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United States Government Accountability Office
Washington, DC 20548

December 1, 2004

The Honorable Joe Barton
Chairman
Committee on Energy and Commerce
House of Representatives

Subject: *Medicare Chemotherapy Payments: New Drug and Administration Fees Are Closer to Providers' Costs*

Dear Mr. Chairman:

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[1] required the Secretary of the Department of Health and Human Services to change the payment rates for chemotherapy-related drugs and chemotherapy administration services. These changes followed reports that Medicare payments for chemotherapy-related drugs were much higher than physicians' costs to acquire them, and oncologists' assertions that drug overpayments were needed to compensate for inadequate payments for chemotherapy administration services.[2] In addition, the Centers for Medicare & Medicaid Services (CMS) made changes in billing rules for chemotherapy administration services.[3] However, oncologists have been concerned that even with these changes, Medicare payments may not cover the costs of providing chemotherapy services in 2005. To respond to your request that we review the adequacy of Medicare payments for chemotherapy-related drugs and chemotherapy administration services in 2004 and 2005, we assessed the changes in these payments and compared the payments to the estimated costs of providing these services.

To estimate payments and costs for chemotherapy-related drugs, we selected 16 drugs billed by oncologists to Medicare that represented three quarters of Medicare

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[1]Pub. L. No. 108-173, § 303, 117 Stat. 2066, 2233.
[2]See GAO, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost*, GAO-01-1118 (Washington, D.C.: Sept. 21, 2001).
[3]For example, prior to 2004, oncologists were allowed to bill for the administration of only one chemotherapy drug per day by injection, referred to as "push technique," regardless of the actual number of drugs administered. MMA required CMS to evaluate this policy and make changes as appropriate. CMS now allows oncologists to bill for each additional drug administered by push technique. See, Medicare Program; Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004, 69 *Fed. Reg.* 1084 (2004) (to be codified at 42 C.F.R. parts 405 and 414).

payments to oncologists for drugs in 2003. We used 2003 utilization data, CMS's published payment rates for 2003 and 2004, and its preliminary 2005 payment rates. We compared the estimated payments in 2004 and 2005 with oncologists' estimated costs for acquiring these drugs based on drug price data compiled by a private vendor.[4] We estimated payments and costs for all drugs billed by oncologists to Medicare based upon the relationship between payments and costs for the 16 drugs.[5] To estimate payment changes for chemotherapy administration services, we reviewed all 22 major chemotherapy administration and related services. We estimated payments for these services using 2003 utilization data, CMS's published physician fees for 2003 and 2004, and estimates of inflation-adjusted 2005 fees. We estimated oncologists' costs of providing these services by using the methodology and data used by CMS to develop its own estimates of oncologists' practice expense costs for purposes of setting payment rates.[6] CMS's cost estimates are based, in part, upon hourly expense estimates from a survey of oncology practices conducted by the American Society of Clinical Oncology (ASCO). We developed alternate cost estimates by removing high-cost outliers from the ASCO survey data. We then compared the relationship between Medicare payments to oncologists and these two estimates of costs for chemotherapy administration services to the relationship between payments and costs for all services provided by all physicians. We conducted our work from March through November 2004 in accordance with generally accepted government auditing standards. (See encl. I for a description of our scope and methodology.)

In summary, we estimate that Medicare payments for drugs billed by oncologists in 2004 and 2005 will decline relative to 2003, while still exceeding physicians' costs for acquiring these drugs, and payments for chemotherapy administration services will increase substantially. Medicare payment rates for the 16 drugs we studied will exceed oncologists' estimated costs for acquiring these drugs by 22 percent in 2004 and 6 percent in 2005. (See encl. II for our estimates of the payment-to-cost ratios for these drugs in 2004 and 2005.) Assuming the same relationship between payments and costs for all drugs billed by oncologists, we estimate that total Medicare drug payments to oncologists will exceed costs by $790 million in 2004 and $202 million in 2005. (See encl. III for our estimates of the payments and costs for all drugs billed by

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[4]Acquisition cost estimates were based on drug price data obtained from IMS Health, a firm that maintains sales data obtained from approximately 100 drug manufacturers and 274 drug wholesalers in the United States. The data we obtained represent national average prices to clinics, including sales to oncology clinics. IMS data are collected from sales invoices and do not include off-invoice discounts or rebates, and thus may overstate the amount clinics actually paid for drugs.
[5]The 16 drugs studied included brand name and generic drugs and chemotherapy and other related drugs (such as drugs used to treat the side effects of chemotherapy) and represented 75 percent of Medicare payments to oncologists for drugs in 2003.
[6]The practice expense component is one of three components of the Medicare physician fee schedule. The practice expense component reflects the costs incurred by physicians in operating their practices, such as nurses' salaries, office space, and equipment; the physician work component provides payment for the physician resources required to provide a service, including time and intensity of effort; and the malpractice component provides payments for the costs of obtaining malpractice insurance.

oncologists to Medicare.) Regarding chemotherapy administration services, we estimate that fees for almost every service will increase in both 2004 and 2005 relative to 2003, in some cases in excess of 300 percent. (See encl. IV for our estimates of the changes in fees for these services between 2003 and 2005.) We estimate that total payments to oncologists for these services will be 130 percent higher in 2005 than they were in 2003, assuming no change in utilization. These estimates do not reflect Medicare billing changes that CMS announced on November 15, 2004.[7] In its comments on a draft of this report, CMS estimated that these changes will further increase Medicare payments to oncologists for chemotherapy administration in 2005. For example, CMS estimated that payments will increase 5 percent due to revised and added billing codes and 15 percent due to a nationwide demonstration project related to the care and assessment of cancer patients. (See encl. V for our estimates of the change in total payments to oncologists for these services between 2003 and 2005.) Further, we estimate that in 2004 Medicare practice expense payments will cover between 24 and 70 percent more of oncologists' practice expense costs than will Medicare payments for all services to all specialties. Though lower in 2005, we estimate that practice expense payments in that year will cover nearly as much or more of oncologists' costs than will payments for all services to all specialties. (See encl. VI for our estimate of the relative share of oncologists' practice expense costs covered for chemotherapy administration services compared with the relative share for all services provided by all specialties.)

Agency and External Reviewer Comments and Our Evaluation

We received comments on a draft of this report from CMS and ASCO. CMS agreed with our findings, and commented that recently announced Medicare billing changes related to chemotherapy administration services that are not reflected in our analyses will further boost payments to oncologists in 2005. We have acknowledged these changes in the report. (See encl. VII for a copy of CMS's comments.)

ASCO cited concerns with our cost estimates for chemotherapy-related drugs and the practice expenses associated with providing chemotherapy services. It also provided technical comments, which we incorporated as appropriate.

Regarding drug costs, ASCO characterized as too high our estimate that Medicare payments to oncologists will exceed acquisition costs by an average of 6 percent in 2005. ASCO cited its own survey with 140 responses that found Medicare payments would exceed costs by about 4 percent in that year. In addition, ASCO commented that our reporting of average acquisition costs for drugs ignores the implications of the variation in actual acquisition costs incurred by individual clinics.

To estimate drug acquisition costs, we obtained average prices charged to clinics, including oncology clinics, from a database representing actual sales by about 100 drug manufacturers and 274 drug wholesalers in the United States. Nearly 20,000 individual transactions from this database were used to estimate costs for the 16 drugs we reviewed. We believe these data provide a more comprehensive

[7]Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, 69 *Fed. Reg.* 66236 (2004) (to be codified at various parts in 42 C.F.R).

representation of clinics' costs for acquiring chemotherapy and related drugs than a survey with 140 voluntary respondents. We noted in the draft report that the acquisition cost estimates we present are an average, and that actual acquisition costs for individual clinics can vary. We also noted that, for most of the drugs we studied, 85 percent of the drugs purchased from wholesalers were acquired for less than the proposed Medicare payment rates for 2005. Among the remaining wholesaler purchases, most were acquired for only slightly more (5 percent or less) than the proposed payment rates. The significance of these higher payments is diminished by two factors. First, our cost estimates are conservative. They do not include off-invoice discounts or rebates providers may receive. Had we included such discounts and rebates, payments would likely exceed costs by more than we estimated and an even higher proportion of purchases would have been made at less than the proposed 2005 payment rates. Second, the purchases included in our data were made in 2004, when Medicare payment rates were significantly higher. The lower expected payment rates in 2005 may provide an incentive for clinics to negotiate lower drug prices, and in its comments on a draft of this report, CMS noted that it would work with oncology practices to obtain the most favorable drug prices.

Regarding our estimates of the practice expense costs associated with providing chemotherapy administration services, ASCO asserted that the use of CMS's fee schedule methodology to estimate costs is not valid. Although it acknowledged that no other source of cost data exists, ASCO commented that indirect costs were underrepresented for chemotherapy administration services that did not have a physician work component. In addition, ASCO commented that our comparison of the share of oncologists' practice expense costs covered by Medicare relative to all services for all specialties is misleading because other specialties derive a larger share of their revenues from payments for the physician work component than do oncologists, and thus have the ability to recoup losses on practice expenses from these payments.

Absent other available data to estimate the costs associated with chemotherapy administration services, we used CMS's fee schedule methodology. The cost data used to develop the fee schedule have been refined in recent years with ASCO's involvement, and all chemotherapy administration services now include a physician work component. In addition, new billing codes announced by CMS on November 15, 2004, will also include a physician work component. Finally, although the share of revenues to oncologists for physician work may continue to be lower than the share for other specialties, this reflects the lower share of physician work associated with chemotherapy administration services than with other services provided by other specialties.

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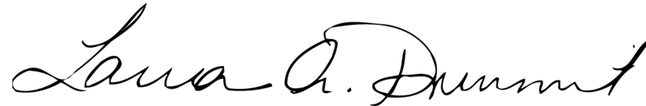
We will send copies of this report to relevant congressional committees and other interested members. We will make copies available to others upon request. The

report is also available at no charge on GAO's Web site at http://www.gao.gov. If you or your staff have any questions regarding this report, please call me at (202) 512-7119 or Randy DiRosa at (312) 220-7671. Gerardine Brennan, Iola D'Souza, and Corey Houchins-Witt were major contributors to this report.

Sincerely yours,



Laura A. Dummit
Director, Health Care—Medicare Payment Issues

Enclosures – 7

Scope and Methodology

To assess changes in Medicare payments for chemotherapy-related drugs and administration services, we estimated payments and compared payments to estimated costs of these services. Following is a description of the methodology we used, including how we selected the drugs and services studied, estimated payments and costs, assessed the reliability of the data used, and obtained input from external stakeholders.

Selection of Drugs Billed by Oncologists to Medicare

We analyzed 2003 Medicare utilization data[1] for drugs using the Healthcare Common Procedure Coding System (HCPCS) drug-pricing background file.[2] We reviewed 16 drugs that represented 75 percent of Medicare payments to oncologists for physician-administered drugs, and included both generic and brand name drugs and chemotherapy and other related drugs, such as those used to treat the side effects of chemotherapy. (See table 1.)

Table 1: Prescription Drugs Codes

HCPCS code[a]	Product name
J0640	Leucovorin calcium, 50 mg
J0880	Darbepoetin alfa, 5 mcg
J1441	Filgrastim (G-CSF), 480 mcg
J1626	Granisetron hydrochloride, 100 mcg
J2405	Ondansetron hydrochloride, 1 mg
J2430	Pamidronate disodium, 30 mg
J2505	Pegfilgrastim, 6 mg
J3487	Zoledronic acid, 1 mg
J9045	Carboplatin, 50 mg
J9170	Docetaxel, 20 mg
J9201	Gemcitabine HCl, 200 mg
J9206	Irinotecan hydrochloride, 20 mg
J9265	Paclitaxel, 30 mg
J9310	Rituximab, 100 mg
J9355	Trastuzumab, 10 mg
Q0136	Epoetin alpha, (Non-ESRD), 1000 units

Source: GAO analysis of Medicare-covered drugs.

[a]Downloaded from **www.cms.hhs.gov/providers/drugs/** May 14, 2004.

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[1]We obtained utilization data from the Medicare Part B Extract and Summary System (BESS). CMS considered the BESS data used in this report to be 96 percent complete so we adjusted them to estimate total utilization for the year.
[2]To identify the HCPCS codes to study we used the HCPCS drug-pricing background file for other than end-stage renal disease (ESRD) or durable medical equipment (DME) infusion—commonly referred to as the NDC to HCPCS crosswalk file (downloaded from www.cms.hhs.gov/providers/drugs/ May 14, 2004).

Payments and Costs for 16 Drugs

To calculate payments to oncologists for these 16 drugs, we used Medicare's 2003 utilization data, 2003 and 2004 published payment rates, and 2005 estimated payment rates.[3] We estimated drug acquisition costs in 2004 based on price data for March 2004 that we obtained from IMS Health.[4] To estimate costs in 2005 we updated the 2004 estimates by the National Health Expenditure price growth factor for prescription drugs between 2004 and 2005 (3.39 percent). We calculated payment-to-cost ratios for each of these 16 drugs for 2004 and 2005. We also calculated an aggregate average payment-to-cost ratio for both years.

Payments and Costs for All Drugs

To estimate total payments for all drugs billed by oncologists to Medicare in 2004, we multiplied 2003 utilization data by the 2004 published payment rates for all drugs billed by oncologists.[5] To estimate total payments in 2005, we adjusted 2004 total payments by the percent difference in payments between 2004 and 2005 for the 16 drugs in our study.[6] To estimate total costs for all drugs billed by oncologists to Medicare in 2004 and 2005, we applied the payment-to-cost ratio for the 16 drugs to the estimate of total payments for all drugs in each year.

Selection of Chemotherapy Administration Services Billed by Oncologists

We reviewed all 22 major service codes related to chemotherapy administration, including injection codes that are often used in conjunction with chemotherapy.[7] (See table 2.)

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[3]Medicare payments for drugs in 2005 will be based on the average sales price (ASP). We used CMS's preliminary estimates of ASP based on first quarter 2004 manufacturer submissions to estimate payment rates for drugs in 2005.

[4]IMS Health maintains sales data obtained from approximately 100 drug manufacturers and 274 drug wholesalers in the United States. IMS data are collected from sales invoices and do not include off-invoice discounts or rebates, and thus may overstate the amount clinics actually pay for drugs. The IMS data represent national average prices for clinics, which would include sales to oncology clinics. Though the actual costs may vary by purchaser, we found most of the purchase prices included in the IMS data were lower than the preliminary Medicare payment rates in 2005. For 13 of the 16 drugs we studied, about 85 percent of all purchase prices charged by wholesalers were lower than the preliminary Medicare payment rates for 2005. An additional 9 percent of these purchase prices were at or no more than 5 percent higher than the preliminary 2005 Medicare payment rates. CMS officials told us that the remaining 3 drugs we studied are among those for which the agency is closely examining transaction cost data supplied by drug manufacturers to ensure that the final 2005 payment rates accurately reflect the ASPs.

[5]To estimate 2004 payments for drugs that have not yet been assigned a specific HCPCS code, commonly referred to as unclassified drugs, we adjusted 2003 total payments for these drugs by the percent change in payments for all other drugs billed by oncologists between 2003 and 2004.

[6]Our estimate of total payments in 2005 assumes that payments for all drugs will be based on the new ASP payment formula. However, drugs that are new to the market will not initially have ASP data available and may be paid by Medicare at higher rates.

[7]These codes represented over 99 percent of the chemotherapy administration services billed to Medicare by oncologists in 2003.

Table 2: Chemotherapy administration services

HCPCS code[a]	Description
90780	IV infusion therapy, 1 hour
90781	IV infusion, additional hour
90782	Injection, subcutaneous/intramuscular
90784	Injection, intravenous
90788	Injection of antibiotic
96400	Chemotherapy, subcutaneous/intramuscular
96405	Intralesional chemotherapy administration
96406	Intralesional chemotherapy administration
96408	Chemotherapy, push technique
96410	Chemotherapy, infusion method
96412	Chemotherapy, infusion method add-on
96414	Chemotherapy infusion method add-on
96420	Chemotherapy, push technique
96422	Chemotherapy, infusion method
96423	Chemotherapy, infusion method add-on
96425	Chemotherapy, infusion method
96440	Chemotherapy, intracavitary
96445	Chemotherapy, intracavitary
96450	Chemotherapy, into central nervous system
96520	Port pump refill & maintenance
96530	System pump refill & maintenance
96542	Chemotherapy injection

Source: GAO analysis of chemotherapy administration service codes.

[a]Obtained from the 2004 Medicare physician fee schedule.

Practice Expense Payments for Chemotherapy Administration Services

We estimated 2003 Medicare total practice expense payments to oncologists for chemotherapy administration services based on 2003 utilization data. For the 2004 and 2005 estimates, we adjusted 2003 utilization data to account for administration of multiple drugs on the same day by push technique, which oncologists were allowed to bill beginning in 2004.[8] We used CMS's estimate that for each day of chemotherapy, at least one additional drug is administered half the time. We estimated total practice expense payments in 2004 using the adjusted 2003 utilization data and 2004 fees. For 2005, we used the adjusted 2003 utilization data and proposed 2005 fees, updated by CMS's 1.5 percent estimate for inflation.

[8]Chemotherapy drugs may be administered by infusion or by slowly injecting the drug directly into either the patient or an intravenous bag containing other drugs or saline solution. The method of slow injection is referred to as push technique.

Practice Expense Costs for Chemotherapy Administration Services

In the absence of reliable data on oncologists' practice expense costs of providing chemotherapy administration services, we used CMS's practice expense methodology and the data it used to estimate costs in 2004.[9] We first estimated the total costs oncologists incur in operating their practices as the product of their hourly practice expenses and total time spent by oncologists treating Medicare patients. The hourly practice expenses were based on survey data from the American Society of Clinical Oncology (ASCO).[10] Oncologist time was the total physician time associated with each service provided by oncologists to Medicare patients, based on 2003 Medicare utilization data. Our physician time estimate includes the time associated with any evaluation and management service provided on the same day as a chemotherapy service.[11]

Based on CMS's methodology, we estimated the costs of individual services and adjusted the cost estimate of each service so that their sum matched the total cost estimates. We then multiplied these per-service costs by 2003 utilization. We adjusted the costs for inflation in each year from 2003 to 2005 using the Medicare Economic Index.[12]

We calculated practice expense payment-to-cost ratios with two cost estimates: costs including all respondents to the ASCO survey, and costs excluding certain outliers. For the latter scenario, we removed survey respondents that were identified as high-cost outliers by the contractor CMS engaged to analyze the practice expense data submitted by ASCO.[13] Finally, we compared payments and estimated costs for chemotherapy administration services and payments and estimated costs for all services provided by all specialties.

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[9]For a description of CMS's practice expense methodology, see GAO, *Medicare Physician Fee Schedule: Practice Expense Payments to Oncologists Indicate Need for Overall Refinements*, GAO-02-53 (Washington, D.C.: Oct. 31, 2001). The data CMS used to calculate practice expenses in 2004 included hourly practice expenses and practice expense inputs, Medicare utilization data from 1997-2002, and physician and clinical staff time (downloaded from http://www.cms.hhs.gov/physician/pfs/default.asp in 2004).

[10]ASCO gathered its own data on oncologists' practice expenses in 2002, and submitted the data to CMS to use in developing Medicare fees for oncologists. CMS used these data to calculate 2004 fees.

[11]We did not include any additional physician time associated with the chemotherapy administration services.

[12]The Medicare Economic Index measures inflation in physician practice costs and general wage levels.

[13]CMS's contractor estimated that oncologists' hourly practice expenses were $189 including all respondents and about $140 if practices with hourly expenses equal to or above the 90th percentile were removed from the survey data. See The Lewin Group, *Recommendations Regarding Supplemental Practice Expense Data Submitted for 2003* (Falls Church, Va.: 2002).

Data Reliability

We assessed the reliability of the published drug payment rates, physician fee schedules, preliminary 2005 drug payment rates, drug-pricing background file, and the data used in the practice expense methodology by reviewing existing information about the data and interviewing agency officials knowledgeable about the data. We assessed the reliability of the BESS and IMS data by performing electronic testing of required data elements, reviewing existing information about the data, and interviewing agency officials and IMS representatives knowledgeable about the data. We determined that the data were sufficiently reliable for this analysis.

Input from External Stakeholders

Throughout this process we held discussions with officials at CMS, the Department of Health and Human Services Office of Inspector General, and the Medicare Payment Advisory Commission to clarify our understanding of the data and of the methodologies used. We also interviewed representatives from ASCO and the Association of Community Cancer Centers to obtain their views on the issues examined.

We conducted our work from March through November 2004 in accordance with generally accepted government auditing standards.

Estimated Payment-to-Cost Ratios for 16 Drugs Billed to Medicare by Oncologists, 2004 and 2005

			2003	2004			2005		
HCPCS[a]	Product name[b]	Estimated 2003 Medicare utilization by oncologists[c]	Medicare payment rate	Medicare payment rate	Estimated acquisition cost	Estimated payment-to-cost ratio[d]	Preliminary Medicare payment rate[e]	Estimated acquisition cost	Estimated payment-to-cost ratio[d]
J9265	Paclitaxel, 30 mg	1,354,922	$164.08	$138.28	$21.73	6.36	$26.72	$22.47	1.19
J9201	Gemcitabine HCl, 200 mg	1,502,050	121.01	111.33	97.87	1.14	111.10	101.19	1.10
J9170	Docetaxel, 20 mg	787,017	357.91	301.40	265.03	1.14	297.33	274.01	1.09
J0640	Leucovorin calcium, 50 mg	3,188,318	17.52	3.00	1.11	2.70	1.24	1.15	1.08
J1441	Filgrastim (G-CSF), 480 mcg	227,206	314.07	267.79	248.35	1.08	276.09	256.77	1.08
J3487	Zoledronic acid, 1 mg	915,702	217.43	194.54	187.51	1.04	209.36	193.87	1.08
J9045	Carboplatin, 50 mg	1,603,935	148.75	135.15	121.55	1.11	136.24	125.67	1.08
J9206	Irinotecan hydrochloride, 20 mg	1,095,571	151.81	130.24	116.97	1.11	128.06	120.94	1.06
J9310	Rituximab, 100 mg	1,087,326	475.00	438.38	412.82	1.06	453.24	426.81	1.06
J9355	Trastuzumab, 10 mg	1,472,565	54.95	52.01	48.05	1.08	52.56	49.68	1.06
J0880	Darbepoetin alfa, 5 mcg	17,572,057	23.69	21.20	17.22	1.23	18.71	17.80	1.05
J2505	Pegfilgrastim, 6 mg	62,742	2,802.54	2,507.52	2,152.23	1.17	2,337.41	2,225.19	1.05
Q0136	Epoetin alpha, (Non-ESRD), 1000 units	69,621,920	12.69	11.62	10.08	1.15	10.72	10.42	1.03
J1626	Granisetron hydrochloride, 100 mcg	3,914,089	18.54	15.62	6.80	2.30	6.64	7.03	0.94[f]
J2430	Pamidronate disodium, 30 mg	392,618	265.87	237.88	71.25	3.34	68.24	73.67	0.93[f]
J2405	Ondansetron hydrochloride, 1 mg	5,541,236	6.09	5.58	4.35	1.28	4.08	4.50	0.91[f]
Total weighted average payment-to-cost ratio for oncologists (based on 2003 utilization)						1.224			1.055

Source: GAO analysis of Medicare payment rates for 2003 and 2004, estimated payment rates for 2005, and IMS physician acquisition cost data.

Note: Estimated acquisition cost data are based on price data obtained from IMS Health. These data are collected from sales invoices and do not include off-invoice discounts or rebates, and thus may overstate the amount clinics actually pay for drugs.

[a]Downloaded from www.cms.hhs.gov/providers/drugs/ May 14, 2004.

[b]These drugs represented 75 percent of Medicare payments to oncologists for drugs in 2003, and include both generic and brand name drugs, as well as chemotherapy and other related drugs.

[c]The 2003 data used to estimate oncologists' utilization of drugs billed to Medicare were based on Medicare billing data assumed to be 96 percent complete. These data were adjusted to estimate 100 percent of billing for the year.

[d]Payment-to-cost ratios depict the relationship between payments and costs. Ratios above one indicate payments exceed costs and ratios below one indicate that costs exceed payments.

[e]CMS's preliminary estimates of payment rates for drugs in 2005 were based on manufacturers' first quarter 2004 ASP data submissions. Actual payments beginning January 2005 will be based on third quarter 2004 ASP data submissions.

[f]CMS officials told us that the agency is closely examining transaction cost data supplied by manufacturers of the three drugs for which we estimated payment-to-cost ratios of less than one to ensure the final payment rates for 2005 accurately reflect the average sales prices for these drugs. The low estimated payment rates for these drugs may be due to discounts or rebates reflected in the ASP data that were not reflected in the IMS data we used to estimate drug acquisition costs. Because discounts and rebates are not included in the IMS data, acquisition cost estimates based on these data may be overstated.

Estimated Payments and Costs for All Drugs Billed to Medicare by Oncologists, 2004 and 2005

	Dollars in millions			
	Estimated payments	Estimated costs	Difference between estimated payments and cost	Estimated payment-to-cost ratio[a]
2004	$4,315	$3,525	$790	1.224
2005	$3,847	$3,645	$202	1.055

Source: GAO analysis of Medicare payment rates for 2004, estimated payment rates for 2005, and IMS physician acquisition cost data.

Note: Payment estimates are based on 2003 utilization data, which are assumed to be 96 percent complete. We adjusted these data to estimate 100 percent of billing for the year.

[a]Payment-to-cost ratios depict the relationship between payments and costs. Ratios above one indicate payments exceed costs and ratios below one indicate that costs exceed payments.

Medicare Physician Payment Rates for Chemotherapy Administration Services, 2003-2005

HCPCS[a]	Description	2003 payment rates	2004 payment rates	Estimated 2005 payment rates	Percent change 2003-2005
96520	Port pump refill & maintenance	$34.58	$205.52	$162.78	371%
96423	Chemotherapy, infusion method add-on	18.39	105.96	83.92	356%
96422	Chemotherapy, infusion method	47.45	268.11	212.35	348%
90782	Injection, subcutaneous/intramuscular	4.41	24.64	19.52	343%
96414	Chemotherapy, infusion method add-on, (prolonged)	51.50	269.59	213.52	315%
90788	Injection of antibiotic	4.78	22.18	17.57	268%
96425	Chemotherapy, infusion method	54.81	245.44	194.39	255%
96408	Chemotherapy, push technique	37.52	154.76	122.57	227%
96530	System pump refill and main	40.46	152.29	120.61	198%
96410	Chemotherapy, infusion method	59.22	217.35	172.14	191%
96420	Chemotherapy, push technique	48.19	150.81	119.45	148%
90780	IV infusion therapy, 1 hour	42.67	117.79	93.29	119%
90784	Injection, intravenous	18.39	49.78	39.42	114%
96400	Chemotherapy, subcutaneous/intramuscular	37.52	64.07	50.74	35%
96405	Intralesional chemotherapy administration	81.66	107.91	109.53	34%
90781	IV infusion, additional hour	21.70	33.02	26.16	21%
96406	Intralesional chemotherapy administration	123.60	146.36	148.56	20%
96450	Chemotherapy, into central nervous system	303.48	346.49	351.69	16%
96542	Chemotherapy injection	200.85	220.66	223.97	12%
96445	Chemotherapy, intracavitary	376.68	403.99	410.05	9%
96440	Chemotherapy, intracavitary	382.94	408.10	414.22	8%
96412	Chemotherapy, infusion method add-on	44.14	48.30	38.26	-13%

Source: GAO analysis of Medicare payment rates in 2003 and 2004, and estimated rates for 2005.

[a]Obtained from the 2004 Medicare physician fee schedule.

Total Estimated Medicare Payments to Oncologists for Chemotherapy Administration Services, 2003-2005

2003 estimated payments (millions)	2004 estimated payments (millions)	2005 estimated payments (millions)[a]	Percent change 2003-2005
$302	$876	$694	130%

Source: GAO analysis of Medicare payment rates in 2003 and 2004, and estimated rates for 2005.

Note: Payment estimates are based on 2003 utilization data, which are assumed to be 96 percent complete. We adjusted these data to estimate 100 percent of billing for the year.

[a]These estimates do not reflect Medicare billing changes that CMS announced on November 15, 2004. In its comments on a draft of this report, CMS estimated that these changes will increase Medicare payments to oncologists for chemotherapy administration in 2005. For example, CMS estimated that payments will increase 5 percent due to revised and added billing codes and 15 percent due to a nationwide demonstration project related to the care and assessment of cancer patients.

Total Estimated Medicare Practice Expense Payment-to-Cost Ratios for Chemotherapy Administration Services Provided by Oncologists Relative to the Average for All Services Provided by All Specialties, 2003-2005

	2003	2004	2005
Payment-to-cost ratio[a] for chemotherapy administration services relative to the average of all services by all specialties based on:			
- Cost estimates including outliers[b]	0.51	1.24	0.97
- Cost estimates excluding outliers[c]	0.70	1.70	1.33

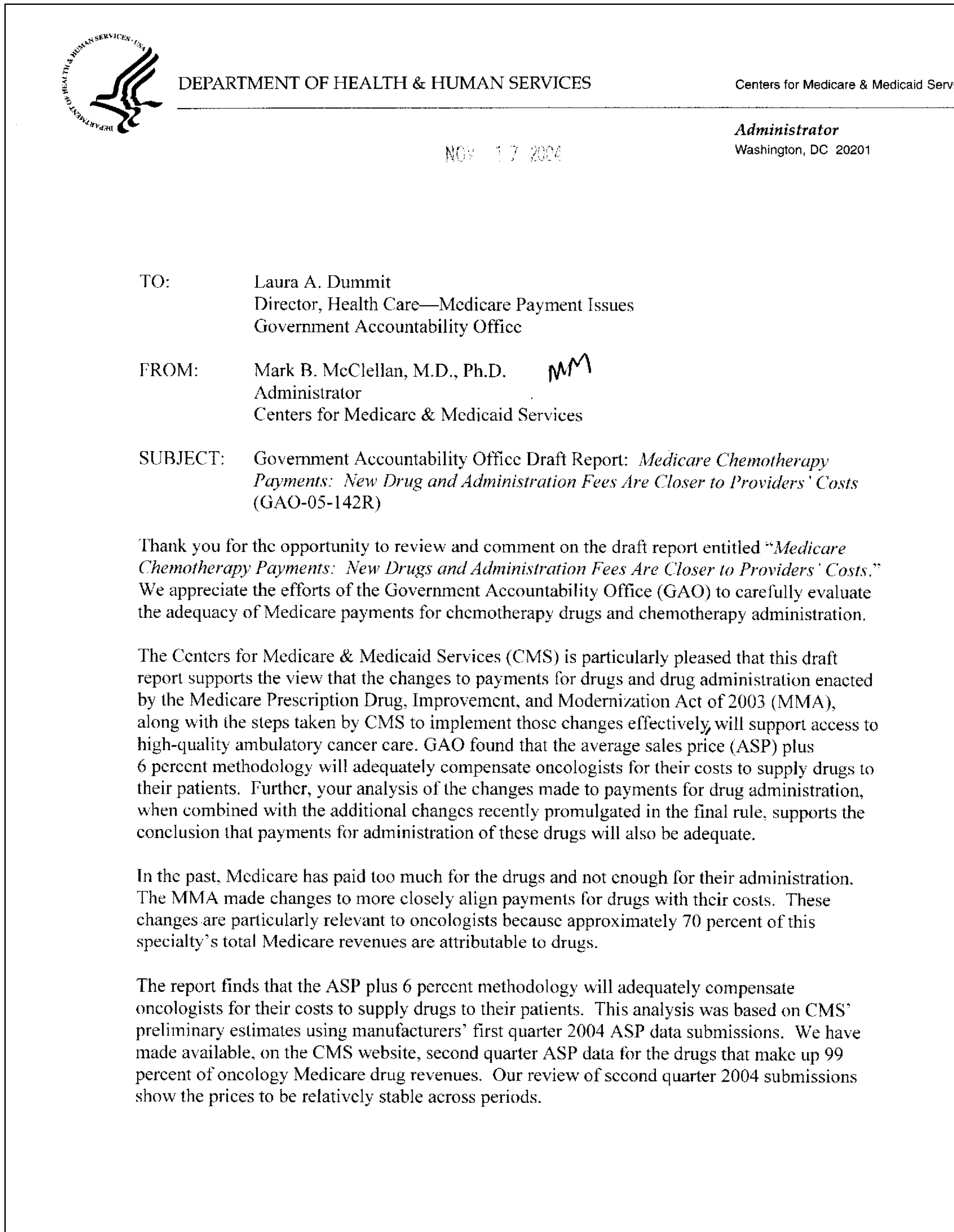
Source: GAO analysis of Medicare payment rates in 2003 and 2004, and estimated rates for 2005.

[a]Payment-to-cost ratios depict the relationship between payments and costs for chemotherapy administration services relative to the average of payments and costs for all services provided by all specialties. Ratios above one indicate that payments for chemotherapy administration cover a greater share of costs than the average for all services, and ratios below one indicate that payments for chemotherapy administration cover a lower share of costs than the average for all services.

[b]Cost estimate based on ASCO's hourly estimate of $189.00.

[c]Cost estimate based on CMS's contractor estimate of $139.52 per hour after removing the high-cost outliers from ASCO's data.

Comments from the Centers for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Servic

Administrator
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TO: Laura A. Dummit
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Government Accountability Office

FROM: Mark B. McClellan, M.D., Ph.D. MM
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Centers for Medicare & Medicaid Services

SUBJECT: Government Accountability Office Draft Report: *Medicare Chemotherapy Payments: New Drug and Administration Fees Are Closer to Providers' Costs* (GAO-05-142R)

Thank you for the opportunity to review and comment on the draft report entitled "*Medicare Chemotherapy Payments: New Drugs and Administration Fees Are Closer to Providers' Costs.*" We appreciate the efforts of the Government Accountability Office (GAO) to carefully evaluate the adequacy of Medicare payments for chemotherapy drugs and chemotherapy administration.

The Centers for Medicare & Medicaid Services (CMS) is particularly pleased that this draft report supports the view that the changes to payments for drugs and drug administration enacted by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), along with the steps taken by CMS to implement those changes effectively, will support access to high-quality ambulatory cancer care. GAO found that the average sales price (ASP) plus 6 percent methodology will adequately compensate oncologists for their costs to supply drugs to their patients. Further, your analysis of the changes made to payments for drug administration, when combined with the additional changes recently promulgated in the final rule, supports the conclusion that payments for administration of these drugs will also be adequate.

In the past, Medicare has paid too much for the drugs and not enough for their administration. The MMA made changes to more closely align payments for drugs with their costs. These changes are particularly relevant to oncologists because approximately 70 percent of this specialty's total Medicare revenues are attributable to drugs.

The report finds that the ASP plus 6 percent methodology will adequately compensate oncologists for their costs to supply drugs to their patients. This analysis was based on CMS' preliminary estimates using manufacturers' first quarter 2004 ASP data submissions. We have made available, on the CMS website, second quarter ASP data for the drugs that make up 99 percent of oncology Medicare drug revenues. Our review of second quarter 2004 submissions show the prices to be relatively stable across periods.

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We recognize that some variation exists in the drug acquisition cost among different physician practices. A recent study by the American Society of Clinical Oncology (ASCO) found considerable variation in drug prices between small and large practices and low and high volume purchasers. Contrary to expectations, large practices and high-volume purchasers do not consistently get better prices for drugs. We plan to work with and support oncology groups in identifying ways in which oncology practices, particularly small practices and rural practices, can obtain the most favorable drug prices possible.

In addition, the report projected oncologists' 2005 Medicare practice expense payments will be adequate to continue providing cancer chemotherapy services in their offices. . The report reached this conclusion even though it did not reflect the further increases in drug administration payments in our final rule published November 15, 2004. For example, in response to the MMA mandate that the existing drug administration codes be promptly evaluated to ensure they accurately represent physicians' cost for these services, the American Medical Association's Current Procedural Terminology Editorial Panel undertook an expeditious review of these codes. The changes recommended as a result of this review were included in the final rule. We estimate a net increase in Medicare payments due to these changes of 5 percent.

We also announced several other important policy changes in the final rule that are not reflected in the analysis in the report. Currently, injections furnished on the same day as other physician fee schedule services are bundled into payment for the medical visit and not paid separately. Beginning with 2005, we are allowing separate payment for injections furnished on the same day as other physician fee schedule services. We estimate payments to oncologists will increase by 3 percent due to this new policy.

In addition, the final rule indicates that we are clarifying that existing CPT codes can be used to report the considerable physician effort that may be required to monitor and attend to patients who develop significant adverse reactions to chemotherapy drugs, or otherwise have complications in the course of chemotherapy treatment. Some physicians are not aware of their ability to bill for these services. Billing for a significant adverse reaction to chemotherapy drugs would be in addition to the billing normally allowed for the physician's care of a cancer patient. With input from physician organizations, Medicare will soon issue a coding guidance to assure appropriate billing for these services, providing additional revenues for practices that have not used these billing codes appropriately.

Also in the final rule, we announced a one-year nationwide demonstration project during 2005. Under the demonstration, an additional payment of $130 per encounter will be paid to physicians treating cancer patients who submit three codes for patient assessment elements. The demonstration project is projected to increase payments by 15 percent. These changes will more than offset the reduction in the MMA transition payments from 29 percent in 2004 to 3 percent in 2005.

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While this report provides further evidence that there should be minimal disruption in the care provided to cancer patients resulting from the MMA changes, nevertheless we plan to monitor our utilization patterns during 2005 for shifts or changes once these payment policy changes are implemented. In addition, the MMA requires the Medicare Payment Advisory Commission to study how these changes affect other specialties.

Once again, thank you for the opportunity to review this draft report. If you have any questions or require additional information, please contact Beth French of my staff at (410) 786-4040.

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