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United States Government Accountability Office
Washington, DC 20548

July 14, 2005

The Honorable Michael O. Leavitt
The Secretary of Health and Human Services

Subject: *Medicare: Radiopharmaceutical Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting*

Dear Mr. Secretary:

In our recent report on hospital outpatient drug purchase prices, *Medicare: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting*, we stated that we would issue a subsequent report with radiopharmaceutical purchase price information.¹ This report contains that information.

Medicare pays hospitals for drugs and other pharmaceutical products that beneficiaries receive as part of their treatment in hospital outpatient departments. Specifically, the Centers for Medicare & Medicaid Services (CMS) in the Department of Health and Human Services (HHS) uses an outpatient prospective payment system (OPPS) to pay hospitals fixed, predetermined rates for services. These services include pharmaceutical products—drugs, biologicals,² and radiopharmaceuticals³—given to beneficiaries in outpatient settings. When OPPS was first developed as directed by the Balanced Budget Act of 1997,⁴ the rates for hospital outpatient services and drugs and radiopharmaceuticals were based on hospitals' 1996 median costs. However, these rates prompted concerns that payments to hospitals would not reflect the cost 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.

¹GAO, [GAO-05-581R](#) (Washington, D.C.: June 30, 2005).

²In this report, the term drugs refers to both drugs and biologicals. Biologicals are products derived from living sources, including humans, animals, and microorganisms.

³Radiopharmaceuticals are radioactive substances used for diagnostic or therapeutic purposes.

⁴Pub. L. No. 105-33, § 4523, 111 Stat. 251, 445—450.

In response to these concerns, the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 authorized pass-through payments, which are a way to augment, on a temporary basis, the OPSS payments for newly introduced pharmaceutical products first used after 1996.⁵ The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) modified this payment method for some of these pharmaceutical products.⁶ As part of the modification, the MMA defined a new payment category—specified covered outpatient drugs (SCOD)—which includes many of these newly introduced pharmaceutical products. The MMA defined a SCOD as a drug or radiopharmaceutical used in hospital outpatient departments, covered by Medicare, and for which CMS has established a separate ambulatory payment classification (APC) group.⁷ The MMA established a methodology for CMS to follow in setting payment rates for SCODs in 2004 and 2005. CMS defines SCODs by their Healthcare Common Procedure Coding System (HCPCS) codes, which CMS assigns to products, supplies, and services for billing purposes. The MMA also directed us to collect data on hospitals' acquisition costs of SCODs and to provide information based on these data to the Secretary of Health and Human Services for his consideration in setting 2006 Medicare payment rates.⁸ The MMA directed us to collect these data by surveying a large sample of hospitals.

In summary, we obtained from our survey data the average and median purchase prices for each of nine radiopharmaceutical SCOD categories. Purchase price refers to the price that hospitals pay upon receiving the product and is the key component of hospital acquisition costs. These nine categories represent 9 percent of all Medicare spending on SCODs in the first 9 months of 2004. The purchase price information takes account of discounts taken at the time hospitals received the product but excludes any rebates paid subsequent to the receipt of the product.

Background

Radiopharmaceuticals are primarily used for diagnostic purposes but are also used in treating some diseases. Radiopharmaceuticals have two components: a medicine or pharmaceutical agent, which is nonradioactive, and a radioisotope, which is

⁵Pub. L. No. 106-113, app. F, § 201(b), 113 Stat. 1501A-321, 1501A-337—1501A-339.

⁶Pub. L. No. 108-173, § 621(a), 117 Stat. 2066, 2307—2310.

⁷Under OPSS, CMS groups services into APCs on the basis of their clinical and cost similarities. All services that are grouped into the same APC have the same base payment rate. The MMA required CMS to establish a separate APC for a pharmaceutical product if the cost per administration is \$50 or more. MMA 117 Stat. 2310. Drugs that cost less than \$50 per administration are bundled with other services for payment purposes. CMS has interpreted the cost per administration as the median cost per day.

⁸MMA 117 Stat. 2308. In addition, the MMA required the Medicare Payment Advisory Commission, known as MedPAC, to report on hospitals' overhead costs and related expenses for SCODs for the Secretary's consideration in setting 2006 payment rates. MMA 117 Stat. 2309. Overhead costs are not part of acquisition costs. MedPAC's mandated report is Chapter 6, "Payment for pharmacy handling costs in hospital outpatient departments," in *Issues in a Modernized Medicare Program* (Washington, D.C.: MedPAC, June 2005).

radioactive. The first component targets specific places in the body (e.g., brain, liver), while the second component emits radiation to allow imaging of the interior of the body.

Hospitals can purchase radiopharmaceuticals in one or more ways. They can purchase a unit dose or a multidose vial of the product that has been prepared by a nuclear pharmacy independent of the hospital, or they can purchase the product's radioactive and nonradioactive components separately and prepare the radiopharmaceutical in-house. For example, to acquire Technetium Tc 99m Sestamibi, a radiopharmaceutical for myocardial imaging, a hospital can either order a ready-to-use unit dose of the product from an independent nuclear pharmacy or create a dose in-house after purchasing separately Technetium Tc 99m—the radioactive component—and a preparation kit that includes the nonradioactive agent. 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.⁹

Scope and Methodology

In our report on hospital drug prices, we presented results drawn from our survey data on purchase price information on 53 SCOD drug categories, for the period July 1, 2003, through June 30, 2004. These 53 SCOD categories represented 86 percent of Medicare spending for SCODs during the first 9 months of 2004.¹⁰ In this report, we present our survey results for nine radiopharmaceutical SCOD categories for the period July 1, 2003, through June 30, 2004. These nine represented 9 percent of Medicare spending for SCODs during the first 9 months of 2004.¹¹ The previous report and this report together provide purchase price information on SCODs that accounted for 95 percent of all Medicare spending on SCODs during the first 9 months of 2004. We report here the average and median purchase prices for the nine radiopharmaceutical SCOD categories. The purchase price information takes account of volume and other discounts, but it excludes rebates, which manufacturers may give after a hospital has paid for the radiopharmaceuticals, and payments made to hospitals by group purchasing organizations, which negotiate prices with manufacturers on behalf of their member hospitals.

Hospitals' purchase prices of the radiopharmaceutical products included here were obtained from the same survey that produced the hospital outpatient drug purchase prices. Specifically, we surveyed 1,400 acute care, Medicare-certified hospitals,¹²

⁹See Denise A. Merlino, "Nuclear Medicine Facility Survey: SNM 2003 Survey Reporting on 2002 Cost and Utilization," *Journal of Nuclear Medicine Technology*, vol. 32, no. 4 (2004), 215-219.

¹⁰See [GAO-05-581R](#).

¹¹In this report, the term SCOD includes both pharmaceutical products that currently meet the definition of SCODs and those that do not meet the definition now but may be considered SCODs in the future.

¹²Forty-eight of these hospitals were in our pilot survey, which began on August 5, 2004.

expecting that this would yield responses from about 1,000 hospitals.¹³ We conducted the survey from September 27, 2004, through February 22, 2005, and received usable information on radiopharmaceuticals from 808 hospitals, which gave us a response rate of 61 percent.¹⁴ We asked the hospitals to provide price data for SCODs purchased from July 1, 2003, through June 30, 2004. Using our survey data, we calculated average and median purchase prices of a product's unit dose. To ensure the soundness of our approach to data collection and analysis, we obtained comments from an advisory panel of experts in pharmaceutical economics, pharmacy, medicine, survey sampling, and Medicare payment. To assess the reliability of our data, we checked for anomalies and outliers, asked hospitals for clarification as needed, and discussed technical issues with a nuclear pharmacist. On this basis, we determined that the data were sufficiently reliable for our purposes. (For details on our methods, see enc. I.)

Our results have certain limitations. First, despite a large overall sample size, our estimates of average and median purchase prices are more precise for radiopharmaceuticals that were purchased by a larger number of hospitals than for radiopharmaceuticals that were purchased by relatively few hospitals. Second, we limited our detailed results to hospitals' purchase prices because we could not fully account for rebates or payments from group purchasing organizations. Third, the average and median purchase prices we report refer to a specific time period and might have increased or decreased since then. In addition, our estimated purchase prices are based on hospitals' unit dose purchases only; we do not report prices for the generally less prevalent forms—multidoses or doses prepared in-house using a kit. We performed our work according to generally accepted government auditing standards from March 2004 through July 2005.

Hospitals' Acquisition Costs for Selected Radiopharmaceutical SCOD Categories

The following section presents detailed information on purchase prices—the key component of hospital acquisition costs—for certain radiopharmaceutical SCOD categories for the period July 1, 2003, through June 30, 2004.¹⁵ We also present limited information on rebates, another component of acquisition costs.

Table 1 contains information on average and median purchase prices. We order the SCOD categories by their rank in Medicare spending for radiopharmaceutical SCODs and have identified the SCOD categories by their HCPCS codes. For each SCOD

¹³We contracted for data collection and much of the data processing with a large survey firm with experience in conducting health care surveys.

¹⁴Of the 1,400 hospitals, 1,322 had submitted Medicare claims for radiopharmaceuticals for the first 6 months of 2003.

¹⁵Although SCODs by definition are used in hospital outpatient departments, the data we received from hospitals may represent radiopharmaceuticals that were used for both inpatients and outpatients and for Medicare and non-Medicare patients.

category, we present both the average and the median purchase prices, as well as other information that provides context, including the CMS payment rate. The CMS payment rate for 2005 is specified for each HCPCS for a billing unit, which, for the products in this report, is a dose or is measured in millicuries (mCi). In table 1, we report the purchase prices by CMS billing unit.

For two radiopharmaceutical products, our data suggest that it may be more meaningful to estimate their purchase prices per dose rather than per billing unit. CMS pays for these radiopharmaceuticals in billing units defined as a certain number of mCi. However, for each of these two radiopharmaceuticals, whether hospitals purchased larger doses (more mCi) or smaller doses (fewer mCi), the price was about the same. For Q3005—Technetium Tc 99m Mertiotide—the billing unit is one mCi, yet doses that differed in size (number of mCi) had purchase prices that were very similar. The two most common doses—5 mCi and 10 mCi—had average purchase prices of \$132.30 and \$130.51, respectively. Similarly, for Q3008—Indium In 111 Pentetreotide—while the billing unit is 3 mCi, this product’s purchase price per dose varied relatively little with the size of the dose purchased. For the two most common doses—3 mCi and 6 mCi—the average purchase prices were \$1,176.10 and \$1,373.89, respectively.

Table 1: Purchase Prices for Radiopharmaceuticals Accounting for 9 Percent of Medicare Spending on SCODs

Rank in Medicare spending on radiopharmaceutical SCODs	HCPCS code	Description	Medicare spending on SCOD, 2004 ^a (\$ in millions)	% of Medicare spending on SCODs, 2004 ^a	Number of hospitals in sample	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 ^g (\$)
1	A9500	Technetium Tc 99m Sestamibi, per dose	66.5	3.4	405	2,477	106.32	75.15	73.24 - 77.06	76.47	75.58 - 77.85
2	A9502	Technetium Tc 99m Tetrofosmin, per dose	38.8	2.0	174	964	104.58	70.70	67.92 - 73.48	67.59	66.23 - 70.98
3	C1775	Fluorodeoxyglucose (FDG) F18, per dose (4-40 mCi/ml)	32.1	1.6	71	687	221.11	287.90	263.24 - 312.55	272.80	261.83 - 308.52
4	C1083	Yttrium 90 Ibritumomab Tiuxetan, per dose	7.1	0.4	80	130	20,948.25	19,614.96	19,498.98 - 19,730.95	19,516.70	19,459.55 - 19,565.02
5	A9505	Thallous Chloride TL 201, per mCi	6.7	0.3	292	1,199	18.29	17.18	16.32 - 18.05	15.49	15.06 - 17.06
6	Q3005	Technetium Tc 99m Mertiatide, per mCi ^h	6.2	0.3	292	1,655	31.13	27.40	26.47 - 28.34	27.58	27.56 - 27.60
7	A9507	Indium In 111 Capromab Pendetide, per dose	4.8	0.2	56	262	1,915.23	1,801.12	1,760.80 - 1,841.43	1,841.23	1,703.46 - 1,860.22
8	Q3008	Indium In 111 Pentetreotide, per 3 mCi ⁱ	4.5	0.2	193	666	1,079.00	1,279.55	1,198.35 - 1,360.76	1,423.87	1,395.49 - 1,437.61
9	A9521	Technetium Tc 99m Exametazime, per dose	3.8	0.2	180	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

^aMedicare 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.

^bThis estimate of the total number of hospitals in the population is based on our sample.

^cThis is the payment rate specified for each HCPCS for 2005. It incorporates CMS's April 2005 update.

^dThis 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.

^eThe confidence interval measures the precision of the estimate. The narrower the interval, the greater the precision.

^fThe 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.

^gThe 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.

^hThe 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.

In contrast to the detailed purchase price information in table 1, our information on the rebate component of hospitals' acquisition costs is limited. About 3 percent of sample hospitals that purchased any of the nine radiopharmaceuticals reported receiving one or more rebates. Most of these rebates were directly attributed to specific radiopharmaceutical SCOD categories. The remaining rebates were for multiple products and could not be attributed to any single SCOD category. Most of the rebates came from one company.

Agency Comments and Our Evaluation

We received comments on a draft of this report from HHS (see enc. II). HHS stated that paying appropriately for radiopharmaceuticals and the overhead costs of handling them within the hospital is a priority. HHS commended our efforts and acknowledged the challenges of accurately surveying hospitals for radiopharmaceutical acquisition costs. It stated that we found at least one radiopharmaceutical SCOD for which rebates may affect its acquisition cost. HHS also stated that it had concerns regarding the limitations of our study. One concern pertained to variation in the dosages of radiopharmaceuticals purchased; the other concern pertained to potential changes in purchase prices since the time of our data collection. HHS stated that it would take into account our data on hospital purchase prices in developing 2006 Medicare payment rates for SCODs. HHS added that, in developing payment rates for 2006 and future years, it considered it important to have a methodology that can be updated appropriately and that reflects rebates and other components of radiopharmaceutical acquisition costs.

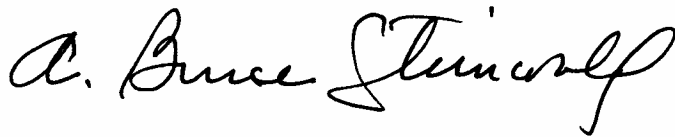
Despite the limitations that HHS noted, we believe our estimates of average purchase price for each radiopharmaceutical SCOD category that we report are sufficiently accurate for use in developing Medicare rates for SCOD categories. We have clarified our report regarding rebates: We did not find that one radiopharmaceutical SCOD accounted for most rebates, but rather that radiopharmaceutical rebates were relatively rare and that most rebates were attributable to specific radiopharmaceuticals. Although it is possible for radiopharmaceuticals in our survey to be purchased in different types of doses—unit doses, multidoses, and kits for doses prepared in-house—as a practical matter, most radiopharmaceuticals are purchased as unit doses, and we have added information on that to the report. In our survey, about 85 percent of hospitals reported purchasing the nine radiopharmaceuticals listed in table 1 only as unit doses, while about 13 percent reported purchasing unit doses as well as multidoses, kits for in-house preparation, or both.¹⁶ HHS also expressed concerns about whether our data are sufficiently current for use in Medicare rate-setting. If HHS uses our purchase price data in developing SCOD payment rates, it can mitigate the effect of time lags by adjusting radiopharmaceutical purchase prices in line with the expected increase or decrease in hospital drug prices for the coming year. HHS regularly uses a similar approach in other payment systems, including the hospital inpatient payment system.

¹⁶Less than 2 percent of hospitals reported purchasing only multidoses, kits, or both.

We are sending copies of this report to the Senate Committee on Finance, the House Committee on Energy and Commerce, and the House Committee on Ways and Means. We will also make copies available to others on request. The report is available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7119 or steinwalda@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in enclosure III.

Sincerely yours,

A handwritten signature in black ink that reads "A. Bruce Steinwald". The signature is written in a cursive style with a large, prominent initial "A".

A. Bruce Steinwald
Director, Health Care

Enclosures - 3

Methodology

This enclosure summarizes the sample design, methods for conducting the survey and processing data submissions, and the methods we used for estimating average and median purchase prices of specified covered outpatient drugs (SCOD). It also names the members of the advisory panel that commented on our approach to data collection and analysis. We did our work in accordance with generally accepted government auditing standards from March 2004 through July 2005.

Sample Design

We developed a stratified random sample of hospitals. The population consisted of 3,450 hospitals (1) that had charged Medicare for SCODs during the first half of 2003 and (2) that were still Medicare providers on July 1, 2004. To achieve a sample of 1,000 hospitals, which we determined would meet the Medicare Prescription Drug, Improvement, and Modernization Act of 2003's (MMA) requirement for a large sample, we drew a sample of 1,400 hospitals from the population, on the basis of an expected response rate for all SCODs of 71 percent. A pilot sample of 48 hospitals was included in the 1,400. (Of the 1,400 hospitals, 1,322 had submitted Medicare claims for radiopharmaceuticals for the first 6 months of 2003.)

To improve the precision of our estimates of average and median purchase price, we stratified the sample of hospitals. The objective was to select strata that would represent very different average purchase prices for SCODs. Because we did not have a measure of purchase price at the time we selected the sample, we used total hospital outpatient SCOD charges to Medicare as a proxy for purchase price. We used a regression model to identify stratification factors (such as teaching hospital status) that would maximize the difference in average purchase price (as proxied by Medicare charges) among strata. We selected the strata of hospitals as follows. First, we grouped them into major teaching hospital, nonmajor teaching hospital, urban nonteaching hospital, and rural nonteaching hospital strata. Second, within each of these strata, we further divided the hospitals into several strata depending on the number of unique SCODs that the hospitals billed for. For example, one stratum contains major teaching hospitals that billed for fewer than 20 unique SCODs. Third, we placed small hospitals in a separate stratum to ensure that hospitals with no or minimal charges for SCODs during the first 6 months of 2003 were appropriately represented.¹

In our sample design, we defined a major teaching hospital as a hospital for which the ratio of resident physicians to the average number of patients was at least 1 to 4 and a nonmajor teaching hospital as one having a ratio of resident physicians to patients of less than 1 to 4. We defined an urban hospital as one located in a county that was considered a metropolitan statistical area (as defined by the

¹Even if these hospitals did not have charges for SCODs in the first 6 months of 2003, they might have made purchases for SCODs after that time period. Therefore, it was important to include them in the sample.

Office of Management and Budget) and a rural hospital as one located in a county that was not considered a metropolitan statistical area. We defined a small hospital as a hospital for which the total charge amount to Medicare for SCODs during the first 6 months of 2003 was less than \$10,000. The number of unique SCODs refers to the number of SCODs for which each hospital submitted Medicare claims during the first 6 months of 2003. (See table 2.)

Table 2: Characteristics of Sample Strata

Stratum	Hospitals in the population ^a	Average total charges ^b (\$)	Standard deviation of total charges ^c (\$)	Neyman allocation for total sample of 1,400 ^d	Target sample of 1,000 ^e	Target response rate in % ^f
Major teaching hospitals						
< 20 unique SCODs	75	238,949	320,349	21	11	52
20-39 unique SCODs	111	861,415	1,805,586	111	96	86
40-59 unique SCODs	96	2,297,626	1,985,026	96	91	95
60+ unique SCODs	73	6,034,849	3,703,998	73	73	100
Nonmajor teaching hospitals						
< 20 unique SCODs	143	196,875	241,523	29	16	55
20-39 unique SCODs	313	714,043	630,105	151	94	62
40-59 unique SCODs	137	1,952,405	1,222,357	129	80	62
60+ unique SCODs	34	5,242,311	3,410,652	34	34	100
Urban nonteaching hospitals						
< 20 unique SCODs	609	161,797	210,080	99	61	62
20-39 unique SCODs	428	735,416	728,106	238	149	63
40+ unique SCODs	126	2,232,851	1,837,833	126	110	87
Rural nonteaching hospitals						
< 20 unique SCODs	730	136,618	141,370	80	49	61
20-39 unique SCODs	321	672,290	560,202	140	86	61
40+ unique SCODs	53	2,072,873	1,382,985	53	35	66
Small hospitals	201	3,679	3,116	20	15	75
Total	3,450			1,400	1,000	71

Source: GAO.

^aHospitals in the population refers to the number of hospitals that made any claims to Medicare for any SCOD from January 1, 2003, through June 30, 2003, and were still Medicare-certified hospitals on July 1, 2004.

^bTotal charges are the hospital outpatient charges to Medicare from January 1, 2003, through June 30, 2003. Average total charges refers to the average total charges per hospital.

^cThe standard deviation is a measure of variation around the average.

^dThe Neyman allocation is a method for determining the optimum sample size, that is, the sample size that results in the greatest precision.

^eWe expected an achieved sample of 1,000 (an overall response rate of 71 percent), and we applied the Neyman allocation to determine the optimum number of hospitals in each stratum. In some strata, the optimum allocation exceeded the number of hospitals in the population. In these instances, the excess hospitals were reallocated to the remaining strata according to the Neyman allocation.

^fThe target response rate is the ratio of the target sample to the total sample for each stratum.

To determine whether we had selected strata that represented substantially different average purchase prices for SCODs, we examined other possible stratification factors and compared the efficiency of our stratified sample with a simple random sample.² Other factors that we examined included hospital size (measured by both annual discharges and average number of patients), ownership status (for-profit, nonprofit), whether the hospital billed Medicare for radiopharmaceuticals, and whether the hospital billed Medicare for blood products. However, these other factors were highly correlated with the factors that we had selected and did not significantly improve the model. Stratification made the sample about 10 times more efficient than a simple random sample.

To determine the appropriate number of hospitals in each stratum, we used the Neyman allocation—a method for determining the optimum sample size, that is, the sample size that results in the greatest precision. After the sample was selected, we established the optimal allocation of 1,000 hospitals—our target response—among strata, using another Neyman allocation. We used the results of this second allocation to establish target response rates by stratum.

Data Collection and Data Processing

We developed a survey instrument and tested it before sending it to the entire sample of 1,400 hospitals. We gave hospitals several options for submitting data, which we extracted from their submissions and put in a standard format.

After consulting a number of experts, including pharmacists, hospital administrators, and representatives from industry groups, on methods of developing and administering the survey, we developed and pretested the survey instrument with 12 hospitals in June 2004. This initial instrument was limited to 22 products. As a result of responses to the pretest, we modified the data collection instrument, and Westat, our data collection contractor, piloted the revised instrument with 48 hospitals beginning on August 5, 2004. As a result of the pilot, we clarified certain instructions and made changes in our procedures but did not significantly change the instrument.

Westat began data collection from the 1,352 hospitals in the sample on September 27, 2004.³ Key components of the data collection protocol were as follows:

- a first mailing to the chief executive officer or chief financial officer of each hospital explaining the survey, followed by a telephone call to identify the main point of contact;
- a second mailing to the main contact outlining the data that were needed and describing the options for submitting the data;

²We measured efficiency by the size of the reduction in sample variation.

³We also used data from the 48 hospitals in the pilot survey, for a total sample of 1,400 hospitals.

- a follow-up telephone call to facilitate the main contact’s understanding of the data collection, provide technical assistance as needed, and obtain some basic information about the hospital; and
- telephone calls at regular intervals to remind the hospitals to submit their data and to provide assistance as needed.

Hospitals could submit data in one of three ways: by uploading electronic files through the study Web site, by sending an e-mail to the study address with data attached, or by sending electronic media or paper submissions through the mail. Electronic submissions took three forms: downloads from distributors’ and suppliers’ ordering systems, extracts from hospitals’ own databases, and entries made in a GAO-supplied Excel form. Paper submissions were most often copies of invoices.

The contractor performed extensive follow-up. On average, Westat interviewers called each hospital 8 times before receiving a complete data submission. Hospitals that were late in responding received 15 calls on average. For drugs, we obtained an overall response rate of 83 percent. For radiopharmaceuticals, we obtained an overall response rate of 61 percent (based on the 1,322 hospitals in our sample that had submitted Medicare claims for radiopharmaceuticals for the first 6 months of 2003).

Table 3: Response Rates for Radiopharmaceutical SCODs

Stratum	Response rate for radiopharmaceutical SCODs ^a (percent)
Major teaching hospitals	
< 20 unique SCODs	42
20-39 unique SCODs	64 ^b
40-59 unique SCODs	67 ^b
60+ unique SCODs	59 ^b
Nonmajor teaching hospitals	
< 20 unique SCODs	69
20-39 unique SCODs	66
40-59 unique SCODs	57
60+ unique SCODs	74 ^b
Urban nonteaching hospitals	
< 20 unique SCODs	60
20-39 unique SCODs	60
40+ unique SCODs	63 ^b
Rural nonteaching hospitals	
< 20 unique SCODs	43
20-39 unique SCODs	60
40+ unique SCODs	62
Small hospitals	100
Total	61

Source: GAO.

^aExcept where otherwise indicated, we counted as responses all hospitals that sent usable data on or before January 15, 2005.

^bWe continued to process data received through February 22, 2005, for certain strata.

We extracted data from hospitals' submissions and placed those data in a standard format for analysis. In many cases, hospitals submitted data on all drugs and radiopharmaceuticals purchased—not just SCODs—and consequently we needed to extract the SCOD drug and radiopharmaceutical data. Most data were submitted for periods of a day or a month, as we requested, but 19 hospitals in our sample submitted annual data on radiopharmaceuticals.

Westat technical staff checked the data for consistency and reviewed each record to confirm that key information had been included. We excluded records that lacked key information and trimmed the data to exclude outliers. On average, 1.8 percent of purchase records were excluded.

Estimates of SCOD Average and Median Purchase Prices

This section describes the rationale and method for weighting the hospital sample data, calculating average purchase price, calculating median purchase price, and calculating their confidence intervals.

Weighting the Hospital Sample Data

To estimate hospitals' average and median purchase prices for SCODs, the sample hospitals' purchase price data are weighted to make them representative of the population of hospitals from which the sample is drawn. A survey sample is drawn from a population. To enable data from the sample to represent data from the population on purchase prices and other variables, the sample data are weighted: the less likely that a hospital will be sampled, the larger its weight. For example, if each hospital has a 1 in 10 probability of being sampled, its sample weight is 10. That is, each hospital in the sample represents 10 hospitals in the population. Consequently, if 5 hospitals in a sample buy a particular drug, and the sample weight is 10, we estimate that 50 hospitals in the population bought that drug. In this report, we refer to sample weights as "hospital weights." Our sample is stratified, so all hospitals in a particular stratum (for example, major teaching hospitals) have the same weight. Since in our sample the probability of a hospital's being selected varied by stratum, hospitals in different strata have different weights.

In calculating weights, we took account of two distinctive facts about our survey: First, our sample is unusual in that we must treat it as a set of separate samples—one for each SCOD—since the population of hospitals that buy a drug or radiopharmaceutical in a particular HCPCS varies depending on the SCOD. Some SCODs are bought by many hospitals, while others are bought by relatively few hospitals. Second, we lacked a direct measure of the number of hospitals in the population that bought a particular SCOD; consequently, we used the number of hospitals that billed for that SCOD, according to Medicare outpatient claims data, as a proxy or indirect measure of the population's size.

We calculated the hospital weight as

$$W_{jh} = \frac{N_{jh}}{R_{jh}}$$

where

- W_{jh} denotes the hospital weight for the j^{th} SCOD in the h^{th} stratum,
- N_{jh} denotes the population (the total number of hospitals) that, according to Medicare outpatient claims, billed for the j^{th} SCOD in the h^{th} stratum, and
- R_{jh} denotes the total number of hospitals in the h^{th} stratum that purchased the j^{th} SCOD, according to their survey submissions.

This weight recognizes that not all hospitals responded to our survey, since the weight's denominator is R_{jh} —the number of hospitals that responded to the survey and indicated that they bought the j^{th} drug.⁴

We made one adjustment to the hospital weight to take account of unusual circumstances. In some cases, the total number of hospitals in a stratum that reported purchasing a particular SCOD exceeded our population estimates. This situation resulted from imperfections in the Medicare claims data used as a proxy for purchase price. That is, in these cases R_{jh} exceeds N_{jh} . Since that situation is implausible, we adjusted the size of the population derived from Medicare claims, as follows:

$$N'_{jh} = N_{jh} * \frac{R_{jh}}{M_{jh}}$$

where

- N'_{jh} denotes the adjusted population and
- M_{jh} represents the number of hospitals in the h^{th} stratum that purchased the j^{th} SCOD, according to their survey submissions, and that submitted an outpatient claim to Medicare for that drug.

This adjustment makes the size of the adjusted population larger than the unadjusted population—the number of hospitals that billed Medicare for the drug. Sampling statisticians call this adjustment “post-stratification.”

⁴Our formulation of the hospital weight is an adaptation of the usual formulation, in which N_{jh} is divided by n_{jh} , the number of hospitals in the h^{th} stratum that purchased the j^{th} SCOD. Unlike R_{jh} , n_{jh} includes hospitals that did not respond to the survey and consequently is not appropriate for our purpose.

Average Purchase Price Using Volume and Hospital Weights

To summarize hospitals' purchase prices for each SCOD—reflecting purchases made, in many cases, at different prices and in different quantities—we calculated an average purchase price for each SCOD. This average purchase price for a particular SCOD is in effect a weighted average. To reflect the differences among hospitals in purchase prices and purchase volumes, we used both the hospital weights and purchase volume as weighting variables in estimating the average purchase price.

The average purchase price is estimated from our sample data, based on the following equation:

$$Y_j = \left(\sum_h \frac{N_h}{n_h} \sum_i y_{jhi}^* \right) / \left(\sum_h \frac{N_h}{n_h} \sum_i x_{jhi}^* \right)$$

where

- N_h represents the total number of hospitals in the h^{th} stratum,
- n_h represents the size of the sample of hospitals in the h^{th} stratum,
- $y_{jhi}^* = \sum_k y_{jhik}$, which represents the total dollar amount summed over all invoice records (k denotes an invoice record) for the j^{th} SCOD purchased by the i^{th} hospital in the h^{th} stratum, and
- $x_{jhi}^* = \sum_k x_{jhik}$, which represents the total number of units summed over all invoice records (k denotes an invoice record) for the j^{th} SCOD purchased by the i^{th} hospital in the h^{th} stratum.

The equation estimates the average purchase price of a SCOD as the ratio of the total amount purchased in dollars to the total number of units purchased. For example, a total purchase amount of \$50,000 and a total number of units purchased of 1,000 milligrams yields an average purchase price of \$50 per milligram.

Median Purchase Price Using Volume and Hospital Weights

In addition to the average purchase price, we calculated the estimated median of each SCOD's purchase price. To calculate this median, we first applied volume and hospital weights to each hospital's purchases of a given SCOD; we then ranked the weighted hospitals' purchase prices from lowest to highest and selected the midpoint of these prices.

More precisely, the estimated median—based on the population cumulative density function F for hospital purchase prices—is given by

$$X_{0.5} = \inf \{ y_{jhik} : F(y_{jhik}) \geq 0.5 \},$$

where

- $X_{0.5}$ denotes the median estimate of hospital purchase price for a particular SCOD,
- y_{jhik} denotes the unit purchase price listed in the k^{th} invoice record submitted in our survey by the i^{th} hospital in the h^{th} stratum,
- F , the cumulative density function, is the probability that the variable Y takes on a value less than or equal to a particular value (in this case, y_{jhik}),
- $\inf \{ a : b \}$ refers to the minimum value of a , which satisfies the condition specified in b (in this case b is the condition that $F(y_{jhik}) \geq 0.5$), and
- the estimated population cumulative density function, F , is defined as

$$F(x) = \left\{ \sum_h \frac{N_h}{n_h} \sum_i \sum_k I(y_{jhik} \leq x) \right\} / \left\{ \sum_h \frac{N_h}{n_h} \sum_i \sum_k \right\}$$

In this equation for $F(x)$, the hospital weights, $\frac{N_h}{n_h}$, enter in both the numerator and the denominator. The term $I(y_{jhik} \leq x)$ equals 1 if $y_{jhik} \leq x$ and is zero otherwise; that is, if the purchase price of a SCOD by a hospital in the h^{th} stratum is less than or equal to x (any specific value), this term takes on the value of 1.

Confidence Intervals for Average Purchase Price and Median Purchase Price

To help assess the precision of our estimates of average and median purchase prices, we calculated confidence intervals for each measure. A confidence interval gives an estimated range of values, calculated from sample data (our survey), that is likely to include the true average of the population (in this case, the average purchase price for a particular SCOD). As is commonly done, we calculated 95 percent confidence intervals.⁵ The narrower the confidence interval around the average calculated from sample data, the more precise the estimated average is considered to be.

We obtained the 95 percent confidence intervals of our estimated average purchase prices by using methods detailed in Cochran⁶ and Hansen, Hurwitz, and

⁵If independent samples are taken repeatedly from the same population, and a confidence interval calculated for each sample, then a certain percentage of the intervals will include the unknown average for the population. The confidence interval is often calculated so that the percentage is 95 percent.

⁶W.G. Cochran, *Sampling Techniques*, 3rd ed., Wiley Series in Probability and Mathematical Statistics, section 11.7 (New York, N.Y.: John Wiley & Sons, 1977), 303.

Madow,⁷ since our estimates were calculated from our survey—that is, from a stratified sample.⁸ To calculate the confidence interval for our estimates of median prices, we used the equations presented in Binder⁹ and Francisco and Fuller.¹⁰ We estimated the average purchase prices, median purchase prices, and the confidence intervals of both these averages and medians using specialized software for survey data analysis—SUDAAN[®].¹¹

Advisory Panel

To provide us with advice on our methodology for collecting and analyzing acquisition cost data concerning SCODs, we convened a panel of experts with experience in pharmaceutical issues or in technical fields relevant to our survey. The panel met twice: first, to consult with us on sample design and the survey, and later to review our preliminary results. The panelists included the chairman, Joseph P. Newhouse, PhD—John D. MacArthur Professor of Health Policy and Management, Harvard University; Robert A. Berenson, MD—Senior Fellow, Urban Institute; Ernst R. Berndt, PhD—Professor of Applied Economics, Sloan School of Management, Massachusetts Institute of Technology; Andrea G. Hershey, PharmD—Clinical Coordinator, Pharmacy Residency Program Director, Union Memorial Hospital (Baltimore, Md.); and Richard L. Valliant, PhD—Senior Research Scientist, University of Michigan.

⁷M.H. Hansen, W.N. Hurwitz, and W.G. Madow, *Sample Survey Methods and Theory*, vol. I, *Methods and Applications*, Wiley Publications in Statistics, sections 6.6 and 6.7 (New York, N.Y.: John Wiley & Sons, Inc., 1953), 252-259.

⁸More precisely, this is a stratified cluster sample. “Cluster” refers to the set of invoice records (for a given SCOD) reported by a hospital. The size of a cluster varied widely among hospitals—from 1 invoice record for a given SCOD to over 800 records.

⁹D.A. Binder, “Use of Estimating Functions for Interval Estimation from Complex Surveys,” *Proceedings of the Survey Research Methods Section, American Statistical Association* (1991).

¹⁰C.A. Francisco and W.A. Fuller, “Quantile Estimation with a Complex Survey Design,” *Annals of Statistics*, 19 (1991), 454-469.

¹¹B.V. Shah, B.B. Barnwell, and G.S. Bieler, *SUDAAN: User’s Manual, Release 7.5*, vols. 1 and 2 (Research Triangle Park, N.C.: Research Triangle Institute, 1997). SUDAAN[®] is a registered trademark of the Research Triangle Institute.

Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JUL 8 2005

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

Dear Mr. Steinwald:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO's) draft correspondence entitled, "Medicare: Radiopharmaceutical Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting" (GAO-05-733R). The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this correspondence is received.

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

Sincerely,

A handwritten signature in cursive script that reads "Daniel R. Levinson".

Daniel R. Levinson
Inspector General

Enclosure

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

COMMENTS OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT CORRESPONDENCE ENTITLED, "MEDICARE: RADIOPHARMACEUTICAL PURCHASE PRICES FOR CMS CONSIDERATION IN HOSPITAL OUTPATIENT RATE-SETTING" (GAO-05-733R)

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

Paying appropriately for radiopharmaceuticals and related overhead resources under the outpatient prospective payment system is a priority for HHS, Centers for Medicare & Medicaid Services (CMS). CMS commends the efforts of GAO and recognizes the challenges of accurately surveying hospitals for radiopharmaceutical acquisition costs. The data provided by GAO focused on hospital radiopharmaceutical purchase prices, which are one component of hospital radiopharmaceutical acquisition costs. As the report points out, costs for at least one category of radiopharmaceutical products may be influenced by rebates. CMS is concerned about some of the limitations about the purchase price survey noted in the report, such as the variation between unit dosing, multi-dosing, and doses prepared in-house using a kit. Also, CMS foresees concerns about the potential for the purchase prices to have changed since the time period that GAO surveyed hospitals.

As with the GAO report on hospital outpatient drug purchase prices, CMS will take the survey data into account as we develop the proposed payment rates for 2006. CMS believes it is important, as we develop the payment rates for 2006 and future years, to have a methodology that can be updated in an appropriate manner and that reflects the rebates and other price concessions that influence radiopharmaceutical acquisition costs.

GAO Contact and Staff Acknowledgments

GAO Contact

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

Acknowledgments

In addition to the contact named above, Phyllis Thorburn, Assistant Director; Todd Anderson; Hannah Fein; Kaycee Misiewicz; Elizabeth T. Morrison; Dae Park; Jonathan Ratner; Anna Theisen-Olson; and Mike Thomas made key contributions to this report.

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