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United States Government Accountability Office
Washington, DC 20548

June 30, 2005

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

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

Dear Mr. Secretary:

Medicare pays hospitals for drugs 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 drugs given to beneficiaries in outpatient settings. When OPPS was first developed as directed by the Balanced Budget Act of 1997,[1] the rates for hospital outpatient services and drugs 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—drugs, biologicals,[2] and radiopharmaceuticals[3]—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 are a way to augment, on a temporary basis, the OPPS payments for newly introduced pharmaceutical products first used after 1996.[4] The Medicare Prescription Drug,

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

[2]In this report, we use the term "drugs" to refer to both drugs and biologicals. Biologicals are products derived from living sources, including humans, animals, and microorganisms.

[3]Radiopharmaceuticals are radioactive drugs used for diagnostic or therapeutic purposes; for this report, radiopharmaceuticals are not included in the term "drugs."

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

Improvement, and Modernization Act of 2003 (MMA) modified this payment method for some of these pharmaceutical products.[5] 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.[6] In addition to these criteria, the MMA required that, for a drug to be a SCOD, it must have been paid for on a pass-through basis on or before December 31, 2002. The MMA established a methodology for CMS to follow in setting payment rates for SCODs in 2004 and 2005. The MMA excluded, among other drugs, orphan drugs—certain drugs or biologicals that are used for rare diseases and conditions—from being paid as SCODs for 2004 and 2005 and was not explicit about whether orphan drugs will be SCODs after 2005.[7] CMS defines SCODs by their Healthcare Common Procedure Coding System (HCPCS) codes, which CMS assigns to products, supplies, and services for billing purposes. Drug HCPCS are categories that include one or more component drugs with similar chemical entities. These drugs within a HCPCS can vary by manufacturer, strength, and package size.

The MMA directed us to collect data on hospital 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 53 SCOD drug categories. We report purchase price information for those SCOD categories containing more than one drug. Purchase price refers to the price that hospitals pay upon receiving the product and is the key component of hospital acquisition costs. The 53 SCOD categories represent 86 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

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

[6]Under OPPS, 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.

[7]MMA 117 Stat. 2308.

[8]MMA 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).

product but excludes any rebates paid to hospitals subsequent to the receipt of the product.

Scope and Methodology

This report presents results drawn from our survey data on 53 SCOD categories for the period July 1, 2003, through June 30, 2004.[9] These 53 SCOD categories represented 86 percent of Medicare spending for SCODs during the first 9 months of 2004.[10] We report the average and median purchase prices for the SCOD categories containing more than one drug; we do not include purchase price information where there is only one drug in a category because of the potential proprietary sensitivity of such information.[11] 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 drugs, and payments made to hospitals by group purchasing organizations, which negotiate prices with manufacturers on behalf of their member hospitals. In a subsequent report, we will provide information on the radiopharmaceuticals that constituted an additional 9 percent of Medicare spending on SCODs during the first 9 months of 2004. These two reports 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.

To produce average and median purchase prices, we conducted a survey of 1,400 acute care, Medicare-certified hospitals,[12] 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 from 1,157 hospitals, which gave us a response rate of 83 percent. 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. 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 hospital pharmacist. On this basis, we determined that the

[9]After September 2004, when we began collecting data, CMS divided two of these categories into two SCOD categories each, in effect adding two categories and resulting in a total of 55 SCOD categories.

[10]For 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 that may be considered SCODs in the future. The pharmaceutical products in this report that do not meet the definition of SCODs include orphan drugs and drugs that are currently on pass-through status.

[11]We have provided HHS with the average and median purchase prices from our survey for all 53 SCOD categories—both those included in and those excluded from this report—and their component drugs.

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

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

data were sufficiently reliable for our purposes. (For details on our methods, see enc. I.)

Our results have certain limitations. First, despite a high survey response rate and a large sample size, our estimates of average and median purchase prices are more precise for drugs that were purchased by many hospitals than for drugs 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. We performed our work according to generally accepted government auditing standards from March 2004 through June 2005.

Hospitals' Acquisition Costs for Selected SCOD Categories

The following section presents detailed information on purchase prices—the key component of hospitals' acquisition costs—for certain SCOD categories[14] for the period July 1, 2003, through June 30, 2004. 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 drug SCODs and have identified the SCOD categories by their HCPCS codes.[15] These SCOD categories accounted for 86 percent of all Medicare spending on SCODs for the period January 1 through September 30, 2004. For each SCOD category with more than one drug, we present both the average and the median purchase prices, as well as other information that provides context, including the CMS payment rate and average sales price (ASP). The CMS payment rate is the payment rate specified for each HCPCS for 2005, and ASP is the average price for a drug based on a manufacturer's sales to all purchasers in the United States, with certain exceptions.

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

[15]For the specific drugs—identified by National Drug Code (NDC)—within each HCPCS, see enc. II.

Table 1: Purchase Prices for Drugs 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	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] ($)	95% confidence interval of the median purchase price[g] ($)
1	Q0136	Injection, Epoetin Alpha (for non-ESRD use), per 1,000 units	199.8	10.1	973	2,758	11.09	9.25	9.74	9.55–9.94	10.12	10.11–10.13
2	J9310	Rituximab, 100 mg	158.4	8.0	871	1,418	437.83	414.92	412.31	407.43–417.20	412.30	412.13–412.52
3	J2505	Injection, Pegfilgrastim, 6 mg	144.8	7.3	759	1,177	2,448.50	2,017.55	[i]	[i]	[i]	[i]
4[j]	Q9941	Injection, Immune Globulin, Intravenous, Lyophilized, 1 g	[k]	[k]	626	[l]	80.68	36.54	36.50	36.37–36.63	37.24	37.15–37.24
4[j]	Q9943	Injection, Immune Globulin, Intravenous, Non-Lyophilized, 1 g	[k]	[k]	281	[l]	80.68	53.04	50.63	50.11–51.15	50.96	50.96–52.06
5	J1745	Injection, Infliximab, 10 mg	114.8	5.8	897	1,903	57.40	50.20	[i]	[i]	[i]	[i]
6	Q0137	Injection, Darbepoetin alfa, 1 mcg (non-ESRD use)	100.6	5.1	743	1,117	3.66	3.04	3.00	2.95–3.05	3.09	3.06–3.11
7	J9170	Docetaxel, 20 mg	73.7	3.7	829	1,257	312.69	278.95	295.03	294.10–295.96	294.61	294.46–294.89
8	J9045	Carboplatin, 50 mg	70.7	3.6	893	1,482	129.96	71.46	132.10	131.65–132.55	132.69	132.55–132.83
9	C9205	Injection, Oxaliplatin, per 5 mg	67.0	3.4	708	1,172	82.53	77.86	75.91	74.90–76.91	77.69	77.65–77.76
10	J3487	Injection, Zoledronic Acid, 1 mg	66.9	3.4	862	1,316	197.87	187.47	185.27	183.71–186.83	190.67	190.26–191.01
11	J9201	Gemcitabine Hcl, 200 mg	55.0	2.8	855	1,317	105.73	108.79	105.69	105.13–106.24	106.54	106.44–106.65
12	J9206	Irinotecan, 20 mg	39.4	2.0	786	1,109	127.33	119.56	116.31	113.87–118.75	122.67	122.16–123.13
13	J2324	Injection, Nesiritide, 0.25 mg	37.6	1.9	892	1,619	66.23	69.64	[i]	[i]	[i]	[i]
14	J9265	Paclitaxel, 30 mg	32.0	1.6	792	1,398	79.04	17.70	14.45	14.44–14.46	14.45	14.45–21.34
15	J9355	Trastuzumab, 10 mg	31.4	1.6	679	1,089	50.79	49.99	46.72	45.92–47.53	47.97	47.93–48.04
16	J9217	Leuprolide Acetate (for depot suspension), 7.5 mg	30.8	1.6	804	1,319	543.72	213.83	234.05	223.21–244.90	198.88	195.83–215.41
17	J0256	Injection, Alpha 1 - Proteinase Inhibitor - Human, 10 mg	20.9	1.1	38	279	3.72	3.06	2.35	2.33–2.37	2.46	2.27–2.46

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	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] ($)	95% confidence interval of the median purchase price[g] ($)
18	J9035[m]	Injection, Bevacizumab, 10 mg	19.8	1.0	436	916	57.11	53.88	53.31	53.01–53.61	53.72	53.69–53.75
19	J1441	Injection, Filgrastim (G-CSF), 480 mcg	17.1	0.9	928	1,679	274.40	261.46	257.21	253.46–260.96	253.64	253.45–253.78
20	J1950	Injection, Leuprolide Acetate (for depot suspension), per 3.75 mg	16.9	0.9	541	904	451.98	409.18	454.10	453.04–455.17	454.66	454.03–455.72
21	J9001	Doxorubicin Hydrochloride, all lipid formulations, 10 mg	16.3	0.8	614	955	343.78	338.66	336.33	332.22–340.44	338.70	338.28–338.97
22	J2353	Injection, Octreotide, depot form for intramuscular injection, 1 mg	15.7	0.8	545	852	69.44	80.95	71.13	69.63–72.62	74.04	73.54–74.87
23	J9055[m]	Injection, Cetuximab, 10 mg	15.1	0.8	286	506	49.66	46.85	[i]	[i]	[i]	[i]
24	J9041[m]	Injection, Bortezomib, 0.1 mg	14.1	0.7	452	631	28.38	26.77	[i]	[i]	[i]	[i]
25	J9350	Topotecan, 4 mg	13.9	0.7	585	858	697.76	699.75	674.91	656.60–693.21	709.19	706.34–710.50
26	J1440	Injection, Filgrastim (G-CSF), 300 mcg	13.0	0.7	956	1,914	162.41	165.23	161.61	156.81–166.42	159.18	159.04–159.31
27	J1785	Injection, Imiglucerase, per unit	12.9	0.7	41	59	3.91	3.69	3.62	3.60–3.64	3.62	3.61–3.66
28	J3396	Injection, Verteporfin, 0.1 mg	12.3	0.6	10	45	8.49	8.48	[i]	[i]	[i]	[i]
29	J9202	Goserelin Acetate Implant, per 3.6 mg	11.4	0.6	392	529	390.09	181.78	201.76	193.30–210.23	206.56	175.73–323.33
30	J1626	Injection, Granisetron Hydrochloride, 100 mcg	11.1	0.6	682	988	16.20	6.71	6.45	6.27–6.62	6.61	6.60–6.64
31	J0585	Botulinim Toxin Type A, per unit	10.8	0.5	480	1,062	4.32	4.44	[i]	[i]	[i]	[i]
32	J0207	Injection, Amifostine, 500 mg	10.5	0.5	477	705	395.75	403.84	[i]	[i]	[i]	[i]
33	J2430	Injection, Pamidronate Disodium, per 30 mg	10.2	0.5	945	1,567	128.74	54.10	58.49	51.51–65.47	72.59	71.50–72.72
34	J9390	Vinorelbine Tartrate, per 10 mg	9.3	0.5	568	833	52.78	58.20	48.15	48.13–48.16	48.14	48.13–52.05
35	J2993	Injection, Reteplase, 18.1 mg	8.9	0.4	505	1,073	1,192.09	832.49	846.53	844.18–848.87	845.36	844.48–846.87

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	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] ($)	95% confidence interval of the median purchase price[g] ($)
36	J9293	Injection, Mitoxantrone Hydrochloride, per 5 mg	8.4	0.4	672	1,181	313.96	305.36	297.00	296.19–297.82	295.62	295.46–295.78
37	J9185	Fludarabine Phosphate, 50 mg	7.6	0.4	669	891	311.09	243.05	293.99	291.43–296.56	298.44	298.37–298.68
38	C1305	Apligraf®, per 44 square centimeters	7.0	0.4	63	450	1,130.88	1,114.74	[i]	[i]	[i]	[i]
39	J9395	Injection, Fulvestrant, 25 mg	6.9	0.3	468	778	79.65	76.78	74.63	74.45–74.80	75.03	74.95–75.18
40	J3100	Injection, Tenecteplase, 50 mg	6.8	0.3	509	1,181	2,350.98	1,901.29	[i]	[i]	[i]	[i]
41	J9305[m]	Injection, Pemetrexed, 10 mg	5.6	0.3	162	251	40.54	38.25	[i]	[i]	[i]	[i]
42	J9160	Denileukin Diftitox, 300 mcg	5.6	0.3	73	95	1,438.80	1,144.18	[i]	[i]	[i]	[i]
43	J0180[m]	Injection, Agalsidase Beta, 1 mg	5.3	0.3	29	49	121.11	114.26	111.33	111.08–111.58	109.71	108.18–111.09
44	Q0166	Granisetron Hydrochloride, 1 mg, oral[n]	4.8	0.2	541	886	39.04	31.04	24.86	24.82–24.89	23.99	21.58–24.94
45	J2469[m]	Injection, Palonosetron Hcl, 25 mcg	4.6	0.2	295	525	18.09	17.06	[i]	[i]	[i]	[i]
46	J9010	Alemtuzumab, 10 mg	4.4	0.2	236	356	541.46	478.73	[i]	[i]	[i]	[i]
47[o]	Q9942	Injection, Immune Globulin, Intravenous, Lyophilized, 10 mg	[p]	[p]	626	[q]	0.75	0.37	0.37	0.36–0.37	0.37	0.37–0.37
47[o]	Q9944	Injection, Immune Globulin, Intravenous, Non-Lyophilized, 10 mg	[p]	[p]	281	[q]	0.75	0.53	0.51	0.50–0.51	0.51	0.51–0.52
48	J7190	Factor VIII (Antihemophilic Factor, Human) per I.U.	4.2	0.2	55	122	0.76	0.60	0.46	0.46–0.46	0.46	[r]
49	J0130	Injection, Abciximab, 10 mg	4.0	0.2	570	797	448.22	417.35	[i]	[i]	[i]	[i]
50	J0850	Injection, Cytomegalovirus Immune Globulin Intravenous (Human), per vial	3.8	0.2	156	260	622.13	632.67	[i]	[i]	[i]	[i]
51	J1327	Injection, Eptifibatide, 5 mg	3.7	0.2	911	1,661	11.21	11.79	12.49	12.35–12.63	11.03	10.75–12.39

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	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] ($)	95% confidence interval of the median purchase price[g] ($)
52	J9214	Interferon, Alfa-2B, Recombinant, 1 million units	3.6	0.2	619	954	13.00	12.25	11.20	11.02–11.37	11.93	11.78–11.98
53	C9201	Dermagraft®, per 37.5 square centimeters	3.4	0.2	2	80	529.54	545.10	[i]	[i]	[i]	[i]

Source: 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.

In contrast to the detailed purchase price information in table 1, our information on the rebate component of hospitals' acquisition costs is limited. Nearly 60 percent of our sample hospitals reported receiving one or more rebates. Over half of those hospitals received one or more rebates for a specific SCOD category, while the others received rebates for a set of drugs (and sometimes other products). In the latter case, it is generally not feasible to allocate rebates to specific drugs.

Rebates were not spread uniformly across SCOD categories. For example, for 14 SCOD categories, no hospital reported receiving a rebate. For nearly all other SCOD categories, rebates were reported by a small number of hospitals. However, the effect of rebates on hospital acquisition costs may be significant for some hospitals purchasing certain drugs. For one high-volume drug, rebates were reported by one-fifth of all hospitals that purchased drugs in at least one SCOD category. For some hospitals, these rebates were as high as 29 percent of the drug's purchase price. Averaged over all hospitals, rebates for this drug relative to its purchase price were likely to be considerably smaller, since most hospitals did not report receiving large rebates.

Agency Comments and Our Evaluation

We received comments on a draft of this report from HHS (see enc. III). HHS commended our efforts and acknowledged the challenges of accurately surveying hospitals for drug acquisition costs. HHS also stated that it had concerns regarding the limitations of our study. For example, HHS cited the difficulties that hospitals had in attributing rebates from manufacturers and payments from group purchasing organizations to hospitals' purchases of individual drug products. In addition, HHS anticipated concerns that purchase prices of drugs might have changed after the sample period for which we collected price data. HHS stated that it would take account of 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 drug acquisition costs.

Despite the limitations that CMS noted, we believe our estimates of average purchase price for each SCOD category that we report are sufficiently accurate for use in developing Medicare rates for SCOD categories. Moreover, these data are the only publicly available source of information on what hospitals are paying for these drugs. As HHS pointed out, our draft report indicated that the lack of comprehensive rebate data was a limitation of our study. However, hospitals reported no rebates for 14 of the 53 SCOD categories. In addition, we found that, for nearly all other SCOD categories, rebates were reported by a small number of hospitals; consequently, the effect of rebates on acquisition cost averaged across all hospitals is likely to be small. We have revised the report to clarify this point. While we believe that purchase price is currently an adequate measure of hospitals' acquisition costs, this measure could be improved by adjusting purchase price for rebates if a different rebate data source or estimating method were available. 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 drug 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.

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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 call me at (202) 512-7119. Another contact and key contributors are listed in enclosure IV.

Sincerely yours,

A. Bruce Steinwald
Director, Health Care

Enclosures - 4

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 drug 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 June 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 of 71 percent. A pilot sample of 48 hospitals was included in the 1,400.

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 drug 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 residents to the average number of patients was at least 1 to 4 and a nonmajor teaching hospital as one having a ratio of residents 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 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

[1]Even 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.

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.

[a]Hospitals in the population refers to the number of hospitals that made any claims to Medicare for outpatient drugs from January 1, 2003, through June 30, 2003, and were still Medicare-certified hospitals on July 1, 2004.

[b]Total charges are the hospital outpatient charges to Medicare from January 1, 2003, through June 30, 2003. Average total charges are average total charges per hospital.

[c]The standard deviation is a measure of variation around the average.

[d]The Neyman allocation is a method for determining the optimum sample size, that is, the sample size that results in the greatest precision.

[e]We 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.

[f]The 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;

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

[3]We 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, such as whether the hospital participated in the 340B program; 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' ordering and order management systems,[4] extracts from hospitals' own databases, and entries made in a worksheet form we supplied. 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. Follow-up calls were most extensive for hospitals in strata with high target response rates. We obtained an overall response rate of 83 percent and met our target response rate in 11 of 15 strata. (See table 3.)

[4]Distributors are intermediaries that buy drugs from manufacturers and sell them to hospitals.

Table 3: Target and Actual Response Rates by Stratum

Stratum	Target response rate in %	Actual response rate[a] in %
Major teaching hospitals		
< 20 unique SCODs	52	71
20-39 unique SCODs	86	82[b]
40-59 unique SCODs	95	79[b]
60+ unique SCODs	100	85[b]
Nonmajor teaching hospitals		
< 20 unique SCODs	55	79
20-39 unique SCODs	62	84
40-59 unique SCODs	62	88
60+ unique SCODs	100	85[b]
Urban nonteaching hospitals		
< 20 unique SCODs	62	80
20-39 unique SCODs	63	84
40+ unique SCODs	87	90[b]
Rural nonteaching hospitals		
< 20 unique SCODs	61	66
20-39 unique SCODs	61	81
40+ unique SCODs	66	85
Small hospitals	75	80
Total	**71**	**83**

Source: GAO.

[a]Except where otherwise indicated, we counted as responses all hospitals that sent usable data on or before January 15, 2005.

[b]We continued to process data received through February 22, 2005, for strata where we had not yet reached our target response rate as of January 15, 2005.

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 purchased—not just SCODs—and consequently we needed to extract the SCOD data. Most data were submitted for periods of a day or a month, as we requested, but 106 hospitals submitted annual data, which we also accepted.

Westat technical staff checked the data for consistency and completeness and followed up with 71 hospitals to resolve specific issues. We trimmed the data to exclude outliers. On average, 2.6 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.[5]

[5]Our 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.

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."

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:

$$Y_j = (\Sigma_h \frac{N_h}{n_h} \Sigma_i y^*_{jhi}) / (\Sigma_h \frac{N_h}{n_h} \Sigma_i x^*_{jhi})$$

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,
- $y^*_{jhi} = \Sigma_k y_{jhik}$, which represents the total dollar amount of the j[th] SCOD purchased by the i[th] hospital in the h[th] stratum, and
- $x^*_{jhi} = \Sigma_k x_{jhik}$, which represents the total number of units of 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

$$F(x) = \{ \Sigma_h \frac{N_h}{n_h} \Sigma_i \Sigma_k I(y_{jhik} \leq x) \} / \{ \Sigma_h \frac{N_h}{n_h} \Sigma_i \Sigma_k \}$$

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.[6] 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 Cochran[7] and Hansen, Hurwitz, and Madow,[8] since our estimates were calculated from our survey—that is, from a stratified sample.[9] To calculate the confidence interval for our estimates of median prices, we used the equations presented in Binder[10] and Francisco and Fuller.[11] 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®.[12]

[6]If 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 level is often calculated so that the percentage is 95 percent.

[7]W.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.

[8]M.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.

[9]More 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.

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

[11]C.A. Francisco and W.A. Fuller, "Quantile Estimation with a Complex Survey Design," *Annals of Statistics*, 19 (1991), 454-469.

[12]B.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.

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.

Naional Drug Codes and Their Names, Grouped by HCPCS

Rank in Medicare spending on drug SCODs	HCPCS and description	National Drug Code	National Drug Code name
1	Q0136, Injection, Epoetin Alpha (for non-ESRD use), per 1,000 units	59676-0302-01	Procrit® 2,000 unit/mL
		59676-0302-02	Procrit® 2,000 unit/mL
		59676-0303-01	Procrit® 3,000 unit/mL
		59676-0303-02	Procrit® 3,000 unit/mL
		59676-0304-01	Procrit® 4,000 unit/mL
		59676-0304-02	Procrit® 4,000 unit/mL
		59676-0310-01	Procrit® 10,000 unit/mL
		59676-0310-02	Procrit® 10,000 unit/mL
		59676-0312-01	Procrit® 10,000 unit/mL
		59676-0320-01	Procrit® 20,000 unit/mL
		59676-0340-01	Procrit® 40,000 unit/mL
2	J9310, Rituximab, 100 mg	50242-0051-21	Rituxan® 10 mg/mL
		50242-0053-06	Rituxan® 10 mg/mL
3	J2505, Injection, Pegfilgrastim, 6 mg	55513-0190-01	Neulasta® 6 mg/0.6 mL
4[a]	Q9941, Injection, Immune Globulin, Intravenous, Lyophilized, 1 g	00053-7486-05	Gammar®-P IV 5 g
		00053-7486-06	Gammar®-P IV 5 g
		00053-7486-10	Gammar®-P IV 10 g
		00078-0124-96	Sandoglobulin® 6 g
		00944-2620-01	Gammagard® S/D 0.5 g
		00944-2620-02	Gammagard® S/D 2.5 g
		00944-2620-03	Gammagard® S/D 5 g
		00944-2620-04	Gammagard® S/D 10 g
		44206-0416-03	Carimune® NF 3 g
		44206-0417-06	Carimune® NF 6 g
		44206-0418-12	Carimune® NF 12 g
		44206-0505-51	Carimune® 1 g
		44206-0507-56	Carimune® 6 g
		44206-0508-62	Carimune® 12 g
		52769-0268-66	Panglobulin® 6 g
		52769-0269-72	Panglobulin® 12 g
		52769-0417-06	Panglobulin® NF 6 g
		52769-0417-12	Panglobulin® NF 12 g
		52769-0418-12	Panglobulin® NF 12 g
		52769-0471-75	Polygam® S/D 5 g
		52769-0471-80	Polygam® S/D 10 g
		54129-0233-50	Iveegam® 5 g
		64193-0250-50	Iveegam® EN 5 g
4[a]	Q9943, Injection, Immune Globulin, Intravenous, Non-Lyophilized, 1 g	00026-0646-24	Gamimune® N 5% 10 g
		00026-0646-25	Gamimune® N 5% 12.5 g
		00026-0646-71	Gamimune® N 5% 5 g
		00026-0648-12	Gamimune® N 10% 1 g
		00026-0648-15	Gamimune® N 10% 2.5 g

Rank in Medicare spending on drug SCODs	HCPCS and description	National Drug Code	National Drug Code name
		00026-0648-20	Gamimune® N 10% 5 g
		00026-0648-24	Gamimune® N 10% 20 g
		00026-0648-71	Gamimune® N 10% 10 g
		49669-1613-01	Venoglobulin®-S 5% 5 g
		49669-1614-01	Venoglobulin®-S 5% 10 g
		49669-1622-01	Venoglobulin®-S 10% 5 g
		49669-1623-01	Venoglobulin®-S 10% 10 g
		49669-1624-01	Venoglobulin®-S 10% 20 g
		61953-0003-03	Flebogamma® 5% 5 g
		61953-0003-04	Flebogamma® 5% 10 g
		68516-1623-01	Venoglobulin®-S 10% 10 g
		68516-1624-01	Venoglobulin®-S 10% 20 g
5	J1745, Injection, Infliximab, 10 mg	57894-0030-01	Remicade® 100 mg
6	Q0137, Injection, Darbepoetin alfa, 1 mcg (non-ESRD use)	55513-0010-01	Aranesp® 25 mcg/mL
		55513-0010-04	Aranesp® 25 mcg/mL
		55513-0011-04	Aranesp® 40 mcg/mL
		55513-0012-04	Aranesp® 60 mcg/mL
		55513-0013-01	Aranesp® 100 mcg/mL
		55513-0013-04	Aranesp® 100 mcg/mL
		55513-0014-01	Aranesp® 200 mcg/mL
		55513-0014-04	Aranesp® 200 mcg/mL
		55513-0015-01	Aranesp® 300 mcg/mL
		55513-0037-01	Aranesp® 40 mcg/0.4 mL
		55513-0037-04	Aranesp® 40 mcg/0.4 mL
		55513-0039-01	Aranesp® 60 mcg/0.3 mL
		55513-0039-04	Aranesp® 60 mcg/0.3 mL
		55513-0041-01	Aranesp® 100 mcg/0.5 mL
		55513-0041-04	Aranesp® 100 mcg/0.5 mL
		55513-0043-04	Aranesp® 150 mcg/0.3 mL
		55513-0044-01	Aranesp® 200 mcg/0.4 mL
		55513-0046-01	Aranesp® 300 mcg/0.6 mL
		55513-0048-01	Aranesp® 500 mcg/mL
		55513-0054-01	Aranesp® 150 mcg/0.75 mL
		55513-0054-04	Aranesp® 150 mcg/0.75 mL
		55513-0058-04	Aranesp® 25 mcg/0.42 mL
7	J9170, Docetaxel, 20 mg	00075-8001-20	Taxotere® 20 mg/0.5 mL
		00075-8001-80	Taxotere® 80 mg/2 mL
8	J9045, Carboplatin, 50 mg	00015-3210-30	Paraplatin® 50 mg/5 mL
		00015-3210-76	Paraplatin® 50 mg/5 mL
		00015-3211-30	Paraplatin® 150 mg/15 mL
		00015-3211-76	Paraplatin® 150 mg/15 mL
		00015-3212-30	Paraplatin® 450 mg/45 mL
		00015-3212-76	Paraplatin® 450 mg/45 mL
		00015-3213-29	Paraplatin® 50 mg
		00015-3213-30	Paraplatin® 50 mg
		00015-3214-29	Paraplatin® 150 mg
		00015-3214-30	Paraplatin® 150 mg

Rank in Medicare spending on drug SCODs	HCPCS and description	National Drug Code	National Drug Code name
		00015-3215-29	Paraplatin® 450 mg
		00015-3215-30	Paraplatin® 450 mg
		00015-3216-30	Paraplatin® 600 mg/60 mL
		00703-3244-11	Carboplatin 50 mg/5 mL
		00703-3246-11	Carboplatin 150 mg/15 mL
		00703-3248-11	Carboplatin 450 mg/45 mL
		00703-3266-01	Carboplatin 150 mg
		00703-3268-01	Carboplatin 450 mg
		63323-0167-20	Carboplatin 150 mg
9	C9205, Injection, Oxaliplatin, per 5 mg	00024-0596-02	Eloxatin™ 50 mg
		00024-0597-04	Eloxatin™ 100 mg
10	J3487, Injection, Zoledronic Acid, 1 mg	00078-0350-84	Zometa® 4 mg
		00078-0387-25	Zometa® 4 mg/5 mL
11	J9201, Gemcitabine Hcl, 200 mg	00002-7501-01	Gemzar® 200 mg
		00002-7502-01	Gemzar® 1 g
12	J9206, Irinotecan, 20 mg	00009-7529-01	Camptosar® 20 mg/mL
		00009-7529-02	Camptosar® 20 mg/mL
13	J2324, Injection, Nesiritide, 0.25 mg	65847-0205-25	Natrecor® 1.5 mg
14	J9265, Paclitaxel, 30 mg	00074-4335-01	Paclitaxel 100 mg/16.7 mL
		00074-4335-02	Paclitaxel 100 mg/16.7 mL
		00074-4335-04	Paclitaxel 300 mg/50 mL
		00172-3753-77	Onxol® 6 mg/mL
		00172-3753-96	Onxol® 6 mg/mL
		00172-3754-73	Onxol® 6 mg/mL
		00172-3754-94	Onxol® 6 mg/mL
		00172-3755-31	Onxol® 100 mg/16.7 mL
		00172-3756-75	Onxol® 6 mg/mL
		00172-3756-95	Onxol® 6 mg/mL
		51079-0961-01	Paclitaxel 30 mg/5 mL
		51079-0962-01	Paclitaxel 100 mg/16.7 mL
		51079-0963-01	Paclitaxel 300 mg/50 mL
		55390-0114-05	Paclitaxel 30 mg/5 mL
		55390-0114-20	Paclitaxel 30 mg/5 mL
		55390-0114-50	Paclitaxel 30 mg/5 mL
		55390-0314-05	Paclitaxel 30 mg/5 mL
		55390-0314-20	Paclitaxel 30 mg/5 mL
		55390-0314-50	Paclitaxel 30 mg/5 mL
		61703-0342-09	Paclitaxel 100 mg/16.7 mL
		61703-0342-22	Paclitaxel 100 mg/16.7 mL
		61703-0342-50	Paclitaxel 100 mg/16.7 mL
15	J9355, Trastuzumab, 10 mg	50242-0134-60	Herceptin® 440 mg
		50242-0134-68	Herceptin® 440 mg
16	J9217, Leuprolide Acetate (for depot suspension), 7.5 mg	00024-0222-05	Eligard® 22.5 mg
		00024-0597-07	Eligard® 7.5 mg
		00024-0597-22	Eligard® 22.5 mg
		00024-0610-30	Eligard® 30 mg

Rank in Medicare spending on drug SCODs	HCPCS and description	National Drug Code	National Drug Code name
		00024-0793-75	Eligard® 7.5 mg
		00300-3346-01	Lupron Depot® 22.5 mg
		00300-3642-01	Lupron Depot® 7.5 mg
		00300-3683-01	Lupron Depot® 30 mg
17	J0256, Injection, Alpha 1 - Proteinase Inhibitor - Human, 10 mg	00026-0601-30	Prolastin® approx 500 mg
		00026-0601-35	Prolastin® approx 1000 mg
		00053-7201-02	Zemaira™ approx 1000 mg
		49669-5800-02	Aralast® approx 1000 mg
18	J9035,[b] Injection, Bevacizumab, 10 mg	50242-0060-01	Avastin™ 100 mg/4 mL
		50242-0060-02	Avastin™ 400 mg/16 mL
19	J1441, Injection, Filgrastim (G-CSF), 480 mcg	55513-0209-01	Neupogen® 480 mcg/0.8 mL
		55513-0209-10	Neupogen® 480 mcg/0.8 mL
		55513-0546-01	Neupogen® 480 mcg/1.6 mL
		55513-0546-10	Neupogen® 480 mcg/1.6 mL
20	J1950, Injection, Leuprolide Acetate (for depot suspension), per 3.75 mg	00300-3641-01	Lupron Depot® 3.75 mg
		00300-3663-01	Lupron Depot® 11.25 mg
21	J9001, Doxorubicin Hydrochloride, all lipid formulations, 10 mg	17314-9600-01	Doxil® 2 mg/mL
		17314-9600-02	Doxil® 2 mg/mL
22	J2353, Injection, Octreotide, depot form for intramuscular injection, 1 mg	00078-0340-84	Sandostatin LAR® Depot 10 mg
		00078-0341-84	Sandostatin LAR® Depot 20 mg
		00078-0342-84	Sandostatin LAR® Depot 30 mg
23	J9055,[b] Injection, Cetuximab, 10 mg	66733-0948-23	Erbitux™ 100 mg/50 mL
24	J9041,[b] Injection, Bortezomib, 0.1 mg	63020-0049-01	Velcade® 3.5 mg
25	J9350, Topotecan, 4 mg	00007-4201-01	Hycamtin® 4 mg
		00007-4201-05	Hycamtin® 4 mg
26	J1440, Injection, Filgrastim (G-CSF), 300 mcg	55513-0530-01	Neupogen® 300 mcg/mL
		55513-0530-10	Neupogen® 300 mcg/mL
		55513-0924-10	Neupogen® 300 mcg/0.5 mL
27	J1785, Injection, Imiglucerase, per unit	58468-1983-01	Cerezyme® 200 unit
		58468-4663-01	Cerezyme® 400 unit
28	J3396, Injection, Verteporfin, 0.1 mg	58768-0150-15	Visudyne® 15 mg
29	J9202, Goserelin Acetate Implant, per 3.6 mg	00310-0950-36	Zoladex® 3.6 mg
		00310-0951-30	Zoladex® 10.8 mg
		00310-0960-36	Zoladex® 3.6 mg
		00310-0961-30	Zoladex® 10.8 mg
30	J1626, Injection, Granisetron Hydrochloride, 100 mcg	00004-0239-09	Kytril® 1 mg/mL
		00004-0240-09	Kytril® 1 mg/mL

Rank in Medicare spending on drug SCODs	HCPCS and description	National Drug Code	National Drug Code name
		00029-4149-01	Kytril® 1 mg/mL
31	J0585, Botulinim Toxin Type A, per unit	00023-1145-01	Botox® 100 unit
32	J0207, Injection, Amifostine, 500 mg	17314-7253-03	Ethyol® 500 mg
		58178-0017-03	Ethyol® 500 mg
33	J2430, Injection, Pamidronate Disodium, per 30 mg	00703-4075-19	Pamidronate Disodium 30 mg/10 mL
		00703-4085-11	Pamidronate Disodium 90 mg/10 mL
		00703-4085-91	Pamidronate Disodium 90 mg/10 mL
		55390-0127-01	Pamidronate Disodium 30 mg
		55390-0129-01	Pamidronate Disodium 90 mg
		55390-0157-01	Pamidronate Disodium 30 mg
		55390-0159-01	Pamidronate Disodium 90 mg
		55390-0204-01	Pamidronate Disodium 30 mg/10 mL
		55390-0604-01	Pamidronate Disodium 30 mg/10 mL
		61703-0325-18	Pamidronate Disodium 6 mg/mL
		63323-0734-10	Pamidronate Disodium 30 mg/10 mL
		63323-0735-10	Pamidronate Disodium 90 mg/10 mL
34	J9390, Vinorelbine Tartrate, per 10 mg	00703-4182-01	Vinorelbine Tartrate 10 mg/mL
		00703-4182-91	Vinorelbine Tartrate 10 mg/mL
		00703-4183-01	Vinorelbine Tartrate 10 mg/mL
		00703-4183-91	Vinorelbine Tartrate 10 mg/mL
		10019-0970-01	Vinorelbine Tartrate 10 mg/mL
		10019-0970-02	Vinorelbine Tartrate 10 mg/mL
		55390-0069-01	Vinorelbine Tartrate 10 mg/mL
		55390-0070-01	Vinorelbine Tartrate 10 mg/mL
		59911-5958-01	Vinorelbine Tartrate 10 mg/mL
		59911-5959-01	Vinorelbine Tartrate 10 mg/mL
35	J2993, Injection, Reteplase, 18.1 mg	57894-0040-01	Retavase® 2x18.1 mg
		57894-0040-02	Retavase® 18.1 mg
36	J9293, Injection, Mitoxantrone Hydrochloride, per 5 mg	44087-1520-01	Novantrone® 2 mg/mL
		44087-1525-01	Novantrone® 2 mg/mL
		44087-1530-01	Novantrone® 2 mg/mL
		58406-0640-03	Novantrone® 2 mg/mL

Rank in Medicare spending on drug SCODs	HCPCS and description	National Drug Code	National Drug Code name
		58406-0640-05	Novantrone® 2 mg/mL
		58406-0640-07	Novantrone® 2 mg/mL
37	J9185, Fludarabine Phosphate, 50 mg	00703-5854-01	Fludarabine Phosphate 50 mg
		50419-0511-06	Fludara® 50 mg
38	C1305, Apligraf®, per 44 square centimeters	09978-0001-99	Apligraf®
39	J9395, Injection, Fulvestrant, 25 mg	00310-0720-25	Faslodex® 125 mg/2.5 mL
		00310-0720-50	Faslodex® 250 mg/5 mL
40	J3100, Injection, Tenecteplase, 50 mg	50242-0038-61	TNKase™ 50 mg
41	J9305,[b] Injection, Pemetrexed, 10 mg	00002-7623-01	Alimta® 500 mg
42	J9160, Denileukin Diftitox, 300 mcg	64365-0503-01	Ontak® 150 mcg/mL
43	J0180,[b] Injection, Agalsidase Beta, 1 mg	58468-0040-01	Fabrazyme® 35 mg
		58468-0041-01	Fabrazyme® 5 mg
44	Q0166, Granisetron Hydrochloride, 1 mg, oral[c]	00004-0237-09	Kytril® 2 mg/10 mL
		00004-0241-26	Kytril® 1 mg
		00004-0241-33	Kytril® 1 mg
		00029-4151-05	Kytril® 1 mg
45	J2469,[b] Injection, Palonosetron Hcl, 25 mcg	58063-0797-25	Aloxi® 0.25 mg/5 mL
46	J9010, Alemtuzumab, 10 mg	50419-0355-10	CamPath® 10 mg/mL
		50419-0355-12	CamPath® 10 mg/mL
47[d]	Q9942, Injection, Immune Globulin, Intravenous, Lyophilized, 10 mg	00053-7486-05	Gammar®-P IV 5 g
		00053-7486-06	Gammar®-P IV 5 g
		00053-7486-10	Gammar®-P IV 10 g
		00078-0124-96	Sandoglobulin® 6 g
		00944-2620-01	Gammagard® S/D 0.5 g
		00944-2620-02	Gammagard® S/D 2.5 g
		00944-2620-03	Gammagard® S/D 5 g
		00944-2620-04	Gammagard® S/D 10 g
		44206-0416-03	Carimune® NF 3 g
		44206-0417-06	Carimune® NF 6 g
		44206-0418-12	Carimune® NF 12 g
		44206-0505-51	Carimune® 1 g
		44206-0507-56	Carimune® 6 g
		44206-0508-62	Carimune® 12 g
		52769-0268-66	Panglobulin® 6 g
		52769-0269-72	Panglobulin® 12 g
		52769-0417-06	Panglobulin® NF 6 g
		52769-0417-12	Panglobulin® NF 12 g
		52769-0418-12	Panglobulin® NF 12 g
		52769-0471-75	Polygam® S/D 5 g
		52769-0471-80	Polygam® S/D 10 g
		54129-0233-50	Iveegam® 5 g
		64193-0250-50	Iveegam® EN 5 g

Rank in Medicare spending on drug SCODs	HCPCS and description	National Drug Code	National Drug Code name
47[d]	Q9944, Injection, Immune Globulin, Intravenous, Non-Lyophilized, 10 mg	00026-0646-24	Gamimune® N 5% 10 g
		00026-0646-25	Gamimune® N 5% 12.5 g
		00026-0646-71	Gamimune® N 5% 5 g
		00026-0648-12	Gamimune® N 10% 1 g
		00026-0648-15	Gamimune® N 10% 2.5 g
		00026-0648-20	Gamimune® N 10% 5 g
		00026-0648-24	Gamimune® N 10% 20 g
		00026-0648-71	Gamimune® N 10% 10 g
		49669-1613-01	Venoglobulin®-S 5% 5 g
		49669-1614-01	Venoglobulin®-S 5% 10 g
		49669-1622-01	Venoglobulin®-S 10% 5 g
		49669-1623-01	Venoglobulin®-S 10% 10 g
		49669-1624-01	Venoglobulin®-S 10% 20 g
		61953-0003-03	Flebogamma® 5% 5 g
		61953-0003-04	Flebogamma® 5% 10 g
		68516-1623-01	Venoglobulin®-S 10% 10 g
		68516-1624-01	Venoglobulin®-S 10% 20 g
48	J7190, Factor VIII (Antihemophilic Factor, Human) per I.U.	00026-0665-20	Koate®-DVI 250 unit
		00026-0665-30	Koate®-DVI 500 unit
		00026-0665-50	Koate®-DVI 1000 unit
		00053-7656-01	Monoclate-P® 250 unit
		00053-7656-02	Monoclate-P® 500 unit
		00053-7656-04	Monoclate-P® 1000 unit
		00944-2935-01	Hemofil® M 200-1000 unit
		49669-4600-01	Alphanate® 250-500 unit
		49669-4600-02	Alphanate® 1000-1500 unit
		52769-0460-01	Monarc-M™ 250-1100 unit
49	J0130, Injection, Abciximab, 10 mg	00002-7140-01	Reopro® 2 mg/mL
50	J0850, Injection, Cytomegalovirus Immune Globulin, Intravenous (Human), per vial	60574-3101-01	CytoGam®
51	J1327, Injection, Eptifibatide, 5 mg	00085-1136-01	Integrilin® 0.75 mg/mL
		00085-1177-01	Integrilin® 2 mg/mL
		00085-1177-02	Integrilin® 2 mg/mL
52	J9214, Interferon, Alfa-2B, Recombinant, 1 million units	00085-0120-02	Intron® A 5 million units
		00085-0285-02	Intron® A 25 million units
		00085-0539-01	Intron® A 50 million units
		00085-0571-02	Intron® A 10 million units
		00085-0647-05	Intron® A 3 million units
		00085-1110-01	Intron® A 18 million units
		00085-1133-01	Intron® A 10 million units/mL
		00085-1168-01	Intron® A 6 million units/mL
		00085-1179-02	Intron® A 10 million units/mL
		00085-1235-01	Intron® A 5 million units/0.2 mL
		00085-1242-01	Intron® A 3 million units/0.2 mL

Rank in Medicare spending on drug SCODs	HCPCS and description	National Drug Code	National Drug Code name
		00085-1254-01	Intron® A 10 million units/0.2 mL
53	C9201, Dermagraft®, per 37.5 square centimeters	38172-0202-00	Dermagraft® 5 cm x 7.5 cm

Sources: GAO survey and CMS.

Note: ESRD = end-stage renal disease, mL = milliliter, mg = milligram, g = gram, mcg = microgram, I.U. = international unit, cm = centimeter.

[a]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.

[b]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.

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

[d]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.

Enclosure III

Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JUN 16 2005

Mr. A. Bruce Steinwald
Director
Health Care—Economic and Payment Issues
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: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting" (GAO-05-581R). The 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.

Enclosure III

COMMENTS OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S REPORT ENTITLED, "MEDICARE: DRUG PURCHASE PRICES FOR CMS CONSIDERATION IN HOSPITAL OUTPATIENT RATE-SETTING" (GAO-05-581R)

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

Paying appropriately for drugs and related pharmacy overhead resources under the outpatient prospective payment system is a priority for the Centers for Medicare & Medicaid Services. We commend the efforts of GAO and recognize the challenges of accurately surveying hospitals for drug acquisition costs. The draft provided by GAO focused on hospital drug purchase prices, which are one component of hospital drug acquisition costs. As the report points out, drug acquisition costs are also influenced by rebates from drug manufacturers and payments from group purchasing organizations. We are concerned about some of the limitations noted in the report about the purchase price survey, such as the difficulties hospitals have in allocating rebates from manufacturers and payments from group purchasing organizations to drug acquisition costs. Also, we foresee concerns about the potential for the purchase prices to have changed since the time period GAO surveyed hospitals.

We will take the survey data into account as we develop the proposed payment rates for 2006. We believe 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 reflects the rebates and other price concessions that influence drug acquisition costs.

Enclosure IV

GAO Contact and Staff Acknowledgments

GAO Contact

Phyllis Thorburn, (202) 512-7012

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