchased.
- Regarding radiopharmaceuticals, GAO found that the diversity of forms in which they can be purchased—ready-to-use unit doses, multidoses, or separately purchased radioactive and non-radioactive substances—complicates CMS's efforts to select a data source that can provide reasonably accurate price data efficiently. Efficiency as well as accuracy is a factor in selecting a data source because radiopharmaceuticals account for only 1.5 percent of Medicare hospital outpatient spending. GAO's experience suggests that the best option available to CMS, in terms of accuracy and efficiency, is to collect price data on radiopharmaceuticals purchased in ready-to-use unit doses, the form in which an estimated three-quarters of hospitals purchase these products.

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Abbreviations

ASP	average sales price
CMS	Centers for Medicare & Medicaid Services
HHS	Department of Health and Human Services
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MSA	metropolitan statistical area
NDC	national drug code
OPPS	outpatient prospective payment system
SCOD	specified covered outpatient drug

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

April 28, 2006

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

In 2003, federal legislation required the establishment of Medicare payment rates for a particular set of new pharmaceutical products that were provided to beneficiaries in hospital outpatient settings but were generally paid for differently than other services paid under Medicare's hospital outpatient prospective payment system (OPPS). These products were newly introduced drugs, biologicals, and radiopharmaceuticals used to treat and in some cases diagnose serious conditions such as cancer.[1] Specifically, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required the Centers for Medicare & Medicaid Services (CMS) in the Department of Health and Human Services (HHS) to set rates for these pharmaceuticals. MMA classified them for

[1]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.

payment purposes as specified covered outpatient drugs (SCOD).[2] In addition, MMA defined a SCOD as a drug or radiopharmaceutical, used in hospital outpatient departments, covered by Medicare, and paid for as an individual product for which CMS established a separate payment category rather than placing it in a category that included other services.

The MMA 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 the cost 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 a large sample 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.[5] We provided information from this survey in two reports[6]—one on drugs and another on radiopharmaceuticals. These reports presented systematic information on hospitals' purchase prices of SCODs and limited information on rebates.[7] Second, we were required to evaluate CMS's proposed rates for SCODs and comment on their

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

[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 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]The Secretary of HHS considered the price data we provided but elected not to use these data as the basis for 2006 rates.

[6]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).

[7]The term purchase price refers to the price that hospitals paid upon receiving a product. The term rebates refers to price concessions given to hospitals by manufacturers subsequent to receipt of the product.

appropriateness in light of the survey of SCOD prices we conducted. We provided our comments in a report issued in October 2005.[8]

Two other MMA requirements had a role for us—to report on any variation found in our survey results in acquisition costs among hospitals and to advise on future data collection efforts by CMS based on our survey experience.[9] This report addresses these requirements and examines (1) the extent to which SCOD prices identified in our survey differed among hospitals with different characteristics, (2) lessons the MMA-mandated survey experience provided for the methodology and frequency of future collection of SCOD price data, and (3) the challenges CMS faces in collecting data to set SCOD payment rates accurately after 2006.

To examine price variation among a sample consisting of 1,157 hospitals purchasing SCOD products, we conducted a multivariate statistical analysis and grouped hospitals by certain key characteristics, including teaching status, location, and size. We defined a hospital's teaching status as major, other teaching, or nonteaching, based on the hospital's intern/resident-to-bed ratio;[10] location as urban or rural based on metropolitan statistical areas (MSA); and size as a hospital's total Medicare outpatient charges, classifying a hospital as large if its Medicare charges were at or above the 80th percentile of all hospital outpatient charges. The prices we examined were drawn from our survey of hospitals' purchase prices for 62 SCODs for the period July 1, 2003, through June 30, 2004.[11] We determined that our survey data were reliable for estimating SCOD prices. For details on our methodology, see appendix I.

[8]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).

[9]MMA 117 Stat. 2308-09.

[10]Major teaching hospitals were defined as having an intern/resident-to-bed ratio of 0.25 or more. Hospitals with other teaching programs had an intern/resident-to-bed ratio above 0 but less than 0.25.

[11]The products in these SCOD categories represented 95 percent of all Medicare spending on SCOD products (53 drugs and 9 radiopharmaceuticals) during the first 9 months of 2004. The nine radiopharmaceuticals accounted for 90 percent of all Medicare hospital outpatient spending on radiopharmaceutical SCODs.

To identify lessons learned from our hospital survey experience as well as challenges for CMS's future data collection,[12] we reviewed the findings from our issued reports on SCOD drug prices,[13] SCOD radiopharmaceutical prices,[14] and CMS's proposed SCOD rates;[15] consulted on methodological issues with an advisory panel of experts in pharmaceutical economics, pharmacy, medicine, survey sampling, and Medicare payment;[16] interviewed officials from CMS and several dozen hospitals; and reviewed CMS's final rule on Medicare's 2006 payment rates for SCODs.[17] In particular, we reviewed CMS's published method for collecting the average sales prices (ASP) of drug SCODs: manufacturers report their ASPs quarterly to CMS, which uses them as a proxy for average acquisition costs in setting drug SCOD payment rates. We performed our work according to generally accepted government auditing standards from September 2005 through April 2006.

Results in Brief

In an analysis of price data collected from our survey of hospitals, we found that prices hospitals paid for the SCOD products they purchased varied across hospitals. Certain factors—namely, whether the hospital had a major teaching program or not, was in an urban or rural area, and had a large or small hospital outpatient department—were associated with whether hospitals paid higher or lower prices for the SCOD products they purchased. Specifically,

- compared with nonteaching hospitals, major teaching hospitals paid prices that were, on average, an estimated 3.2 percent lower for drug SCODs;
- compared with urban hospitals, rural hospitals paid prices that were, on average, an estimated 4.4 percent higher for radiopharmaceutical SCOD;, and
- compared with smaller hospitals, large hospitals paid prices that were, on average, an estimated 1.4 percent lower for drug SCODs and 3.1 percent lower for radiopharmaceutical SCODs.

[12]For setting SCOD payment rates after 2006, the Secretary was directed to conduct periodic surveys to obtain cost information.

[13]GAO-05-581R.

[14]GAO-05-733R.

[15]GAO-06-17R.

[16]See app. I.

[17]70 Fed. Reg. 68,516 (Nov. 10, 2005).

Combining the three factors, we found that large, urban, major teaching hospitals generally paid lower prices, on average, for all SCOD products than did hospitals grouped by other combinations of factors.

A key lesson for CMS that we learned from conducting the 2004 MMA-mandated hospital survey is that such a survey would not be practical for collecting the data needed to set and update SCOD rates routinely. However, it would be useful, on occasion, for CMS to survey hospitals so that the rate-setting data it obtained from other sources could be validated by an independent source. Our 2004 hospital survey produced accurate hospital drug price data, but it also created a considerable burden for hospitals as data suppliers and considerable costs for us as the data collector—signaling the difficulties that CMS would face in implementing similar surveys in the future. Hospitals told us that, to submit the required price data, they had to divert staff from their normal duties, thereby incurring additional costs. Similarly, we incurred substantial staff and contractor costs to make data obtained from diverse information systems comparable and usable for SCOD rate-setting. Nevertheless, we found that the benefit of obtaining data on actual prices paid by hospitals could make such surveys advantageous for validating, on an occasional basis—possibly every 5 or 10 years—ASP data that manufacturers report to CMS for developing SCOD payment rates.

CMS will face important challenges as it seeks to obtain accurate data on hospitals' acquisition costs for both drug and radiopharmaceutical SCODs.

- With regard to drug SCODs, CMS lacks the detail on manufacturers' ASP data needed to determine if the Medicare payment rates developed from these data are appropriate specifically for hospitals. Manufacturers report ASP as a single price paid by all purchasers—as defined by law—but do not identify purchasers by type or share of purchases. Therefore, CMS could not determine whether hospitals pay more or less than physicians, for example, for drug SCODs. If other providers paid more or less than hospitals, that could result in an average that was either higher or lower than what hospitals paid. In our October 2005 report, we recommended that CMS collect information on manufacturers' ASP that would identify purchaser types.[18] In addition, CMS instructs manufacturers to report ASP net of rebates but does not provide guidance on how to allocate to an individual product rebates that are based on purchases of more than one product.

[18]GAO-06-17R.

- With regard to radiopharmaceutical SCODs, their complex nature as compared with drugs poses challenges for collecting and interpreting cost data. Because radiopharmaceuticals consist of a radioisotope and a medicine or pharmaceutical agent, hospitals can purchase them in ready-to-use unit dose form, as most hospitals do, multidose, or as separate components to be subsequently compounded. The different purchase options available to hospitals make pricing radiopharmaceuticals uniformly across hospitals infeasible. In addition, the short half-life of certain radioisotopes, which causes these products to decay over time, makes the hospital's distance from its supplier a factor in how much is purchased. This can lead to differences among hospitals in the amount purchased per beneficiary served. Given the complexities of radiopharmaceuticals, it is also important to note that the amount spent on radiopharmaceuticals is less than 1.5 percent of total Medicare spending on hospital outpatient services. This small percentage together with the complexities of radiopharmaceuticals complicate CMS's ability to select a data source that can provide reasonably accurate data efficiently.

In this report, we make recommendations to the Secretary of Health and Human Services regarding both drugs and radiopharmaceuticals. We recommend that CMS occasionally validate manufacturers' reported ASPs as a measure of hospitals' acquisition costs, using hospital purchases obtained from a survey or other method. We also recommend the use of ready-to-use unit-dose prices as the data source for radiopharmaceutical SCOD rate-setting. In commenting on a draft of this report, HHS agreed to consider our recommendations, but expressed several reservations. In particular, it was concerned about the burden of a hospital survey for both hospital staff and the agency. We recognize the burden of hospital surveys and for this reason recommended only occasional hospital surveys—or an alternative method—to validate price data reported by manufacturers.

Background

In the period following the enactment of legislation establishing Medicare's OPPS and leading up to the MMA in 2003, concerns were expressed about the adequacy of payments for innovative pharmaceutical products. The MMA addressed these concerns by establishing a payment policy for SCODs. As mandated by the MMA, we conducted a hospital survey and provided HHS with information about prices hospitals paid for SCOD products. Details follow on the background of SCODs, our survey, CMS's new rates for drug SCODs, and the nature of radiopharmaceutical products.

MMA Established SCOD Payment Categories for Certain Pharmaceutical Products to Ensure Beneficiary Access to New Products

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,[19] the 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.[20] The MMA modified this payment method for some of these pharmaceutical products. As part of the modification, the MMA defined the new SCOD payment category, which includes many of these newly introduced pharmaceutical products. The MMA requires that SCODs be placed in separate payment categories—that is, not packaged with related services.

MMA Required Us to Survey Hospitals to Determine Their Acquisition Costs for SCOD Products

As directed by the MMA, we conducted a survey of a large sample of hospitals to determine their acquisition costs for SCOD products. We surveyed 1,400 hospitals and received usable data from 83 percent of the hospitals for drug SCODs and from 61 percent of the 1,322 hospitals that had submitted Medicare claims for radiopharmaceutical SCODs in the first 6 months of 2003. We found that we could not obtain data that would permit calculation of hospitals' acquisition costs, because, in general, hospitals were unable to report accurately or comprehensively on rebates.[21] Consequently, we reported average purchase prices for drug and radiopharmaceutical SCODs, which are prices net of discounts but not

[19]Pub. L. No. 105-33, § 4523, 111 Stat. 251, 445—50.

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

[21]Rebates are price concessions given to hospitals by manufacturers subsequent to receipt of the product. For a discussion of rebates and their relationship to hospital acquisition costs, see GAO-06-17R, p. 5.

rebates.[22] Of the 251 SCODs that we identified, we reported average purchase prices for the 62 SCODs that accounted for 95 percent of Medicare spending on all SCODs in the first 9 months of 2004. (These prices and related information are included as app. II and app. III.)

MMA Defined ASP, Which Is Reported by Manufacturers and Used to Set Rates for Drug SCODs

ASP is a price measure established in the MMA to provide a basis for payment rates for physician-administered drugs and now used by CMS in setting rates for drug SCODs.[23] 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 of a drug, net of volume, prompt pay, and cash discounts; free goods contingent on a purchase requirement; and charge-backs and rebates.[24] Under CMS's final rule governing 2006 payment rates for hospital outpatient services, including SCOD products, CMS uses manufacturers' ASPs in setting drug SCOD rates.[25] For radiopharmaceuticals, CMS has set 2006 rates based on an estimate of hospitals' costs derived from charges, but the agency has not decided how to pay for radiopharmaceutical SCODs after 2006.[26]

Radiopharmaceuticals Can Be Purchased in Different Forms

Hospitals can purchase radiopharmaceuticals, which consist of a radioisotope and a medicine or pharmaceutical agent, in different forms. They can purchase vials of the product in ready-to-use unit doses or in multidoses, or they can purchase a product's radioactive and nonradioactive components separately and compound them in-house. In a survey conducted by the Society of Nuclear Medicine and the Society of

[22]Discounts are price concessions given by manufacturers and wholesalers that are reflected in the purchase price—the price hospitals pay at the time of delivery.

[23]MMA 117 Stat. 2239-45. MMA specifically required use of ASP to set rates for drugs furnished in physicians' offices on or after January 1, 2005; CMS began using ASP to set rates for SCOD products delivered in hospital outpatient departments on or after January 1, 2006.

[24]MMA 177 Stat. 2240—41.

[25]70 Fed. Reg. 68,642. In total, the payment rate for drug SCODs is ASP+6 percent, which includes overhead and handling that CMS had previously estimated at 2 percent of ASP. The implied rate for the product without overhead is ASP+4 percent.

[26]70 Fed. Reg. 68,654.

Nuclear Medicine Technologist Section, 76 percent of hospitals reported that they purchased their radiopharmaceuticals in unit doses.[27]

Hospitals' Teaching Status, Location, and Size Affected Prices for SCOD Products by Different Magnitudes

Using our hospital survey of prices hospitals paid for SCOD drugs and radiopharmaceuticals, we examined the extent to which prices varied among the approximately 1,200 hospitals that submitted survey data. To do this, we looked at several hospital characteristics, or factors—including teaching status, location, and size of the outpatient department—while controlling for differences in the costliness of the mix of SCODs that hospitals purchased. We analyzed both (1) the separate effect of each factor, controlling for other factors; and (2) the effect of the three factors combined. We found that teaching status had the largest separate effect on drug SCOD prices, whereas location had the largest effect on radiopharmaceutical SCOD prices. Combining the three factors, we found, for example, that large, urban, hospitals with major teaching programs paid lower prices, on average, for drug SCODs—compared with small urban hospitals with other teaching programs.

Teaching Status, Location, and Size Were Each Significant Factors Affecting Price Variation among Hospitals

The importance of the three factors in accounting for variation in SCOD prices among hospitals differed by type of product purchased—that is, drug or radiopharmaceutical.[28] A hospital's teaching status, for example, affected prices paid for drug SCODs but did not matter for the radiopharmaceutical SCOD prices pertaining to unit dose purchases in our survey. In contrast, a hospital's location was an important factor linked to price differences for radiopharmaceuticals but did not matter with respect to prices for drugs. In addition, hospital size was important in affecting price differences for both drugs and radiopharmaceuticals. (See table 1.)

[27]See Denise A. Merlino, "Nuclear Medicine Faculty Survey: SNM 2003 Survey Reporting on 2002 Cost and Utilization," *Journal of Nuclear Medicine Technology*, vol. 32, no. 4 (2004), pp. 215-219.

[28]Our estimated purchase prices for radiopharmaceutical SCODs were based on hospitals' purchases of ready-to-use unit-doses only; we did not report prices for the generally less prevalent forms—multidoses or doses prepared in-house using a kit.

Table 1: Factors Accounting for Variation in SCOD Prices among Hospitals

Hospital characteristic	Drugs	Radiopharmaceuticals
Teaching status	×	
Location		×
Size	×	×

Sources: GAO analysis of GAO survey data and CMS data on hospital characteristics.

Note: We determined the importance of these factors using a multivariate statistical analysis that examined how prices varied for SCODs by hospitals' teaching status, location, and size of outpatient department, while controlling for differences in the costliness of the mix of SCODs that hospitals purchased. Factors marked with an "x" are statistically significant at the 5 percent level.

In assessing the magnitude of each factor's separate effect on prices, we found the following results:

- *Teaching status*: Compared with nonteaching hospitals, major teaching hospitals paid prices that were, on average, an estimated 3.2 percent lower for drug SCODs. Teaching status had no independent effect on the prices of radiopharmaceutical SCODs purchased in ready-to-use unit doses.[29]
- *Location*: Compared with hospitals located in urban areas, the prices paid by hospitals located in rural areas for radiopharmaceutical SCODs were, on average, an estimated 4.4 percent higher.
- *Size*: Compared with smaller hospitals, hospitals with large outpatient departments paid prices, on average, that were an estimated 1.4 percent lower for drugs and 3.1 percent lower for radiopharmaceuticals.

Certain circumstances may help explain why each factor had an effect on price. Regarding the effect of teaching status on drug prices, for example, manufacturers may want to influence prescribing patterns of physicians in training and may therefore offer drugs at lower prices to hospitals with teaching programs. As for location's effect on radiopharmaceutical SCOD prices, industry experts suggested that the short half-life of certain radioactive products could make transporting them to hospitals in rural areas more costly. As for hospital size, hospitals with large outpatient departments may have benefited from volume discounts.

[29]Compared with nonteaching hospitals, some teaching hospitals may obtain a larger proportion of their radiopharmaceuticals by compounding components purchased separately than by purchasing unit doses. Therefore, the result might have been different had we been able to include the prices hospitals paid for radiopharmaceuticals purchased as multidoses or as separate components.

Hospitals with Combination of Major Teaching Status, Urban Location, and Large Size Obtained Lowest SCOD Prices

To examine the combined effect of the three key factors on prices paid by hospitals, we compared hospitals grouped by one combination—major teaching program, urban location, and large outpatient department—with hospitals grouped by other combinations. Our analysis indicates that large, urban, major teaching hospitals generally paid lower prices, on average, for all SCOD products than did hospitals grouped by other combinations of factors. For example, compared with small urban hospitals with other teaching programs, large major teaching hospitals in urban areas paid prices, on average, that were an estimated 4 percent lower for drugs and 3 percent lower for radiopharmaceuticals. In contrast, compared with small urban hospitals with other teaching programs, small rural hospitals with no teaching programs paid prices, on average, that were about the same for drugs and 4 percent higher for radiopharmaceuticals.[30]

Our Survey of Hospitals Suggests that the Burden of Large-Scale Annual Surveys Could Outweigh Gains in Data Accuracy

Our MMA-mandated survey of hospitals produced accurate hospital price data. However, for CMS to use such a survey to routinely collect data in the future for SCOD rate-setting, the burden could outweigh the benefit. Instead, similar surveys of hospitals could be a useful tool to validate price data obtained from manufacturers, if conducted on an occasional basis.

Using Hospitals as Data Source for SCOD Prices Had A Major Advantage and Serious Drawbacks

Based on our survey experience, we noted that hospitals as a SCOD data source had one important advantage as well as substantial drawbacks. We found that, as a data source for estimating hospitals' SCOD acquisition costs, hospitals offered a key advantage: our average purchase prices obtained from hospitals, by definition, represent actual prices paid by hospitals.[31] In this respect, our data differ from other data sources available to CMS—such as suggested list prices, ASPs, and hospitals'

[30]The estimated percentage differences were derived from two multivariate statistical models—one explaining variation in prices of 53 drug SCODs, the second explaining price variation of 9 radiopharmaceutical SCODs. Each model attributed variation in SCOD prices to three hospital characteristics (teaching status, size, and location) and to the particular set of SCODs purchased by each hospital.

[31]CMS collects ASPs from manufacturers that include prices paid by all purchasers, not just hospitals. Average prices paid by hospitals may not be equal to average prices paid by other purchasers, such as physicians' offices.

Medicare claims. As a result, none of these alternatives provide, as our survey data do, nationwide data on the actual purchase prices paid by hospitals for drugs and radiopharmaceutical SCODs.

However, based on our experience, we found that there would be drawbacks in using hospitals as an annual data source on SCOD prices, owing primarily to the considerable burden created for hospitals as suppliers of data and the considerable costs we incurred as data collectors, signaling the difficulties that CMS would face in implementing similar surveys in the future. Hospitals 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. The burden was more taxing for some hospitals than for others. Most hospitals had the advantage of relying on price data downloaded from their drug wholesalers' information systems. A number of hospitals, however, either collected the data manually, provided us with copies of paper invoices, or had automated information systems that were not designed to retrieve the detailed price data needed and required additional data processing effort. Hospitals' data collection difficulties were particularly pronounced regarding information on manufacturers' rebates, which affect a drug's net acquisition cost. Typically, hospitals did not systematically track all manufacturers' rebates on drug purchases, although nearly 60 percent of hospitals reported receiving one or more rebates.[32]

As collectors of data on SCOD prices, we also experienced difficulties obtaining the information needed from hospitals. Hospitals' information systems were diverse and produced data in many different formats, causing substantial resource and timing difficulties in the data collection process.[33] Specifically, we had to reconfigure data submitted in multiple formats to produce data comparable across hospitals and usable for SCOD rate-setting. This reconfiguration required us to deploy substantial resources and to allow additional time for processing before the data could be made available to CMS. The difficulties we encountered would

[32]Many hospitals reported receiving rebates for a set of drugs (and sometimes drugs and other products). In these cases, it was generally not feasible to allocate rebates to specific drugs.

[33]We accepted data from hospitals in any format. We believed that we had to make the task of submitting data as easy as possible for hospitals in order to gain their cooperation. Reflecting on our experience, we think that this decision was critical to achieving good response rates.

likely be faced by any organization undertaking a survey using a similar approach.

As we previously reported, using SCOD price and related data from drug manufacturers—as CMS is doing in 2006—is a practical strategy for setting Medicare payment rates to hospitals for SCODs.[34] However, our experience obtaining information on actual purchase prices and our observation of the pace of change in the drug marketplace suggest that an occasional survey of hospitals—possibly once or twice in a decade—may be advantageous for validating the accuracy of manufacturers' price information as a proxy for hospital acquisition cost.[35] Drawing on our experience and using data about sampling variability from our 2004 hospital survey,[36] CMS could design a similar but streamlined hospital survey.[37] Other options available to CMS for validating the accuracy of the price data as a proxy for hospitals' acquisition costs include audits of manufacturers' price submissions or an examination of proprietary data the agency considers reliable for validation purposes.

[34]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). In addition to the product's ASP, manufacturers must report the manufacturer's name, the product's National Drug Code (NDC), and the number of units.

[35]Although HHS chose to use ASP data submitted by manufacturers to set 2006 payment rates, it is required to conduct hospital surveys subsequent to ours to determine hospital acquisition costs. MMA 117 Stat. 2308.

[36]We refer to our survey of hospitals as the 2004 survey because data collection began in 2004. We collected data for SCODs purchased from July 1, 2003, through June 30, 2004.

[37]For details on the sample design for our survey, see GAO-05-581R, enclosure I.

Survey Indicates that Accounting for Dynamic Drug Market and Infrequently Purchased Drugs Has Implications for Accuracy and Efficiency

Our hospital survey experience not only identified data collection issues associated with hospitals but also underscored accuracy and efficiency concerns in collecting SCOD data from any source. Specifically, the accuracy of the rates Medicare pays for drugs within a SCOD payment category, based on the average price of drugs included in the SCOD, may be compromised if the price of any drug—that is, any national drug code (NDC)—is omitted from the average price of the SCOD category.[38] In the conduct of our 2004 survey, we began with a list, which CMS provided to us, of drug categories that included SCODs as well as other drugs that potentially could be considered SCODs in the future. To ensure the accuracy of our calculation of a hospital's average purchase price for SCODs, we took additional steps using industry experts and data sources to classify the NDCs and assign them to the appropriate SCOD categories.[39] Since the drug market is dynamic—new drugs enter the market and other drugs drop out in the course of a year—CMS's list of SCOD drugs and their component NDCs could become out of date unless updated frequently to ensure that all SCOD drugs purchased by hospitals are identified and figured into the calculation of a SCOD's average price.

With regard to efficiency in analyzing our survey results, we concentrated our data processing and statistical resources on the roughly one-quarter of SCODs that account for most of Medicare's total SCOD spending. In particular, the 62 SCODs for which we produced price estimates accounted for 95 percent of Medicare spending on all 251 SCODs in the first 9 months of 2004.[40] We would not have been able to produce price estimates for all SCODs in time for CMS to take account of our data in setting the 2006 rates. Our experience—especially the amount of time and resources necessary for each step in the data collection and analysis process—could be used by CMS to determine in advance the number of SCODs on which to collect data and estimate prices. There might be some benefit in gathering data and producing price estimates for all SCODs; on

[38]A SCOD category may contain one or many NDCs. NDCs may differ by manufacturer, strength, or package size.

[39]Each SCOD and each NDC is assigned a specific number of units (for example, 10 mg.), and the NDC units must also be converted to SCOD units, in order to place on the same basis all the NDCs that make up a SCOD. For a discussion of issues in converting NDC prices to SCOD prices, see Department of Health and Human Services, Office of Inspector General, *Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs*, OEI-03-05-00310 (Washington, D.C.: February 2006).

[40]The number of SCODs can change from year to year as CMS designates additional SCODs or combines previously separate SCODs.

the other hand, if resources were limited, CMS might choose to focus on fewer SCODs.

CMS Faces Challenges in Future Data Collection Efforts to Set SCOD Payment Rates Accurately

CMS will face important challenges in its efforts to collect accurate data for setting SCOD payment rates. In our October 2005 report on CMS's proposed SCOD rates, we expressed reservations about the ASP data CMS used to set 2006 payment rates for drug SCODs. We cautioned that manufacturers' reporting of ASPs in summary form—without any further detail—does not provide the agency the information needed to ensure that ASPs are a sufficiently accurate measure of hospitals' acquisition costs. Data collection and rate-setting for radiopharmaceutical SCODs present unique challenges because of these products' distinctive characteristics.

Validating ASP Would Pose Challenges for CMS Because of Lack of Detail in Data

Under CMS's current policy, manufacturers are required to report only summary ASP data, limiting CMS's ability to validate the data's accuracy. Specifically, manufacturers report ASP as a single price, with no breakdown of price and volume by type of purchaser. CMS instructs manufacturers to average together prices for each drug paid by all U.S. purchasers. However, different purchaser types—for example, hospitals, physicians, and wholesalers—may receive prices that, by purchaser type, are on average higher or lower than one another's. Because CMS does not receive price data at this level of detail, it cannot determine whether price differences among purchaser types exist. To the extent that nonhospital providers pay different prices than hospitals and account for a proportion of the SCODs purchased, ASP will differ from the prices paid on average by hospitals.[41] CMS has not presented evidence, in its final rule or in discussions with us, that physicians and hospitals pay the same prices.

An additional weakness in CMS's instructions for computing ASPs compounds the challenge of testing the accuracy of the ASPs that manufacturers report. No instruction is provided to manufacturers on the treatment of rebates that apply to several drug products in calculating ASP.[42] This is of particular concern to the extent that manufacturers differ in their rules for calculating these rebates. When a rebate applies to a

[41]We recommended in a previous report that CMS collect information on ASP by purchaser type to validate its reasonableness as a measure of hospital acquisition cost. See GAO-06-17R.

[42]42 C.F.R. §§ 414.800—414.806 (2005).

group of a manufacturer's products—which may include several SCODs, other pharmaceuticals, and other products—netting out the rebate attributable to a specific SCOD's purchase is less than straightforward. In the absence of clear and specific instructions, each manufacturer must identify or develop a method for allocating rebates to each of its drug SCOD products. To the extent that manufacturers' methods differ, they are likely to yield inconsistent results. Moreover, CMS's final rule does not provide for a follow-up process to check that rebate allocations have been made or have been made appropriately.

Radiopharmaceuticals Pose Unique Challenges for Obtaining Accurate Cost Data Efficiently

The complex nature of radiopharmaceuticals as compared with drugs poses special challenges for collecting and interpreting cost data. These challenges include (1) obtaining consistent data for radiopharmaceutical SCODs produced in very different forms and (2) the short half-life for certain products. Moreover, since Medicare spends relatively little on radiopharmaceuticals—less than 1.5 percent of Medicare spending on hospital outpatient services—the challenge is to find a source of data for setting rates that is low cost and reasonably accurate.

In our hospital survey, we faced the challenge of uniformly pricing products purchased in very different forms. We focused on prices for radiopharmaceuticals purchased in unit doses. Most of the hospitals purchased radiopharmaceuticals in this ready-to-use form, and only a small fraction of hospitals purchased radiopharmaceuticals in separate components (the radioisotope and the nonradioactive substance), which need to be compounded.[43] We were unable to make prices for separately purchased components comparable to those obtained for unit doses, as the labor costs for compounding the products are included in hospitals' reported prices of ready-to-use products but not in their reported prices of products they purchased as separate components.

The short half-life of certain radiopharmaceutical SCODs can also pose challenges for collecting and interpreting price data. Because the radioactive component decays over time, the amount of the product purchased for a given patient may vary with the distance between where the radiopharmaceutical is compounded and where it is administered. The

[43]In a survey conducted by the Society of Nuclear Medicine and the Society of Nuclear Medicine Technologist Section, 76 percent of hospitals reported that they purchased their radiopharmaceuticals in unit doses. See Merlino, pp. 215-219.

result is that for those short-lived radiopharmaceuticals paid on a per-dose basis, the cost per dose is more for the doses prepared far from the point of administration than for those prepared closer by, as more of a radioactive product must be purchased to account for its decay in transit. This applies most commonly to F-18 radiopharmaceuticals, the most common of which, F-18 FDG, has a half-life of 1.8 hours.[44] F-18 radiopharmaceuticals, including F-18 FDG, are used in the diagnosis of various diseases, such as cancer, heart disease, and liver disease.

Finally, CMS faces the challenge of balancing accuracy and efficiency in obtaining price data on radiopharmaceutical SCODs. Our approach in estimating prices from our survey data was to use only information on unit dose prices, the form purchased by most hospitals.[45] CMS, as stated in the 2006 final rule governing payment rates for SCODs, has not found what it considers a satisfactory method for obtaining data on acquisition costs of radiopharmaceuticals and is continuing to explore both ASP and other alternatives.[46] Hospitals and manufacturers[47] are the most direct source of price data because both are parties to the transactions in which the hospitals acquire the radiopharmaceuticals.[48] In its notice of proposed rulemaking for radiopharmaceutical SCODs, CMS proposed collecting ASPs from manufacturers for use in setting 2007 payment rates.[49] In light of many comments regarding the difficulty of this undertaking, CMS decided not to collect radiopharmaceutical ASPs for 2007 rates, but left open the possibility of using ASP in the future.

CMS has also discussed the possibility of using charges from hospitals' Medicare claims to approximate acquisition costs for radiopharmaceutical SCODs, rather than obtaining price data from invoices provided by

[44]Of the nine radiopharmaceuticals for which we estimated prices, F-18 FDG is the only one that is an F-18 radiopharmaceutical. However, as more F-18 labeled products become available, the category may expand.

[45]See GAO-05-733R.

[46]70 Fed. Reg. 68,656—57.

[47]We consider manufacturers to include independent nuclear pharmacies and hospitals that compound radiopharmaceuticals that they supply to other hospitals.

[48]A small part of the business of some independent nuclear pharmacies, as well as retail outlets for large radiopharmaceutical manufacturers, involves supplying ready-to-use radiopharmaceuticals from their parent companies and other manufacturers.

[49]70 Fed. Reg. 42,674, 42,727—28 (July 25, 2005).

hospitals or from manufacturers. Using claims data may be a more efficient but less accurate means of obtaining price estimates than obtaining price data directly from manufacturers or from hospitals' invoices. In its final rule, CMS stated that it was basing 2006 payments on hospitals' charges (derived from outpatient claims) for radiopharmaceuticals. CMS plans to adjust these charges to reflect costs and noted that it did not plan to use this methodology permanently. For rate-setting after 2006, CMS also noted the possibility of using invoice data submitted to Medicare by physicians who administer radiopharmaceuticals in their offices.[50] In its final rule, CMS did not present evidence that hospitals and physicians pay similar prices for these radiopharmaceutical drugs nor, if these prices differ, whether using these physician data would be appropriate for use in setting hospital outpatient rates.

Conclusions

Basing Medicare's payment rates for hospitals' SCOD purchases on current, accurate price data is important both to ensuring that Medicare pays appropriately—neither too much nor too little—and to ensuring beneficiary access to these innovative pharmaceutical products. As we previously reported, we agree with CMS that ASP is a practical data source for setting and updating rates for drug SCODs on a routine basis. However, we remain concerned about whether CMS can determine that ASP accurately represents purchases made by hospitals and believe that CMS should implement our October 2005 recommendation to collect sufficient information on ASP to make such a determination. We are also concerned about the likelihood that ASPs are not calculated consistently across all manufacturers, owing to CMS's lack of detailed instructions. As for validating the data CMS collects to set payment rates equal to hospitals' acquisition costs, an examination of hospitals' actual purchase prices, by definition, is optimal for assessing accuracy. Recognizing the operational difficulties of a hospital survey and using the knowledge gained from our survey, CMS could conduct a similar but streamlined hospital survey, possibly once or twice in a decade. Other options available to CMS for validating price data could include audits of manufacturers' price submissions or an examination of proprietary data the agency considers reliable for validation purposes.

[50]70 Fed. Reg. 68,656.

In contrast, we found that the diversity of forms in which radiopharmaceutical SCODs can be purchased—ready-to-use unit doses, multidoses, or separately purchased radioactive and nonradioactive components—complicates CMS's efforts to select a data source that can provide reasonably accurate price data efficiently. Our experience suggests that the best option available to CMS, in terms of accuracy and efficiency, is to collect price data on radiopharmaceuticals purchased in ready-to-use unit doses, the form in which an estimated three-quarters of hospitals purchase these products.

Recommendations for Executive Action

To ensure that Medicare payments for SCOD products are based on sufficiently accurate data, we recommend that the Secretary of Health and Human Services take the following two actions:

- validate, on an occasional basis, manufacturers' reported drug ASPs as a measure of hospitals' acquisition costs using a survey of hospitals or other method that CMS determines to be similarly accurate and efficient; and
- use unit-dose prices paid by hospitals when available as the data source for setting and updating Medicare payment rates for radiopharmaceutical SCODs.

Agency Comments and Our Evaluation

We received written comments on a draft of this report from HHS (see app. IV), which noted that it had considered information from our survey of hospitals in developing 2006 hospital outpatient payment policy and expressed appreciation for our effort and analysis.

Regarding the first recommendation—that HHS validate ASPs as a measure of hospital acquisition costs through occasional hospital surveys or other methods—HHS highlighted our finding that an annual hospital survey could place considerable burdens on both the agency and hospital staff. However, HHS agreed to consider this recommendation, saying that it would continue to analyze the best approach for setting payment rates for drugs and radiopharmaceutical SCODs in view of our recommendation. It will also continue to analyze the adequacy of paying for drugs at ASP+6 percent in the light of claims data, which persuaded HHS that for 2006 ASP + 6 percent was the best available proxy for hospital acquisition and handling costs.

Regarding the second recommendation—that HHS use unit-dose prices to set and update payment rates for radiopharmaceuticals—HHS agreed with us that the multiple forms in which radiopharmaceuticals can be

purchased makes setting their payment rates difficult. While agreeing to consider our recommendation, HHS expressed several reservations. First, it noted that we had not specified whether the survey to collect acquisition cost data should be a survey of hospitals or manufacturers and asked that we clarify this point. Second, it noted that we had emphasized the burden of annual surveys of hospital drug prices and expressed the concern that an annual survey of hospital radiopharmaceutical prices would be equally burdensome. Finally, HHS noted that we had confined our report to 9 of the approximately 55 radiopharmaceuticals that are paid separately, and questioned whether unit-dose data would be available for all or most radiopharmaceuticals.

Our recommendation that HHS validate ASPs through occasional surveys or by using other methods is based in considerable part on our experience of the difficulty of a hospital survey. The burden that annual surveys would place on both hospitals and the agency is the reason that we rejected annual surveys as a source of acquisition cost data and instead proposed only occasional surveys to validate ASPs. Furthermore, as we noted in the recommendation, HHS could use a method other than a survey if that method were similarly accurate and efficient.

In our recommendation on radiopharmaceuticals, we did not comment on whether the survey to collect acquisition cost data should be a survey of hospitals or manufacturers, because we have not analyzed the feasibility of obtaining these data from manufacturers. We recognize the potential burden of hospital surveys; this burden would need to be taken into account in weighing the merits of a hospital survey versus other alternatives. Regarding our recommendation to collect unit-dose prices, we have clarified it, saying that unit-dose prices should be used when available. In our survey, we used unit-dose data when we reported purchase prices for the 9 radiopharmaceuticals that accounted for 90 percent of Medicare's costs for hospital outpatient drugs. For radiopharmaceuticals that are prepared exclusively in-house HHS could, if necessary, establish an alternative method for determining payment rates.

We are sending copies of this report to the Secretary of Health and Human Services, the Administrator of the Centers for Medicare & Medicaid Services, and other interested parties. We will also make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff members have any questions about this report, please contact me at (202) 512-7119 or at steinwalda@gao.gov. Contact points for our Office 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 appendix V.

A. Bruce Steinwald
Director, Health Care

Appendix I: Methodology for Analysis of SCOD Price Differences among Hospital Types

This appendix describes the data and methods we used to examine SCOD price variation among hospitals purchasing SCOD products. In particular, we describe (1) the SCOD price data we analyzed, (2) the factors potentially affecting SCOD prices and the measurement of these factors, and (3) the methods underlying the statistical analysis of prices we conducted and the statistical results we obtained.

SCOD Price Data

Drawing on data from our survey of 1,157 hospitals,[1] we examined hospitals' purchase prices for 53 drug SCODs and 9 radiopharmaceutical SCODs for the period July 1, 2003, through June 30, 2004.[2] Combined, these 62 SCOD categories represented 95 percent of Medicare spending on SCOD products during the first 9 months of 2004. We analyzed invoice data that hospitals submitted to us; specifically, our analysis included one SCOD price for each SCOD purchase listed on an invoice. As a result, for a hospital that purchased SCODs and other drugs once a month, our analysis included 1 price for each month's purchase of a particular SCOD or a total of up to 12 invoice prices for that SCOD during the 12-month period. We were advised in our analysis by an expert panel consisting of 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.

Factors Potentially Affecting SCOD Prices

To analyze SCOD price variation among hospitals purchasing SCODs, we identified characteristics of hospitals that could plausibly explain why prices vary: teaching status, location, and size. We also identified a fourth factor: differences in the costliness of the mix of SCODs that hospitals purchased. Table 2 lists these factors and describes operational measures of these factors and the sources of data used to calculate these measures.

[1]See GAO-05-581R for technical details on the survey we conducted.

[2]Purchase price refers to the price that hospitals paid upon receiving a product. Purchase price incorporates a manufacturer's or other vendor's discounts but excludes any rebates, which manufacturers may pay a hospital purchaser at a later date. In this appendix, price refers to purchase price, unless otherwise stated.

Table 2: Factors Included in Analysis of Price Variation among Hospitals Purchasing SCODs

Factor	Measure	Source and date of data used to calculate measure
Teaching status[a]	Major teaching: Binary variable equal to • 1 if the hospital had a major teaching program • 0 if hospital had no major teaching program Other teaching: Binary variable equal to • 1 if the hospital had other teaching program • 0 if hospital had no other teaching program Nonteaching: Binary variable equal to • 1 if the hospital had no teaching program. • 0 if hospital had a teaching program	CMS: Medicare Hospital Cost Report, 2002
Location	Binary variable equal to • 1 if the hospital was in a rural area—that is, outside a metropolitan statistical area (MSA) • 0 if the hospital was in an urban area—that is, in an MSA	CMS: Provider of Services File, end of 2004
Size[b]	Binary variable equal to • 1 if hospital is large–indicated by outpatient Medicare charges at or above the 80th percentile of all Medicare hospital outpatient charges • 0 if small—less than this amount	CMS: Health Care Information System, 2003
Mix of SCODs purchased	Binary variable equal to • 1 if the product purchased as a given SCOD – that is, the it h SCOD, where i = 1,…n • 0 if the product purchased were any other SCOD	GAO: Survey of Hospitals' SCOD Prices, 2003 and 2004

Sources: GAO analysis of CMS and GAO information.

[a]Major teaching hospitals were defined as hospitals with an intern/resident-to-bed ratio of 0.25 or more. Hospitals with other teaching programs were defined as hospitals with an intern/resident-to-bed ratio above 0 but less than 0.25.

[b]Hospitals with outpatient Medicare charges of $59.1 million or higher were at the 80th percentile or higher of hospitals, ranked by their outpatient Medicare charges, for our analysis of drug SCODs.

In addition to the measures listed in table 2, we considered alternative measures for location and for size:

- We examined two geographic classification systems as alternatives to an MSA (metropolitan statistical area)/nonMSA classification: (1) urban influence codes, which classify counties based on each county's largest city and its proximity to other areas with large, urban, populations; and (2) rural-urban continuum codes, which classify metropolitan counties (that is, those in an MSA) by the size of the urban area and classify

nonmetropolitan counties by the size of the urban population and proximity to a metropolitan area.[3]

- Before selecting our preferred measure of hospital size (hospital outpatient charges at the 80th percentile or higher, where hospitals were ranked by their outpatient Medicare charges), we considered other measures of hospital size: the number of hospital beds, the number of unique SCODs purchased by a hospital, and the number of hospital outpatient visits.

In assessing our regression results for each of the several measures of location and size that we considered, we took into account statistical criteria including the statistical significance of each measure and the overall explanatory power of each model. We also considered qualitative factors when selecting our preferred measures of location and size. For example, we selected hospital outpatient charges as our measure of size, instead of number of hospital beds, because both measures had similar statistical properties and our analysis focuses on the hospital outpatient setting.

In addition to conducting separate regression analyses of the price data for drug SCODs and for radiopharmaceutical SCODs, we analyzed price variation separately for each of four therapeutic categories of drug SCODs. We also conducted separate regression analyses of SCOD price variation for drugs without biologicals, for biologicals, and for radiopharmaceuticals. We determined that any gains in statistical properties did not outweigh the greater complexity of these analyses.

Methods and Results of Price Analysis

In analyzing SCOD price variation, our dependent variable was the natural logarithm of SCOD price.[4] SCOD prices are not distributed symmetrically around the average. SCOD prices are skewed to the right and are not distributed normally, reflecting some SCODs with particularly high prices. Taking the natural logarithm of price is intended to take skewness into

[3]For more information on urban influence codes, see Measuring Rurality: Urban Influence Codes, http://www.ers.usda.gov/Briefing/Rurality/urbaninf/ (downloaded Feb. 2, 2006). For more information on rural-urban continuum codes, see Rural-Urban Commuting Area Codes, http://www.ers.usda.gov/Briefing/Rurality/RuralurbCon/ (downloaded Feb. 14, 2006).

[4]Each observation of price was drawn from a particular invoice for the purchase of a particular SCOD purchased by a particular hospital.

account and make the resulting distribution consistent with the statistical assumptions of a regression.

We weighted prices paid by hospitals for individual drugs and radiopharmaceuticals by the purchase amount of each invoice. That is, we weighted prices more heavily in the statistical analysis for invoices that represented a larger proportion of total annual purchases of a particular SCOD than for invoices that represented a smaller proportion of purchases. In addition, our analysis took into account the fact that multiple prices paid by a particular hospital were not necessarily statistically independent of each other—a phenomenon known as clustering. In estimating our statistical models, we corrected the potential bias in our estimates due to clustering by using the robust and cluster options in STATA, a statistical software package.[5]

To gauge the effects of our explanatory factors on price variation among hospitals, we estimated one regression model for drug SCODs and a separate model for radiopharmaceutical SCODs. Table 3 shows estimates of the first model, which indicate the effects of three hospital characteristics on the natural logarithm of price of drug SCODs.

[5]StataCorp, *Stata Statistical Software: Release 9* (College Station, Tex.: StataCorp LP, 2003).

Table 3: Estimated Effects of Selected Factors on Prices Hospitals Paid for Drug SCODs

Factor	Measure of factor	Estimated coefficient	t-value
Teaching status	Major teaching program	-.0321	-5.33[a]
	Other teaching program	-.0054	-1.54
	Nonteaching (reference group)	n/a[b]	n/a[b]
Location	Rural	.0009	0.17
	Urban (reference group)	n/a[b]	n/a[b]
Size	Large	-.0138	-2.18[a]
	Small (reference group)	n/a[b]	n/a[b]
Mix of SCODs purchased by a particular hospital	SCOD category (one binary variable for each of 53 drug SCODs)	(not reported)	
	Intercept	4.11	1810.16[a]
	R-squared	.9974	
	Number of observations	439,988	

Source: GAO analysis.

Notes: SCOD refers to a specified covered outpatient drug. The results in this table pertain to the top 53 drug SCOD products, ranked by Medicare spending on SCODs during the first 9 months of 2004.

This table presents estimates from a regression model. The model's dependent variable is the natural logarithm of the purchase price paid by a particular hospital for a SCOD. SCOD prices are not distributed symmetrically around the average SCOD price but are skewed to the right, reflecting some SCODs with particularly high prices. Taking the natural logarithm of price takes this skewness into account. The effect of a measure, such as rural location, is estimated relative to a reference group (urban location). Therefore, the reference group is not explicitly included in the model. A major teaching program refers to a hospital that has an intern/resident-to-bed ratio of 0.25 or more. Urban refers to a hospital inside a metropolitan statistical area. Large refers to a hospital at or above the 80th percentile of hospitals, ranked by Medicare outpatient charges.

[a]Significant at the 5 percent level.

[b]Not available because the method calculates estimated coefficients for the included groups relative to the reference group.

To examine the separate effect of each factor, holding constant the effects of the remaining factors, we referred to the estimated coefficients for each factor in the model. From the estimated coefficient, we calculated the

percentage difference in price attributable to each factor.[6] For example, major teaching hospitals paid lower prices for drugs compared to nonteaching hospitals: major teaching hospitals paid 3.2 percent less than nonteaching hospitals, holding constant location, size, and the mix of SCODs purchased. In contrast, we found no statistically significant difference in prices paid by hospitals with other teaching programs and those paid by nonteaching hospitals, holding the other factors constant.

Although the R-squared statistic in table 3 indicates that the model accounts for over 99 percent of the variation in the logarithm of the SCOD price, this feature of the estimated model requires careful interpretation. Most of the variation in the logarithm of the drug SCOD price was due to the particular SCODs that were purchased—for some, hospitals paid on average about $300 per unit while for others, hospitals paid about $3 per unit. Consequently, after accounting for differences in the mix of SCODs purchased by different hospitals, only a small amount of variation in price remains to be explained by other factors. As a result, the R-squared for this model should not be interpreted as an indicator of the three factors' success in explaining SCOD price variation. Instead, the t-statistics associated with teaching status, location, and size are more useful, since they signal these factors' statistical significance—that is, whether the difference between the estimated effect of each factor and zero is statistically significant.

Table 4 presents the results for the second model, which estimates the effects of the three factors on the prices of radiopharmaceutical SCODs.

[6]Since each of the three "hospital characteristic" factors (teaching status, location, and size) is measured as one or more binary variables and the dependent variable, price, is measured as the natural logarithm, we used a standard method to calculate the percentage difference in price attributable to a particular measure of the factor, relative to its comparison group. Paul Kennedy, *A Guide to Econometrics*, 4th Ed. (Cambridge, Mass.: MIT Press, 1998), p. 108.

Table 4: Estimated Effects of Selected Factors on Prices Hospitals Paid for Radiopharmaceutical SCODs

Factor	Measure of factor	Estimated coefficient	t-value
Teaching status	Major teaching program	-.0021	-.12
	Other teaching program	-.0001	-.01
	Nonteaching (reference group)	n/a[a]	n/a[a]
Location	Rural	.0434	2.23[b]
	Urban (reference group)	n/a[a]	n/a[a]
Size	Large	-.0311	-2.55[b]
	Small (reference group)	n/a[a]	n/a[a]
Mix of SCODs purchased by a particular hospital	SCOD category (one binary variable for each of 9 radiopharmaceutical SCODs)	(not reported)	
	Intercept	4.74	522.06
	R-squared	.9913	
	Number of observations	185,237	

Source: GAO analysis.

Notes: SCOD refers to a specified covered outpatient drug. The results in this table pertain to the top nine radiopharmaceutical SCOD products, ranked by Medicare spending on SCODs during the first 9 months of 2004. This table presents estimates from a regression model. The model's dependent variable is the natural logarithm of the purchase price paid by a particular hospital for a radiopharmaceutical SCOD. SCOD prices are not distributed symmetrically around the average SCOD price but are skewed to the right, reflecting some SCODs with particularly high prices. Taking the natural logarithm of price takes this skewness into account. The effect of a measure, such as rural location, is estimated relative to a reference group (urban location). Therefore, the reference group is not explicitly included in the model. A major teaching program refers to a hospital that has an intern/resident-to-bed ratio of 0.25 or more. Urban refers to a hospital inside a metropolitan statistical area. Large refers to a hospital at or above the 80th percentile of hospitals, ranked by Medicare outpatient charges.

[a]Not available because the method calculates estimated coefficients for the included groups relative to the reference group.

[b]Significant at the 5 percent level.

As table 4 shows, two factors—location and size—are statistically significant in the model examining radiopharmaceutical SCOD prices. Other things equal, a rural hospital paid prices for radiopharmaceutical SCODs that were an estimated 4.4 percent higher than urban hospitals, while large hospitals paid prices an estimated 3.1 percent lower than small hospitals.

To examine the effect of the three factors combined, while controlling for differences in the costliness of SCODs that hospitals purchased, we used the estimates from two models—one for drug SCODs and one for radiopharmaceutical SCODs—to simulate the prices that certain groups of hospitals paid. In particular, we focused on comparing the prices paid by hospitals with one combination of characteristics—major teaching, urban, and large—with the prices paid by hospitals with a different combination of characteristics—nonteaching, rural, and small.

Appendix II: Purchase Prices for Drug SCODs

Table 5 appears as table 1 in our report *Medicare: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting*, GAO-05-581R (Washington, D.C.: June 30, 2005). The label of the second column—HCPCS code—refers to the Healthcare Common Procedure Coding System, which CMS uses to define SCODs.

Table 5: Purchase Prices for SCODs Accounting for 86 Percent of Medicare Spending on SCODs

Rank in Medicare spending on drug SCODs	HCPCS code	Description	Medicare spending on SCOD, 2004[a] ($ in millions)	% of Medicare spending on SCODs, 2004[b]	Number of hospitals in sample
1	Q0136	Injection, Epoetin Alpha (for non-ESRD use), per 1,000 units	199.8	10.1	973
2	J9310	Rituximab, 100 mg	158.4	8.0	871
3	J2505	Injection, Pegfilgrastim, 6 mg	144.8	7.3	759
4[j]	Q9941	Injection, Immune Globulin, Intravenous, Lyophilized, 1 g	[k]	[k]	626
4[j]	Q9943	Injection, Immune Globulin, Intravenous, Non-Lyophilized, 1 g	[k]	[k]	281
5	J1745	Injection, Infliximab, 10 mg	114.8	5.8	897
6	Q0137	Injection, Darbepoetin alfa, 1 mcg (non-ESRD use)	100.6	5.1	743
7	J9170	Docetaxel, 20 mg	73.7	3.7	829
8	J9045	Carboplatin, 50 mg	70.7	3.6	893
9	C9205	Injection, Oxaliplatin, per 5 mg	67.0	3.4	708
10	J3487	Injection, Zoledronic Acid, 1 mg	66.9	3.4	862
11	J9201	Gemcitabine Hcl, 200 mg	55.0	2.8	855
12	J9206	Irinotecan, 20 mg	39.4	2.0	786
13	J2324	Injection, Nesiritide, 0.25 mg	37.6	1.9	892
14	J9265	Paclitaxel, 30 mg	32.0	1.6	792
15	J9355	Trastuzumab, 10 mg	31.4	1.6	679
16	J9217	Leuprolide Acetate (for depot suspension), 7.5 mg	30.8	1.6	804
17	J0256	Injection, Alpha 1 - Proteinase Inhibitor - Human, 10 mg	20.9	1.1	38
18	J9035[m]	Injection, Bevacizumab, 10 mg	19.8	1.0	436
19	J1441	Injection, Filgrastim (G-CSF), 480 mcg	17.1	0.9	928
20	J1950	Injection, Leuprolide Acetate (for depot suspension), per 3.75 mg	16.9	0.9	541
21	J9001	Doxorubicin Hydrochloride, all lipid formulations, 10 mg	16.3	0.8	614
22	J2353	Injection, Octreotide, depot form for intramuscular injection, 1 mg	15.7	0.8	545
23	J9055[m]	Injection, Cetuximab, 10 mg	15.1	0.8	286
24	J9041[m]	Injection, Bortezomib, 0.1 mg	14.1	0.7	452
25	J9350	Topotecan, 4 mg	13.9	0.7	585
26	J1440	Injection, Filgrastim (G-CSF), 300 mcg	13.0	0.7	956

Total number of hospitals[c]	CMS payment rate for 2005[d] ($)	ASP (average sales price)[e] ($)	Average purchase price[f] ($)	95% confidence interval of the average purchase price[g] ($)	Median purchase price[h] ($)	95% confidence interval of the median purchase price[g] ($)
2,758	11.09	9.25	9.74	9.55–9.94	10.12	10.11–10.13
1,418	437.83	414.92	412.31	407.43–417.20	412.30	412.13–412.52
1,177	2,448.50	2,017.55	[i]	[i]	[i]	[i]
[i]	80.68	36.54	36.50	36.37–36.63	37.24	37.15–37.24
[i]	80.68	53.04	50.63	50.11–51.15	50.96	50.96–52.06
1,903	57.40	50.20	[i]	[i]	[i]	[i]
1,117	3.66	3.04	3.00	2.95–3.05	3.09	3.06–3.11
1,257	312.69	278.95	295.03	294.10–295.96	294.61	294.46–294.89
1,482	129.96	71.46	132.10	131.65–132.55	132.69	132.55–132.83
1,172	82.53	77.86	75.91	74.90–76.91	77.69	77.65–77.76
1,316	197.87	187.47	185.27	183.71–186.83	190.67	190.26–191.01
1,317	105.73	108.79	105.69	105.13–106.24	106.54	106.44–106.65
1,109	127.33	119.56	116.31	113.87–118.75	122.67	122.16–123.13
1,619	66.23	69.64	[i]	[i]	[i]	[i]
1,398	79.04	17.70	14.45	14.44–14.46	14.45	14.45–21.34
1,089	50.79	49.99	46.72	45.92–47.53	47.97	47.93–48.04
1,319	543.72	213.83	234.05	223.21–244.90	198.88	195.83–215.41
279	3.72	3.06	2.35	2.33–2.37	2.46	2.27–2.46
916	57.11	53.88	53.31	53.01–53.61	53.72	53.69–53.75
1,679	274.40	261.46	257.21	253.46–260.96	253.64	253.45–253.78
904	451.98	409.18	454.10	453.04–455.17	454.66	454.03–455.72
955	343.78	338.66	336.33	332.22–340.44	338.70	338.28–338.97
852	69.44	80.95	71.13	69.63–72.62	74.04	73.54–74.87
506	49.66	46.85	[i]	[i]	[i]	[i]
631	28.38	26.77	[i]	[i]	[i]	[i]
858	697.76	699.75	674.91	656.60–693.21	709.19	706.34–710.50
1,914	162.41	165.23	161.61	156.81–166.42	159.18	159.04–159.31

Rank in Medicare spending on drug SCODs	HCPCS code	Description	Medicare spending on SCOD, 2004[a] ($ in millions)	% of Medicare spending on SCODs, 2004[b]	Number of hospitals in sample
27	J1785	Injection, Imiglucerase, per unit	12.9	0.7	41
28	J3396	Injection, Verteporfin, 0.1 mg	12.3	0.6	10
29	J9202	Goserelin Acetate Implant, per 3.6 mg	11.4	0.6	392
30	J1626	Injection, Granisetron Hydrochloride, 100 mcg	11.1	0.6	682
31	J0585	Botulinim Toxin Type A, per unit	10.8	0.5	480
32	J0207	Injection, Amifostine, 500 mg	10.5	0.5	477
33	J2430	Injection, Pamidronate Disodium, per 30 mg	10.2	0.5	945
34	J9390	Vinorelbine Tartrate, per 10 mg	9.3	0.5	568
35	J2993	Injection, Reteplase, 18.1 mg	8.9	0.4	505
36	J9293	Injection, Mitoxantrone Hydrochloride, per 5 mg	8.4	0.4	672
37	J9185	Fludarabine Phosphate, 50 mg	7.6	0.4	669
38	C1305	Apligraf®, per 44 square centimeters	7.0	0.4	63
39	J9395	Injection, Fulvestrant, 25 mg	6.9	0.3	468
40	J3100	Injection, Tenecteplase, 50 mg	6.8	0.3	509
41	J9305[m]	Injection, Pemetrexed, 10 mg	5.6	0.3	162
42	J9160	Denileukin Diftitox, 300 mcg	5.6	0.3	73
43	J0180[m]	Injection, Agalsidase Beta, 1 mg	5.3	0.3	29
44	Q0166	Granisetron Hydrochloride, 1 mg, oral[n]	4.8	0.2	541
45	J2469[m]	Injection, Palonosetron Hcl, 25 mcg	4.6	0.2	295
46	J9010	Alemtuzumab, 10 mg	4.4	0.2	236
47[o]	Q9942	Injection, Immune Globulin, Intravenous, Lyophilized, 10 mg	[p]	[p]	626
47[o]	Q9944	Injection, Immune Globulin, Intravenous, Non-Lyophilized, 10 mg	[p]	[p]	281
48	J7190	Factor VIII (Antihemophilic Factor, Human) per I.U.	4.2	0.2	55
49	J0130	Injection, Abciximab, 10 mg	4.0	0.2	570
50	J0850	Injection, Cytomegalovirus Immune Globulin Intravenous (Human), per vial	3.8	0.2	156
51	J1327	Injection, Eptifibatide, 5 mg	3.7	0.2	911
52	J9214	Interferon, Alfa-2B, Recombinant, 1 million units	3.6	0.2	619
53	C9201	Dermagraft®, per 37.5 square centimeters	3.4	0.2	2

Total number of hospitals[c]	CMS payment rate for 2005[d] ($)	ASP (average sales price)[e] ($)	Average purchase price[f] ($)	95% confidence interval of the average purchase price[g] ($)	Median purchase price[h] ($)	95% confidence interval of the median purchase price[g] ($)
59	3.91	3.69	3.62	3.60–3.64	3.62	3.61–3.66
45	8.49	8.48	[i]	[i]	[i]	[i]
529	390.09	181.78	201.76	193.30–210.23	206.56	175.73–323.33
988	16.20	6.71	6.45	6.27–6.62	6.61	6.60–6.64
1,062	4.32	4.44	[i]	[i]	[i]	[i]
705	395.75	403.84	[i]	[i]	[i]	[i]
1,567	128.74	54.10	58.49	51.51–65.47	72.59	71.50–72.72
833	52.78	58.20	48.15	48.13–48.16	48.14	48.13–52.05
1,073	1,192.09	832.49	846.53	844.18–848.87	845.36	844.48–846.87
1,181	313.96	305.36	297.00	296.19–297.82	295.62	295.46–295.78
891	311.09	243.05	293.99	291.43–296.56	298.44	298.37–298.68
450	1,130.88	1,114.74	[i]	[i]	[i]	[i]
778	79.65	76.78	74.63	74.45–74.80	75.03	74.95–75.18
1,181	2,350.98	1,901.29	[i]	[i]	[i]	[i]
251	40.54	38.25	[i]	[i]	[i]	[i]
95	1,438.80	1,144.18	[i]	[i]	[i]	[i]
49	121.11	114.26	111.33	111.08–111.58	109.71	108.18–111.09
886	39.04	31.04	24.86	24.82–24.89	23.99	21.58–24.94
525	18.09	17.06	[i]	[i]	[i]	[i]
356	541.46	478.73	[i]	[i]	[i]	[i]
[q]	0.75	0.37	0.37	0.36–0.37	0.37	0.37–0.37
[q]	0.75	0.53	0.51	0.50–0.51	0.51	0.51–0.52
122	0.76	0.60	0.46	0.46–0.46	0.46	[r]
797	448.22	417.35	[i]	[i]	[i]	[i]
260	622.13	632.67	[i]	[i]	[i]	[i]
1,661	11.21	11.79	12.49	12.35–12.63	11.03	10.75–12.39
954	13.00	12.25	11.20	11.02–11.37	11.93	11.78–11.98
80	529.54	545.10	[i]	[i]	[i]	[i]

Sources: GAO survey and CMS.

Notes: ESRD = end-stage renal disease, g = gram, I.U. = international unit, mcg = microgram, and mg = milligram.

[a]Medicare spending is for the period January 1, 2004, through September 30, 2004.

[b]The percentage of Medicare spending is based on Medicare spending for all SCODs—both drugs and radiopharmaceuticals.

[c]This estimate of the total number of hospitals in the population is based on our sample.

[d]This is the payment rate specified for each HCPCS for 2005. It incorporates CMS's April 2005 update.

[e]CMS publishes the ASP plus 6 percent for certain drugs used in physicians' offices. These amounts are based on data provided by manufacturers each quarter. We are reporting ASPs for the quarter beginning in April 2005. ASPs reported here do not include the 6 percent added by CMS.

[f]This price is based on data provided by the hospitals in our survey and does not reflect any other costs associated with purchasing or administering the product. We asked hospitals to report prices for drugs purchased from July 1, 2003, through June 30, 2004. We weighted the prices by the volume purchased as well as by the sample weights. We have excluded prices under the 340B program, a federal program that provides drug price discounts for certain health care entities, including those that provide health care services for low-income individuals and individuals in medically underserved areas. (42 U.S.C. § 256b (2000)).

[g]The confidence interval measures the precision of the estimate. The narrower the interval, the greater the precision.

[h]The median purchase price is the midpoint of all prices reported by hospitals in our sample. Half of the prices reported by hospitals are above the median and half are below. The median is weighted by volume purchased and by hospital sample weights. The average purchase price excludes prices paid under the 340B program.

[i]For HCPCS codes that contain only one National Drug Code (NDC), we do not include information on the average or median purchase price because of the potential proprietary sensitivity of such information.

[j]On April 1, 2005, CMS replaced J1563, Injection, Immune Globulin, Intravenous, 1g, with two new codes: Q9941 and Q9943. J1563 was ranked fourth in total Medicare spending on SCODs from January 1, 2004, to September 30, 2004.

[k]J1563, Injection, Immune Globulin, Intravenous, 1g, accounted for $127.1 million in Medicare spending from January 1, 2004, through September 30, 2004, which was 6.4 percent of total Medicare spending on SCODs for that time period.

[l]On April 1, 2005, CMS replaced J1563, Injection, Immune Globulin, Intravenous, 1g, with two new codes: Q9941 and Q9943. Because J1563 was replaced by two codes, we could not estimate the total number of hospitals in the population for these new codes individually.

[m]On January 1, 2005, CMS replaced C9214, C9215, C9207, C9213, C9208, and C9210 with J9035, J9055, J9041, J9305, J0180, and J2469, respectively. The ranks for the new codes correspond to the ranks in total Medicare spending on SCODs from January 1, 2004, to September 30, 2004, for the former codes.

[n]The complete description for HCPCS Q0166 is "Granisetron Hydrochloride, 1 mg, Oral, Food and Drug Administration (FDA) Approved Prescription Anti-Emetic, for Use as a Complete Therapeutic Substitute for an IV (intravenous) Anti-Emetic at the Time of Chemotherapy Treatment, Not to Exceed a 24 Hour Dosage Regimen."

[o]On April 1, 2005, CMS replaced J1564, Injection, Immune Globulin, Intravenous, 10 mg, with two new codes: Q9942 and Q9944. J1564 was ranked 47th in total Medicare spending on SCODs from January 1, 2004, to September 30, 2004.

[p]J1564, Injection, Immune Globulin, Intravenous, 10 mg accounted for $4.4 million in Medicare spending from January 1, 2004, through September 30, 2004, which was 0.2 percent of total Medicare spending on SCODs for that time period.

[q]On April 1, 2005, CMS replaced J1564, Injection, Immune Globulin, Intravenous, 10 mg, with two new codes: Q9942 and Q9944. Because J1564 was replaced by two codes, we could not estimate the total number of hospitals in the population for these new codes individually.

[r]For this SCOD, our sample data cannot be extrapolated to compute a confidence interval for the median.

Appendix III: Purchase Prices for Radiopharmaceuticals SCODs

Table 6 appears as table 1 in our report Medicare: Radiopharmaceutical Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting, GAO-05-733R (Washington, D.C.: July 14, 2005). The label of the second column—HCPCS code—refers to the Healthcare Common Procedure Coding System, which CMS uses to define SCODs.

Table 6: Purchase Prices for Radiopharmaceutical Accounting for 9 Percent of Medicare Spending on SCODs

Rank in Medicare spending on radio-pharmaceutical SCODs	HCPCS code	Description	Medicare spending on SCOD, 2004[a] ($ in millions)	% of Medicare spending on SCODs, 2004[a]	Number of hospitals in sample
1	A9500	Technetium Tc 99m Sestamibi, per dose	66.5	3.4	405
2	A9502	Technetium Tc 99m Tetrofosmin, per dose	38.8	2.0	174
3	C1775	Fluorodeoxyglucose (FDG) F18, per dose (4-40 mCi/ml)	32.1	1.6	71
4	C1083	Yttrium 90 Ibritumomab Tiuxetan, per dose	7.1	0.4	80
5	A9505	Thallous Chloride TL 201, per mCi	6.7	0.3	292
6	Q3005	Technetium Tc 99m Mertiatide, per mCi[g]	6.2	0.3	292
7	A9507	Indium In 111 Capromab Pendetide, per dose	4.8	0.2	56
8	Q3008	Indium In 111 Pentetreotide, per 3 mCi[h]	4.5	0.2	193
9	A9521	Technetium Tc 99m Exametazime, per dose	3.8	0.2	180

Total number of hospitals[b]	CMS payment rate for 2005[c] ($)	Average purchase price[d] ($)	95% confidence interval of the average purchase price[e] ($)	Median purchase price[f] ($)	95% confidence interval of the median purchase price[e] ($)
2,477	106.32	75.15	73.24 - 77.06	76.47	75.58 - 77.85
964	104.58	70.70	67.92 - 73.48	67.59	66.23 - 70.98
687	221.11	287.90	263.24 - 312.55	272.80	261.83 - 308.52
130	20,948.25	19,614.96	19,498.98 - 19,730.95	19,516.70	19,459.55 - 19,565.02
1,199	18.29	17.18	16.32 - 18.05	15.49	15.06 - 17.06
1,655	31.13	27.40	26.47 - 28.34	27.58	27.56 - 27.60
262	1,915.23	1,801.12	1,760.80 - 1,841.43	1,841.23	1,703.46 - 1,860.22
666	1,079.00	1,279.55	1,198.35 - 1,360.76	1,423.87	1,395.49 - 1,437.61
773	778.13	455.59	358.29 - 552.89	456.30	379.90 - 523.95

Sources: GAO survey and CMS.

Notes: mCi = millicurie, ml = milliliter

[a]Medicare spending is for the period January 1, 2004, through September 30, 2004. The percentage of Medicare spending is based on all SCODs—both drugs and radiopharmaceuticals.

[b]This estimate of the total number of hospitals in the population is based on our sample.

[c]This is the payment rate specified for each HCPCS for 2005. It incorporates CMS's April 2005 update.

[d]This price is based on data provided by the hospitals in our survey and does not reflect delivery fees or any other ancillary costs associated with purchasing or administering this product. We asked hospitals to report prices for drugs purchased from July 1, 2003, through June 30, 2004. We weighted the prices by the volume purchased as well as by the sample weights.

[e]The confidence interval measures the precision of the estimate. The narrower the interval, the greater the precision.

[f]The median purchase price is the midpoint of all prices reported by hospitals in our sample. This price does not reflect delivery fees or any other ancillary costs associated with purchasing or administering this product. Half of the prices reported by hospitals are above the median and half are below. The median is weighted by volume purchased and by hospital sample weights.

[g]The billing unit of measure for Q3005, Technetium Tc 99m Mertiatide, is per mCi. The per mCi purchase price reported is based on purchase prices for two commonly reported dose sizes, 5 mCi and 10 mCi. Since in our data the 5 mCi dose is more common than the 10 mCi dose and the purchase price of a 5 mCi dose and of a 10 mCi dose were similar, we treated a 10 mCi dose as if it were a 5 mCi dose.

[h]The billing unit of measure for Q3008, Indium In 111 Pentetreotide, is per 3 mCi. The per mCi purchase price reported is based on purchase prices for two commonly reported dose sizes, 3 mCi and 6 mCi. Since a 3 mCi dose is the billing unit specified by CMS for Q3008 and since in our data the purchase price of a 3 mCi dose and of a 6 mCi dose varied relatively little, we treated a 6 mCi dose as if it were a 3 mCi dose.

Appendix IV: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

APR 12 2006

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) draft report entitled "MEDICARE HOSPITAL PHARMACEUTICALS: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS" (GAO-06-372). 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,

Daniel R. Levinson

Daniel R. Levinson
Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report 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.

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED "MEDICARE HOSPITAL PHARMACEUTICALS: SURVEY SHOWS PRICE VARIATION AND HIGHLIGHTS DATA COLLECTION LESSONS AND OUTPATIENT RATE-SETTING CHALLENGES FOR CMS" (GAO-06-372)

The Department of Health and Human Services (HHS) appreciates the opportunity to comment on the draft report.

General Comments

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 costs, beginning in 2006. The MMA also included a provision requiring GAO to conduct a survey in years 2004 and 2005 on hospital acquisition costs of drugs in the outpatient department and share the results with CMS for purposes of informing hospital drug acquisition costs. CMS is committed to ensuring appropriate payment for drugs, and continued beneficiary access to drugs being provided in a hospital outpatient department.

The GAO survey data were provided to CMS in time for consideration in the calendar year (CY) 2006 outpatient prospective payment system (OPPS) proposed rule, and we considered this information when developing our proposed and final CY 2006 OPPS payment policy. In our CY 2006 OPPS final rule with comment period, we explain our methodology for arriving at a payment rate of average sales price (ASP) +6 for CY 2006, and we discuss the various data we used to inform our final policy, including the GAO survey data.

This report includes information specific to the MMA mandate to GAO to conduct surveys in each of 2004 and 2005 to determine hospital acquisition costs for each specific covered outpatient drug (SCOD), provide recommendations on the frequency and methodology for subsequent surveys, and to report on the variation in hospital acquisition costs for drugs among hospitals based on the volume of covered outpatient department services performed. Additional GAO reports mandated by the MMA that are specific to the OPPS include reports on CY 2006 OPPS proposed payment rates for drugs and biologicals and a report on appropriate payment amounts for brachytherapy sources.

This GAO report supports the concerns noted in the CY 2006 OPPS proposed rule regarding the difficulty, both for CMS and for participating hospitals, in recreating the GAO survey in future years in order to update SCOD payment rates. In addition, the GAO report reinforces previous findings that there is no simple methodology for determining radiopharmaceutical acquisition costs.

We appreciate the effort that went into this report and the considerable analysis included in these recommendations. We look forward to working with GAO on this and other pertinent issues addressed in this report.

Recommendations

To ensure that Medicare payments for specified covered outpatient drug (SCOD) products are based on sufficiently accurate data, GAO recommends that the Secretary of Health and Human Services take the following two actions:

GAO Recommendation 1

Validate, on an occasional basis, manufacturers' reported drug average sales prices (ASPs) as a measure of hospitals' acquisition costs using a survey of hospitals or other method that CMS determines to be similarly accurate and efficient.

HHS Response

As in all aspects of our payment system, we are committed to providing appropriate payments to hospitals for the resources expended during the care of a Medicare beneficiary. While we strive to make payments as accurate as possible, we are also interested in eliminating unnecessary administrative burdens hospitals encounter. CMS agrees with GAO's finding that an annual survey could place an onerous burden on hospital staff in order to produce such information, and additional burdens on Agency staff in preparing submitted information for analysis. We will continue to consider the best approach for setting payment rates for drugs and biologicals in light of GAO's recommendation, and we will consider performing such an occasional hospital survey in order to validate our payment methodologies. We will also continue to analyze the adequacy of ASP-based pricing in the light of our claims data, which indicated for CY 2006 that ASP +6 was the best available proxy for hospitals' average acquisition costs, plus the handling costs of drugs.

GAO Recommendation 2

Use unit-dose prices paid by hospitals as the data source for setting and updating Medicare payment rates for radiopharmaceutical SCODs.

HHS Response

CMS appreciates GAO's comments on this difficult payment issue. We agree with GAO that various purchasing options provided to hospitals make uniform pricing difficult, and that any methodology for setting radiopharmaceutical payment rates should be low cost and reasonably accurate. For CY 2006, we therefore adopted the methodology of paying for radiopharmaceuticals on the basis of charges adjusted to cost as the best available proxy for capturing both the acquisition costs and the handling costs of radiopharmaceuticals. We appreciate GAO's recommendation to collect price data on radiopharmaceuticals purchased in ready-to-use doses, and to use unit-dose prices as the basis for payment rates. We will consider this methodology in developing our policy for radiopharmaceutical payments.

2

However, we wish to raise several questions, and to express some reservations about this recommendation. First, GAO did not specify whether the survey would be conducted with hospitals or manufacturers. Several statements in the report seem to imply that the survey would be conducted with hospitals, but it might be advisable to clarify this point in the report.

Second, the report emphasizes the expense, administrative burden, and other difficulties of conducting surveys of drug purchase prices in general. The report concludes that the burden of annual surveys of hospital drug purchase prices could outweigh the potential gains in data accuracy. We suspect that surveys of the unit dose prices paid by hospitals for radiopharmaceuticals might pose similar levels of expense and administrative burden. GAO's assessment of the expense and burdens of such a survey in relation to the potential gains in data accuracy would be useful in fully evaluating the recommendation.

Third, GAO conducted its study on only 9 of the approximately 55 radiopharmaceutical agents for which we pay separately under the outpatient prospective payment system. In order for a survey of unit dose prices to be effective, we would need to be able to obtain unit price data for all, or very nearly all, of the radiopharmaceuticals for which we pay separately. However, we believe that certain radiopharmaceuticals would rarely be available for purchase in ready-to-use doses, but would, rather, tend to be manufactured by hospitals in-house. We would, therefore, not be able to obtain useable data on the prices of these radiopharmaceuticals by collecting data on the prices paid by hospitals for ready-to-use doses. GAO's assessment of this limitation on the usefulness of a survey of prices for ready-to-use radiopharmaceutical doses would be valuable in fully evaluating this recommendation.

3

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

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

Acknowledgments

Phyllis Thorburn, Assistant Director; Hannah Fein; Dae Park; Jonathan Ratner; and Thomas Walke made key contributions to this report.

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