

GAO

Report to the Chairman, Subcommittee
on Health, Committee on Ways and
Means, House of Representatives

September 2004

MEDICARE

Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services



G A O

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Highlights of [GAO-04-772](#), a report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives.

Why GAO Did This Study

Under the Medicare hospital outpatient prospective payment system (OPPS), hospitals receive a temporary additional payment for certain new drugs and devices while data on their costs are collected. In 2003, these payments expired for the first time for many drugs and devices. To incorporate these items into OPPS, the Centers for Medicare & Medicaid Services (CMS) used its rate-setting methodology that calculates costs from charges reported on claims by hospitals. At that time, some drug and device industry representatives noted that payment rates for many of these items decreased and were concerned that hospitals may limit beneficiary access to these items if they could not recover their costs. GAO was asked to examine whether the OPPS rate-setting methodology results in payment rates that uniformly reflect hospitals' costs for providing drugs and devices, and other outpatient services, and if it does not, to identify specific factors of the methodology that are problematic.

What GAO Recommends

GAO recommends that the Administrator of CMS collect data on excluded claims and analyze variation in hospital charge setting to determine if the OPPS payment rates uniformly reflect hospitals' costs of providing outpatient services, and, if they do not, to make appropriate changes to the methodology. CMS stated that it will consider GAO's recommendations.

www.gao.gov/cgi-bin/getrpt?GAO-04-772.

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

MEDICARE

Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services

What GAO Found

The rate-setting methodology used by CMS may result in OPSS payment rates for drugs, devices, and other services that do not uniformly reflect hospitals' costs of providing those services. Two areas of the methodology are particularly problematic. The hospital claims for outpatient services that CMS uses to calculate hospitals' costs and set payment rates may not be a representative sample of all hospital outpatient claims. For Medicare payment purposes, an outpatient service consists of a primary service and the additional services or items associated with the primary service, referred to as packaged services. CMS has excluded over 40 percent of multiple-service claims, claims that include more than one primary service along with packaged services, when calculating the cost of all OPSS services, including those with drugs and devices. It excludes these multiple-service claims because, when more than one primary service is reported on a claim, CMS cannot associate each packaged service with a specific primary service. Therefore, the agency cannot calculate a total cost for each primary service on that claim, which it would use to set payment rates. The data CMS has available do not allow for a determination of whether excluding many multiple-service claims has an effect on OPSS payment rates. However, if the types or costs of services on excluded claims differ from those on included claims, the payment rates of some or all services may not uniformly reflect hospitals' actual costs of providing those services. In addition, in calculating hospitals' costs, CMS assumes that, in setting charges within a specific department, a hospital marks up the cost of each service by the same percentage. However, based on information from 113 hospitals, GAO found that not all hospitals use this methodology: charge-setting methodologies for drugs, devices, and other outpatient services vary greatly across hospitals and across departments within a hospital. CMS's methodology does not recognize hospitals' variability in setting charges, and therefore, the costs of services used to set payment rates may be under- or overestimated.

Number and Percentage of Hospitals that Reported Methods to Mark Up Drug and Device Charges, 2003

	Drugs		Devices	
	Number	Percentage	Number	Percentage ^a
Same percentage for all items	40	43	39	46
Graduated percentage, higher for low-cost items	33	36	39	46
Graduated percentage, lower for low-cost items	6	7	4	5
Other	13	14	3	4

Source: GAO.

^aPercentage of total hospitals does not total 100 percent due to rounding.

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Abbreviations

AAMC	Association of American Medical Colleges
ACCC	Association of Community Cancer Centers
AdvaMed	Advanced Medical Technology Association
AHA	American Hospital Association
APC	ambulatory payment classification
AWP	average wholesale price
BIO	Biotechnology Industry Organization
CMS	Centers for Medicare & Medicaid Services
FAH	Federation of American Hospitals
HCPCS	Healthcare Common Procedure Coding System
PhRMA	Pharmaceutical Research and Manufacturers of America
PPS	prospective payment system
OPPS	outpatient prospective payment system

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United States Government Accountability Office
Washington, D.C. 20548

September 17, 2004

The Honorable Nancy L. Johnson
Chairman
Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Chairman Johnson:

Since 2000, hospitals have been paid fixed, predetermined amounts under a prospective payment system (PPS) for outpatient services delivered to Medicare beneficiaries. By paying hospitals under a PPS, Medicare seeks to encourage them to operate efficiently, as they retain the difference if their payments exceed their costs of providing necessary services. However, unlike most other Medicare PPSs, where each payment amount is designed to cover the combined costs of a large bundle of services, the outpatient prospective payment system (OPPS) is more like a fee schedule and pays a designated rate for each outpatient service provided to a beneficiary.

By law, the initial 2000 OPPS rates were based on hospitals' 1996 median costs.¹ During the development of OPPS, the anticipated use of 1996 data prompted concerns that the costs of new technology items, such as drugs, biologicals,² and devices, first used after 1996 would not be represented in the 2000 payment rates and that hospitals might not provide the newest technology because of a perceived shortfall in payment. Accordingly, Congressional concerns were raised that beneficiaries might lose access to some of these items upon implementation of the payment system.

The Centers for Medicare & Medicaid Services (CMS),³ the agency that administers Medicare, sets OPPS payment rates by using charges hospitals report to CMS for the outpatient services they provide. The agency has used this methodology since setting the 2000 rates. CMS converts each hospital's charge to that hospital's cost for each service using a specific

¹ The Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4523, 111 Stat. 251, 445 (1997).

² In this report, we use the term "drugs" to refer to both drugs and biologicals.

³ In July 2001, the agency's name was changed from the Health Care Financing Administration to CMS.

adjustment for each of the hospital's departments. Under OPPS, an outpatient service consists of a primary service and its packaged services, the additional services or items associated with the primary service. For example, the surgical insertion of a pacemaker, a primary service, includes packaged services such as operating and recovery room services, anesthesia, and surgical and medical supplies, including the pacemaker. CMS combines the costs of the primary service and packaged services to calculate a total cost for that primary service. It assigns primary services to ambulatory payment classification (APC) groups and calculates a payment rate from the costs of the services in that group. An APC may consist of one primary service, but more often consists of two or more primary services with clinical and cost similarity. All primary services assigned to one APC are paid the same rate.

In response to concerns that the 1996 data that would be used to set the 2000 OPPS payment rates did not include cost data for new drugs and devices first used after 1996, in 1999, the Congress required that a payment be made for a temporary period, in addition to the OPPS amount, for certain drugs and devices used in the delivery of outpatient services.⁴ New drugs and devices are eligible to receive these temporary additional payments, known as pass-through payments, for 2 to 3 years depending on when their eligibility first began and when cost data become available to incorporate these items into OPPS as either a primary or packaged service. These temporary payments for pass-through drugs generally are equal to 95 percent of the average wholesale price (AWP),⁵ and the temporary payments for pass-through devices are equal to CMS's calculation of the hospital's cost for the device.

In 2003, the first year for which pass-through eligibility expired for any drugs or devices, 236 drugs and 95 categories of devices⁶ were incorporated

⁴ The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113, App. F, § 201(b), 113 Stat. 1501A-321, 1501A-337 (1999).

⁵ Often described as a "sticker price" or "list price," AWP is the average price that a manufacturer suggests wholesalers charge pharmacies.

⁶ Devices were initially eligible for pass-through payments based on the individual device. Effective April 1, 2001, devices are eligible for pass-through payments based on device categories, with an individual device eligible if it meets a category description.

into OPPS.⁷ Of these drugs and devices, CMS designated 115 of the drugs primary services and the remaining 121 drugs and all devices packaged services. While those drugs that became primary services have assigned payment rates, the packaged drugs and devices do not. At the time CMS made the designations, some drug and device and hospital industry representatives noted that in basing the payment for these items on hospitals' costs, Medicare payments for many had declined significantly. The drug and device industry representatives were concerned that if hospitals could not recover their costs through OPPS payments, hospitals would not purchase these items—in essence, limiting beneficiary access to the products. Some hospital association representatives were concerned that certain types of hospitals may provide a higher number of services associated with drugs and devices, such as cancer center hospitals providing chemotherapy services or teaching hospitals performing cardiac procedures involving devices, and therefore may be disproportionately affected by payment rate decreases for these items. Furthermore, the decrease in payment rates for drugs and devices led to broader concerns about how CMS ensures that OPPS payment rates for all services reflect hospitals' costs.

You asked us to examine these issues. Specifically, we (1) describe how payment rates changed for those drugs and devices whose pass-through eligibility expired in 2003 and 2004, (2) determine whether a particular type or types of hospitals provide a disproportionate number of Medicare outpatient services associated with drugs and devices, and (3) examine whether the OPPS rate-setting methodology results in payment rates that uniformly reflect hospitals' costs for providing drugs and devices, as well as all other outpatient services, to beneficiaries, and if it does not, to identify specific factors of the methodology that are problematic.

⁷ Since this group included all drugs and devices eligible over a 4-year period (from January 1, 1997 through January 1, 2001), many more items expired in 2003 than are expected to expire in any subsequent year.

To address these objectives, we analyzed 2003 and 2004⁸ OPPS payment rates and the 2003 and 2004 AWP for former pass-through drugs that are primary services, which we refer to as separately paid drugs. The remaining drugs and all devices were packaged. Therefore, no identifiable 2003 or 2004 payment rate for these items exists and we could not analyze any payment rate change. We also analyzed the Medicare hospital claims, the bills hospitals submit to CMS for payment, that were used to set the 2003 OPPS rates.⁹ These claims were the latest data available at the time of our analysis, and we determined they were reliable for our purposes. From the claims data, we identified the outpatient services most often associated with drugs or devices.¹⁰ We determined whether any hospital type provided a disproportionate number of these outpatient services, such as hospitals with and without an outpatient cancer center or major teaching status, with major teaching hospitals defined as those having an intern/resident-to-bed ratio of 0.25 or more. We also analyzed hospitals by their urban/rural location and by their volume of outpatient services. We analyzed information from 113 hospitals on how they set their charges for drugs, devices, and other outpatient services. Of these hospitals, we interviewed officials from 5, received information from another 50 through association and industry representatives who gathered the information on our behalf, and received information from another 58 who were contacted by 7 state hospital associations in geographically diverse areas on our behalf. Because these 113 hospitals are not statistically representative of all hospitals, we cannot generalize our results to other hospitals. Finally, we spoke with officials at CMS, individual hospitals, hospital associations, drug and device manufacturers, and trade associations representing manufacturers of drugs and devices. We also spoke with consultants who advise hospitals on setting charges for their services. Our methodology is detailed in appendix I. We conducted our work from March 2003 through

⁸ In our analysis, we used the 2004 OPPS payment rates set by CMS in the November 7, 2003 final rule, which were based on hospital costs and hospital outpatient claims. 68 *Fed. Reg.* 63,398 (2003). These rates do not reflect provisions that limited the amount of fluctuation between the 2003 and 2004 rates that were implemented on January 1, 2004 as a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. We did not analyze the updated rates because they were not based on hospital costs or hospital outpatient claims. Pub. L. No. 108-173, § 621, 117 Stat. 2066, 2307 (2003).

⁹ These claims are for services performed from April 1, 2001 through March 31, 2002.

¹⁰ We analyzed all outpatient drugs that were individually identified in the outpatient claims data, not only the drugs classified as pass through. We could analyze only pass-through devices because these devices were individually identified in the outpatient claims, while other devices were not.

August 2004 in accordance with generally accepted government auditing standards.

Results in Brief

The OPPS payment rates of former pass-through, separately paid, drugs were generally lower than the pass-through payment rate, but the payment rates of former pass-through drugs and devices that were packaged cannot be evaluated, as these items are not assigned a distinct payment rate. The payment rates for the 115 of 236 former pass-through drugs that expired from pass-through eligibility in 2003 and became separately paid drugs almost universally decreased from the pass-through payment rate of 95 percent of AWP. Because the remaining 121 pass-through drugs and the devices in the 95 pass-through device categories were packaged and are not assigned to an APC, we cannot evaluate any payment rate changes for these items. In 2003, over 90 percent, and in 2004, 100 percent, of former pass-through drugs that CMS designated as separately paid drugs had payment rates lower than 95 percent of AWP. In both years, the payment rates were often considerably lower than AWP, but decreases varied substantially. For example, although the 2003 median drug payment rate was 55 percent of AWP, one drug had a 2003 payment rate about 7 percent of AWP, while another had a 2003 payment rate about 94 percent of AWP.

No type of hospital provided a disproportionate number of Medicare outpatient services associated with certain drugs and devices; in 2001, these outpatient services as a percentage of total Medicare outpatient services varied little among different hospital types. For example, chemotherapy administrations—the outpatient services most frequently associated with the use of drugs—accounted for an average of 1.8 percent of all hospitals' total number of Medicare outpatient services. Chemotherapy administration services accounted for an average of 2.0 percent of cancer center hospitals' and 1.8 percent of noncancer center hospitals' total Medicare outpatient services. Cardiac procedures—the outpatient services most frequently associated with the use of devices—accounted for an average of 0.4 percent of all hospitals' total number of Medicare outpatient services. Similarly, these cardiac procedures accounted for an average of 0.4 percent of both major teaching and all other hospitals' total Medicare outpatient services.

The OPPS rate-setting methodology used by CMS may result in APC payment rates for drugs, devices, and other outpatient services that do not uniformly reflect hospitals' costs of providing those services. Two areas of the methodology are particularly problematic. First, the claims that CMS

uses to calculate hospitals' costs and set payment rates may not be a representative sample of hospital claims, as CMS has excluded over 40 percent of multiple-service claims, claims that include more than one primary service as well as packaged services, when calculating the cost of all OPSS services, including those with drugs and devices. It excludes these multiple-service claims because outpatient claims list all the services delivered during a visit and do not provide a link between primary and packaged services. Because CMS cannot associate each packaged service on the claim with one of the primary services listed on the claim, the agency cannot calculate a total cost for each primary service on that claim. The data CMS has available do not allow for the determination of whether excluding a sizable percentage of the multiple-service claims has an effect on OPSS payment rates. However, if the types or costs of services on excluded claims differ from the types or costs of services on included claims, the payment rates of some or all APCs will not uniformly reflect hospitals' costs of providing those services. Second, in calculating hospitals' costs, CMS assumes that, in setting charges within a specific department, a hospital marks up the cost of each service by the same percentage. However, many hospitals do not use this methodology; charge-setting methodologies for drugs, devices, and other outpatient services vary greatly both across hospitals and departments of a hospital. CMS's methodology does not recognize hospitals' variability in setting charges. This may lead to an under or overestimation of hospitals' costs for certain services. As these costs are used to set payment rates, payment rates may not uniformly reflect hospitals' costs.

We recommend that the Administrator of CMS gather the necessary data and perform an analysis of the types and costs of services on excluded multiple-service claims to determine if they are different from the types and costs of services on the claims it includes in setting OPSS rates. The Administrator should also analyze the effect that the variation in hospital charge-setting practices has on the rate-setting methodology. Finally, the Administrator should, in the context of the first two recommendations, analyze whether the OPSS rate-setting methodology results in payment rates that uniformly reflect hospitals' costs of the outpatient services they provide to Medicare beneficiaries, and, if it does not, make appropriate changes in that methodology. In commenting on a draft of this report, CMS stated that it has continued to review and refine its OPSS data collection and analysis. CMS stated that it is searching for ways to use more data from multiple-service claims, and it has made efforts in recent rate-setting analyses to include data from more of these claims. We included a discussion of these changes in the draft report. In its comments, CMS

stated that we should recognize that its rate-setting methodology that converts hospital charges to costs using a cost-to-charge ratio does so at the level of an individual hospital department. The draft report noted the fact that cost-to-charge ratios were generally calculated on a department-specific basis; however, we have revised the report to highlight that information throughout. CMS stated that it will consider our recommendations as it continues to assess and refine the rate-setting methodology. Industry representatives who reviewed a copy of this draft generally agreed with the findings, conclusions, and recommendations.

Background

Medicare beneficiaries receive a wide range of services in hospital outpatient departments, such as emergency room and clinic visits, diagnostic services such as x-rays, and surgical procedures. To receive Medicare payment, hospitals report the services they provided to a beneficiary on a claim form they submit to CMS along with their charge for each service. For Medicare payment purposes, an outpatient service consists of a primary service and packaged services, the additional services or items associated with that primary service. CMS assigns each primary service to an APC, which may include other similar primary services, and pays the hospital at the designated APC payment rate, adjusted for variation in local wages. A hospital can receive multiple APC payments for a single outpatient visit if more than one primary service is delivered during that visit.

CMS Methodology for Determining APC Payment Rates

On outpatient claims, hospitals identify the primary services they provided using a Healthcare Common Procedure Coding System (HCPCS)¹¹ code, while they identify packaged services by either specific HCPCS codes or revenue codes that represent general hospital departments or centers, such as “pharmacy,” “observation room,” or “medical social services.” In addition to claims, hospitals submit annual cost reports to CMS that state their total charges and costs for the year and the individual hospital department charges and costs.

As a first step in calculating the OPPS payment rate for each APC, CMS obtains hospital charge data on each outpatient service from the latest

¹¹ The HCPCS is a uniform system of codes used by providers and medical suppliers to report professional services, procedures, and supplies.

available year of outpatient claims. It calculates each hospital's cost for each service by multiplying the charge by a cost-to-charge ratio that is computed from the hospital's most recent cost report, generally on an outpatient department-specific basis. In those instances when a cost-to-charge ratio does not exist for an outpatient department in a given hospital, CMS uses one from a related outpatient department or the hospital's overall cost-to-charge ratio for outpatient department services. The cost of each primary service is then combined with the costs of the related packaged services to calculate a total cost for that primary service. On single-service claims, claims with one primary service, CMS can associate packaged services with the primary service and calculate a total cost for the service (see fig. 1). However, in the case of multiple-service claims, claims with more than one primary service, packaged services and their costs listed on the claim cannot be associated with particular primary services, as the costs of a packaged service may be associated with one or a combination of primary services (see fig. 2). For this reason, CMS excluded all multiple-service claims from rate setting prior to 2003. Beginning with the 2003 payment rates, CMS identified several methods that allowed it to convert some multiple-service claims into single-service claims, and therefore include them in its rate-setting calculations.¹²

¹² For multiple-service claims that have no packaged services, CMS considers each primary service its own single-service claim. Similarly, CMS treats each pathology service on a multiple-service claim as its own single-service claim. If a multiple-service claim contains one primary service together with certain other primary services that CMS states do not typically have packaged services associated with them, such as a chest X-ray or an electrocardiogram, CMS assigns all packaged services to that one primary service and treats it as a single-service claim. In addition, if the claim includes the date for each service and each primary service has a different date, CMS uses the dates of service associated with packaged services listed on the claims to match them to primary services with the same dates of service, and makes each primary service its own single-service claim.

Figure 1: Example of a Single-Service Claim with Packaged Services

Single-Service Claim: This claim has one primary service (emergency department visit). All of the packaged services (pharmacy, supplies) are associated with that primary service. This claim would be included by CMS in setting APC payment rates.

DESCRIPTION	HCPCS	SERVICE DATE	TOTAL CHARGES
Pharmacy		10/2/02	120.00
Supplies		10/2/02	30.00
Emergency department visit	99284	10/2/02	400.00

Source: GAO.

Figure 2: Example of a Multiple-Service Claim with Packaged Services

Multiple-Service Claim: This claim has more than one primary service (emergency department visit and treat humerus fracture) performed on the same date. The packaged services (pharmacy, supplies) may be associated with either or both primary services. This claim would be excluded by CMS in setting the APC payment rates.

DESCRIPTION	HCPCS	SERVICE DATE	TOTAL CHARGES
Pharmacy		10/2/02	120.00
Supplies		10/2/02	30.00
Emergency department visit	99284	10/2/02	400.00
Treat humerus fracture	24538	10/2/02	2000.00

Source: GAO.

After calculating the cost of each primary service assigned to an APC for each hospital claim, CMS arrays the costs for all claims and determines the median cost. To calculate the APC’s weight relative to other APCs, CMS compares the median cost of each APC to the median cost of APC 0601, a mid-level clinic visit, which is assigned a relative weight of 1.00. For example, if the median cost of APC 0601 is \$100 and the median cost of “APC A” is \$50, CMS assigns APC A a relative weight of 0.50.

To obtain a payment rate for each APC, CMS multiplies the relative weight by a factor that converts it to a dollar amount. In addition, CMS annually reviews and revises the services assigned to a particular APC and uses the

new APC assignments and the charges from the latest available outpatient hospital claims to recalibrate the relative weights, and therefore the payment rates.

Expiration of Drug and Device Pass-Through Eligibility

New drugs and devices are eligible to receive temporary pass-through payments for 2 to 3 years, depending on when each drug and device's eligibility began. January 1, 2003 was the first time that pass-through eligibility expired for any drugs or devices. Once pass-through eligibility for these items expires, CMS determines whether they will be considered a primary service and assigned to a separate APC or a packaged service and included with the primary services with which they are associated on a claim.

On January 1, 2003, 236 drugs and on January 1, 2004, 7 drugs expired from pass-through eligibility. For those drugs expiring in 2003, CMS designated any drug with a median cost exceeding \$150 (115 drugs) as a primary service, and each was assigned to its own, separately paid APC. The remaining drugs (121 drugs), those with a median cost less than \$150, were designated as packaged services, that is, their costs were included with the costs of the primary service they were associated with on the claim. CMS stated that many of these latter drugs were likely present on claims with a primary service of drug administration and were therefore packaged with the services assigned to the six drug administration APCs, that is, the three chemotherapy administration and three drug injection and infusion APCs.¹³ For these packaged drugs, although hospitals had previously received two payments, one for the administration of the drug or other primary service and an additional pass-through payment for the drug itself, when eligibility expires, hospitals receive only one payment for both the administration or other primary service and the packaged drug. In 2004, all 7 drugs for which pass-through eligibility expired were designated as primary services and assigned to their own, separately paid APCs.

On January 1, 2003, the devices in 95 device categories, and on January 1, 2004, the devices in 2 device categories, expired from pass-through eligibility; in both years, the devices in all device categories were

¹³ CMS expects that most drug charges would be present on claims that also include the service for the administration of the drug; however, it is possible that drug charges are present on claims with primary services other than an administration and are included in the APCs to which those primary services are assigned.

designated as packaged services and their costs were included with the costs of the primary service they were associated with on the claim. Although hospitals had previously received two payments, one for the procedure associated with the device and an additional pass-through payment for the device, hospitals then received only one payment for both the procedure and its associated device.

Payment Rates Were Generally Lower for Separately Paid Drugs, but Cannot Be Evaluated for Packaged Drugs and Devices

The OPPS payment rates of former pass-through, separately paid drugs were generally lower than the pass-through payment rate, but the payment rates of former pass-through drugs and devices that were packaged cannot be evaluated, as these items are not assigned a distinct payment rate. In 2003, the payment rates for the 115 of 236 former pass-through drugs that were designated as separately paid drugs almost universally decreased from the pass-through payment rates. In 2004, for all 7 former pass-through drugs were designated as separately paid drugs and the payment rates for all 7 decreased. In 2003, for the remaining 121 pass-through drugs and the devices in 95 pass-through device categories and, in 2004, the devices in 2 device categories, all of which were packaged, we cannot evaluate the payment rate changes because individual payment rates were not assigned for these items when they expired from pass-through eligibility.

Payment Rates Generally Decreased For Separately Paid, Former Pass-Through Drugs

In 2003, about half of all drugs for which pass-through eligibility expired (115 of 236) were assigned to their own APC and paid separately. For these drugs, we determined that over 90 percent had payment rates lower than 95 percent of AWP, the pass-through payment rate; the median payment rate was 55 percent of AWP.¹⁴ Individual payment rates were often considerably lower than AWP, but decreases varied substantially. For example, 1 drug had a payment rate of about 7 percent of AWP, while another had a payment rate of about 94 percent of AWP. However, 10 drugs had a payment rate of more than 100 percent of AWP. In addition, payment as a percentage of AWP varied by drug source. The majority of the 113 separately paid drugs that we analyzed were sole-source (70 percent), followed by multi-source

¹⁴ This analysis excludes 2 drugs: 1 for which we were unable to determine a reliable AWP, and 1 for which the payment rate was an extremely high percentage of AWP.

(19 percent), and generic (10 percent).¹⁵ Generic drugs, which were paid the highest percentage of AWP of the three categories, had a median payment rate of 74 percent of AWP, multi-source drugs had a median of 56 percent of AWP, and sole-source drugs had a median of 53 percent of AWP.

In 2004, all seven drugs for which pass-through eligibility expired were assigned to separate APCs. The individual payment rate of each drug was lower than the pass-through rate of 95 percent of AWP, with a median payment rate of 69 percent of AWP. All drugs were sole-source.

Although the decreases in payments for these drugs were often substantial and varied greatly across individual drugs, some level of decrease is expected when pass-through eligibility expires and payments become based on hospital costs instead of AWP, which often exceeds providers' acquisition costs. In 2001, we reported that certain drugs purchased by individual physicians were widely available at costs from 66 to 87 percent of AWP.¹⁶

Packaged Drugs and Devices Do Not Have Distinct Payment Rates

In 2003, the costs of 121 former pass-through drugs and devices in 95 former pass-through device categories were packaged. Because CMS combines the costs of these items with the costs of the primary services with which they are associated on each claim, a specific payment rate for each of these drugs and devices does not exist. However, to indirectly assess the payment rates of packaged drugs and devices, we reviewed the payment rates of the APCs with which CMS stated they were likely packaged. CMS stated that, in 2003, former pass-through drug costs were most likely packaged with the six drug administration APCs. The payment rates for five of the six APCs decreased in 2003, when the costs of packaged former pass-through drugs were included, compared to 2002, when the costs of these drugs were not considered in the rate-setting calculations (see table 1). We are unable to determine why the costs of these APCs decreased because fluctuations in costs for any of the primary or packaged services in these APCs, in addition to the costs of the

¹⁵ Generally, "sole-source" drugs are brand-name drugs produced by only one manufacturer, "multi-source" drugs are drugs with generic equivalents or drugs for which there are two or more competing therapeutically-equivalent brand-name products, and "generic" drugs are not patented and can be produced by many manufacturers.

¹⁶ GAO, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost*, GAO-01-1118 (Washington, D.C.: Sept. 21, 2001).

packaged drug, could have affected the payment rates. However, we would have expected that combining the costs of up to \$150 of packaged former pass-through drugs with the costs of the primary services in these APCs would have increased the 2003 payment rates for more of these APCs as more than half of them are less than \$150.

Table 1: Payment Rates for Drug Administration APCs, 2002-2003

APC	Description	2002	2003	Difference	Percent change
0116	Chemotherapy administration by other technique except infusion	\$46.32	\$40.43	-\$5.89	-13%
0117	Chemotherapy administration by infusion only	205.14	187.98	-17.16	-8
0118	Chemotherapy administration by both infusion and other technique	214.81	286.02	71.21	33
0120	Infusion therapy except chemotherapy	157.80	113.70	-44.10	-28
0352	Level I injections	20.87	11.62	-9.25	-44
0359	Level II injections	91.63	59.12	-32.51	-35

Source: GAO analysis of APC payment rates (67 *Fed. Reg.* 9,556, 9,569, 9,572 (2002); 67 *Fed. Reg.* 66,815, 66,818 (2002)).

To indirectly assess the payment rates of the devices in the 95 device categories expiring from pass-through eligibility in 2003, we reviewed APCs for which CMS determined that device costs made up at least 1 percent of the APC's total cost.¹⁷ We found that the payment rates of these APCs varied substantially between 2002 and 2003, when the former pass-through device costs likely were included. For example, the payment rate of APC 0688 (Revision/Removal of Neurostimulator Pulse Generator Receiver) decreased by 48 percent, while the payment rate of APC 0226 (Implantation of Drug Infusion Reservoir) increased by 94 percent. However, we cannot attribute these fluctuations solely to the packaging of pass-through devices, because changes between 2002 and 2003 in the costs of the primary services and other packaged services assigned to the APCs also could have affected the payment rates.

In 2004, the devices in two device categories expired from pass-through eligibility. The devices in one category were associated with services in

¹⁷ These APCs are identified in 67 *Fed. Reg.* 66,801-2 (2002).

one APC—APC 0674 (Prostate Cryoablation). The payment rate for this APC almost doubled. We were unable to examine the change in payment for the APC or APCs associated with the devices in the other expired pass-through device category because CMS did not identify the APC or APCs into which the costs of the devices in this device category were packaged.

No Type of Hospital Provided a Disproportionate Number of Services Associated with Certain Drugs and Devices

No type of hospital provided a disproportionate number of Medicare outpatient services associated with certain drugs and devices, as these services, as a percentage of total Medicare outpatient services, varied little among hospitals with differences in characteristics such as the presence of an outpatient cancer center, teaching status, urban or rural location, or outpatient service volume.¹⁸

In 2001, outpatient drugs were most often associated with APCs for chemotherapy administration services, and devices in pass-through device categories were most often associated with APCs for cardiac services.¹⁹ We found that chemotherapy administration and cardiac services composed only a small proportion of total Medicare outpatient services for all hospitals (see table 2). In addition, these proportions varied little among different types of hospitals.

¹⁸ We defined “cancer center hospitals” as those hospitals that were members of the Association of Community Cancer Centers as of February 28, 2003, the latest data available when we performed this analysis. We defined teaching status by a hospital’s intern/resident-to-bed ratio. We defined a major teaching hospital as a hospital with an intern/resident-to-bed ratio of 0.25 or more and a hospital without major teaching hospital status having a ratio of less than 0.25.

¹⁹ We analyzed all outpatient drugs identified by a HCPCS code in the outpatient claims data, not only the drugs that had pass-through eligibility. We could analyze only pass-through devices because these devices were specifically identified in the outpatient claims while other devices were not.

Table 2: Percentage of Medicare Outpatient Services by Type for All Hospitals and for Hospitals with Various Characteristics

	Number of hospitals	Chemotherapy administration services as a percent of total Medicare outpatient services	Cardiac services as a percent of total Medicare outpatient services
All hospitals	4,034	1.8	0.4
Cancer center hospitals	555	2.0	0.5
Noncancer center hospitals	3,479	1.8	0.3
Major teaching hospitals	288	2.4	0.4
Hospitals without major teaching hospital status	3,746	1.7	0.4
Urban hospitals	2,493	1.7	0.5
Rural hospitals	1,541	2.3	0.2
Small volume hospitals	1,258	1.0	0.1
Medium volume hospitals	1,840	1.3	0.3
Large volume hospitals	936	2.2	0.5

Source: GAO analysis of CMS data.

Notes: We used hospital outpatient claims from April 1, 2001 through March 31, 2002, the claims CMS used to set the 2003 OPPS rates, applied to hospital categories defined in 2003. We defined “cancer center hospitals” as those hospitals that were members of the Association of Community Cancer Centers as of February 28, 2003, the latest data available when we performed this analysis. We defined a major teaching hospital as a hospital with an intern/resident-to-bed ratio of 0.25 or more and a hospital without major teaching hospital status as a ratio of less than 0.25. We defined the urban or rural location of a hospital using Medicare’s classification of that hospital under OPPS. We defined volume based on the number of outpatient services a hospital provided. Small volume hospitals were those with fewer than 11,000 services, medium volume hospitals were those with at least 11,000 services but fewer than 43,000 services, and large volume hospitals were those with at least 43,000 services.

Payment Rates May Not Uniformly Reflect Hospitals’ Costs

The OPPS rate-setting methodology used by CMS may result in APC payment rates for drugs, devices, and other outpatient services that do not uniformly reflect hospitals’ costs. Two areas of CMS’s methodology are particularly problematic. First, the claims that CMS uses to calculate hospitals’ costs and set payment rates may not be a representative sample of hospital claims, as CMS excluded many multiple-service claims when calculating the cost of OPPS services, including those with drugs and devices. The data CMS has available do not allow for the determination of whether excluding many multiple-service claims has an effect on OPPS payment rates. However, if the types or costs of services on excluded

claims differ from the types or costs of services on included claims, the payment rates of some or all APCs may not uniformly reflect hospitals' costs of providing those services. Second, when calculating hospitals' costs, CMS assumes that, in setting charges within a specific department, a hospital marks up the cost of each service by the same percentage. However, not all hospitals use this methodology, and charge-setting methodologies for drugs, devices, and other outpatient services vary greatly across hospitals and across departments within a hospital. CMS's methodology does not recognize hospitals' variability in setting charges, and, therefore, the costs of services used to set payment rates may be under or overestimated.

CMS May Not Be Using a Representative Sample of Claims to Set Payment Rates

The claims CMS uses to calculate hospitals' costs and set payment rates may not be a representative sample of hospital claims. When calculating the cost of all OPSS services, including drugs and devices, to set payment rates, CMS excluded over 40 percent of all multiple-service claims because CMS could not associate particular packaged services with a specific primary service on these claims.²⁰ Drug and device industry representatives we spoke with raised concerns that certain drugs and devices are often billed on multiple-service claims that are largely excluded from rate setting. For example, they stated that chemotherapy administration and the drugs themselves are typically billed on a 30-day cycle; therefore, one claim likely includes chemotherapy administration and other primary and packaged services and is likely excluded from CMS's rate-setting calculations.²¹ Device industry representatives we spoke with also asserted that multiple-service claims represent more complex, and therefore, potentially costlier, outpatient visits and excluding them from the rate-setting calculations underestimates the actual cost of a service. Because of the structure of the outpatient claim, the data CMS has

²⁰ In 2003 and 2004, CMS used 53 percent of the approximately 20.4 million and 58 percent of the approximately 16.9 million multiple-service claims to set its rates, respectively. In the same years, the exclusion of the multiple-service claims from the analysis resulted in CMS using only 81 and 83 percent of all claims, respectively.

²¹ Beginning in 2004, CMS uses the dates of service associated with packaged services listed on a claim to match them to primary services with the same dates of service to create a single service claim. Thus, claims with only chemotherapy administration and packaged services including drugs, and no other primary services delivered on the same dates, would be included in rate setting, however claims with chemotherapy administration, packaged services, and additional primary services delivered on the same date or dates would be excluded.

available do not allow for the comparison of single-service claims and multiple-service claims to determine whether excluding many multiple-service claims has an effect on OPPS payment rates. It is possible that excluding many multiple-service claims has little or no effect on OPPS payment rates. However, if the types or costs of services on excluded claims differ from the types or costs of services on included claims, the payment rates of some or all APCs may not uniformly reflect hospitals' costs of performing these services.

Rate-Setting Methodology Does Not Account for Variation in Hospital Charge-Setting Practices

The costs of drugs, devices, and other outpatient services that CMS calculates from hospital charges and uses to set payment rates may not uniformly approximate hospitals' costs. CMS multiplies charges by hospital-specific cost-to-charge ratios to calculate hospitals' costs, which decreases the charges by a constant percentage. This methodology is based on the assumption that each hospital marks up its costs by a uniform percentage within each department to set each service's charge. However, we found that not all hospitals use this methodology to establish their charges, and that drug, device, and general charge-setting methodologies vary greatly among hospitals and even among departments within the same hospitals.

We received information from 113 hospitals, although not all hospitals responded to each question. Of the 92 hospitals responding, 40 reported that they mark up all drug costs by a uniform percentage to establish charges, but 33 reported that they mark up low-cost drugs by a higher percentage and high-cost drugs by a lower percentage. Of 85 hospitals responding, 39 reported that they mark up all device costs using a uniform percentage, but 39 reported that they mark up low-cost devices using a higher percentage and high-cost devices using a lower percentage. In addition, 19 hospitals reported using other methods to set drug charges and 7 reported doing so for devices, such as a lower percentage markup for low-cost drugs and devices than for high-cost drugs and devices. (See appendix II for a more detailed description of hospital charge-setting methodologies.)

Because CMS uses the same rate-setting methodology to determine drug and device payment rates as it uses for all other OPPS services, we also asked hospitals about more general charge-setting practices and found that they varied as well. To set base charges for clinic visits, hospitals reported using a wide variety of prices and methods, including cost, market comparisons, and the rates Medicare pays for outpatient services as well as

payment rates for other benefit categories. To mark up clinic visits, 29 of the 45 hospitals responding used a uniform percentage increase; the remaining 16 hospitals reported using a variety of other methods, including using a higher percentage markup for low-cost visits than for high-cost visits.

In addition to variation in charge-setting methodologies among hospitals, variation also can exist within an individual hospital. Hospital consultants told us that a single item can be assigned different charges if it is provided through more than one department within the same hospital.

All 58 hospitals responding reported that they update their charges for inflation; 40 reported they did so annually, 12 did so at other times, and 6 did so both annually and at other times. Of the 58 hospitals that reported updating their charges for inflation, 25 reported that they apply a uniform, across-the-board percentage increase to all their charges, and 4 hospitals reported using both a uniform percentage and another type of increase. The remaining 29 hospitals reported using another method, such as applying an increase only to selected departments within the hospital. In addition, 33 of the 57 hospitals reported that they excluded some charges from these updates. The type of charges they excluded varied widely, but included drug and laboratory charges. The variation in methods hospitals use to update their charges reduces the likelihood that charges will uniformly reflect costs.

Conclusions

CMS's rate-setting methodology may result in OPPS payment rates that do not uniformly reflect hospitals' costs of providing services. We identified two areas of this methodology that are of particular concern because not enough data are currently available to assess their impact. First, CMS excludes many multiple-service claims from its rate-setting calculations. To the extent that the types and costs of services on these claims are different from services on the claims included in the analysis, OPPS payment rates may not reflect hospitals' costs. The current structure of the outpatient claims does not allow for an analysis to determine the effect of these exclusions. Second, in its rate-setting calculations, CMS assumes that each hospital uses a uniform markup percentage to set its charges within each department, although we found that hospitals use a variety of markup methodologies. Therefore, CMS's application of a constant cost-to-charge ratio may not result in an accurate calculation.

Recommendations for Executive Action

We recommend that the Administrator of CMS take the following three actions. First, the Administrator should gather the necessary data and perform an analysis that compares the types and costs of services on single-service claims to those on multiple-service claims. Second, the Administrator should analyze the effect that the variation in hospital charge-setting practices has on the OPPS rate-setting methodology. Third, the Administrator should, in the context of the first two recommendations, analyze whether the OPPS rate-setting methodology results in payment rates that uniformly reflect hospitals' costs of the outpatient services they provide to Medicare beneficiaries, and, if it does not, make appropriate changes in that methodology.

Agency and External Reviewer Comments and Our Evaluation

We received written comments on a draft of this report from CMS (see app. III). We also received oral comments from external reviewers representing seven industry organizations. They included the Advanced Medical Technology Association (AdvaMed), which represents manufacturers of medical devices, diagnostic products, and medical information systems; the American Hospital Association (AHA); the Association of American Medical Colleges (AAMC), which represents medical schools and teaching hospitals; the Association of Community Cancer Centers (ACCC); the Biotechnology Industry Organization (BIO), which represents biotechnology companies and academic institutions conducting biotechnology research; the Federation of American Hospitals (FAH), which represents for-profit hospitals; and the Pharmaceutical Research and Manufacturers of America (PhRMA).

CMS Comments and Our Evaluation

In commenting on a draft of this report, CMS stated that it has continued to review and refine its OPPS data collection and analysis. In responding to our recommendation that CMS gather the necessary data and perform an analysis comparing the types and costs of services on single-service claims to those on multiple-service claims, CMS stated that it is searching for ways to use more data from multiple-service claims, and it has made efforts in recent rate-setting analyses to include data from more of these claims. We noted these efforts in the draft report. CMS noted that there are continuing challenges and costs, to both the federal government and hospitals, to expanding its efforts in this area. In its comments, CMS suggested that an analysis could be done using an algorithm to allocate charges among multiple-service claims, but noted that such an approach could create further distortions in the relative weights. Our recommendation to CMS,

however, is that the agency should gather additional data on the relative costs of services on single and multiple-service claims, rather than continuing to analyze existing data.

In response to our recommendation that CMS analyze the effect of hospital charge-setting practices on the OPSS rate-setting methodology, CMS stated that we should recognize that its rate-setting methodology that converts hospital charges to costs using a cost-to-charge ratio does so at the level of an individual hospital department. The draft report noted the fact that CMS generally calculates cost-to-charge ratios on a department-specific basis; however, we have revised the report to highlight that information throughout. CMS also said that the application of cost-to-charge ratios to charges of a hospital has long been the recognized method of establishing reasonable costs for hospital services and was an important component of the cost-based reimbursement system that was used by Medicare to pay for hospital outpatient services before OPSS was implemented. While we agree that it was an important component of the prior payment system, we believe the implementation of the current payment system has changed the relevance of applying cost-to-charge ratios to determine hospitals' costs. OPSS, rather than reimbursing individual hospitals on the basis of their costs of providing outpatient services, uses costs from individual hospitals to construct a prospective payment system that sets rates for individual services that apply to all hospitals. Finally, CMS stated that the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 specified that cost-to-charge ratios would be used to set payment amounts for brachytherapy sources; however, a discussion of brachytherapy payment is outside of the scope of this report.

In response to our recommendation that CMS analyze whether the OPSS rate-setting methodology results in payment rates that uniformly reflect hospitals' costs of the services they provide to Medicare beneficiaries and make any appropriate changes in the methodology, CMS stated that it will consider our recommendations as it continues to assess and refine the rate-setting methodology. CMS said that it believes it has made great strides on this issue and is continuing to pursue the analyses necessary to create means by which all claims can be used to set the OPSS relative payment weights and rates.

CMS also made technical comments, which we incorporated where appropriate.

Industry Comments and Our Evaluation

Industry representatives generally agreed with the findings, conclusions, and recommendations in the draft report. Comments on specific portions of the draft report centered on three areas: payment rates of former pass-through drugs and devices, provision of services associated with drugs and devices, and CMS's rate-setting methodology.

Several industry representatives commented on our analysis of Medicare payment for former pass-through drugs and devices. AHA stated that although when drugs have expired from pass-through status their payment rates may have decreased, they are now more consistent, relative to costs, with the payment rates for other OPPTS services. PhRMA agreed with our finding that the payment rates for former pass-through drugs and devices that are packaged cannot be evaluated and suggested that we recommend that CMS specifically address this problem.

Industry representatives commented on our analysis of the provision of services associated with drugs and devices among different types of hospitals. ACCC agreed with the percentages of Medicare outpatient services related to chemotherapy administration and cardiac services in the draft report; however, it stated that it believed that these percentages demonstrated that large hospitals provided a disproportionate share of chemotherapy administration. ACCC and AAMC stated that these percentages also demonstrated that major teaching hospitals provided a disproportionate share of chemotherapy administration services. In addition, both groups suggested that we perform other analyses by type of hospital, such as the proportion of total payments, proportion of total services excluding clinic services, or absolute number of services for which chemotherapy administration and cardiac services accounted.

Many of the reviewers addressed our finding that CMS's rate-setting methodology may result in OPPTS payment rates that do not uniformly reflect hospitals' costs. Representatives from AAMC, ACCC, AdvaMed, BIO, and PhRMA agreed with our conclusion that CMS may not be using a representative sample of claims to set payment rates and that CMS's rate-setting methodology does not account for variation in hospital charge-setting practices. Several of these representatives suggested we analyze and discuss other factors that could further skew CMS's calculation of hospital costs, such as its use of incorrect or incomplete claims in rate setting.

Regarding the suggestion that we specifically recommend that CMS address the issue that the payment rates for former pass-through drugs that

are packaged and former pass-through devices cannot be evaluated, we believe that our more general recommendation allows the agency the flexibility to determine the most appropriate analyses for examining the rate-setting methodology.

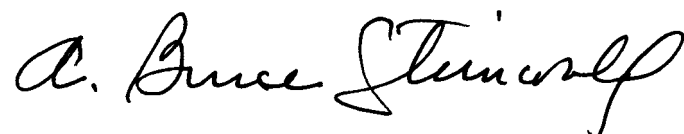
With respect to the comment that the percentages of Medicare outpatient services accounted for by chemotherapy administration demonstrate that certain types of hospitals provide a disproportionate share of these services, we disagree. As noted in the draft report, we found that these percentages differ by type of hospital, but the differences are not substantial, as all types of hospitals provided a relatively small proportion of these services. No type of hospital provided a disproportionately large number of these services. We analyzed the proportion of services, rather than payments as industry representatives suggested, because we believe that is the better analysis for determining whether a certain type of hospital provides a disproportionate share of these services. We did not analyze the proportion of total services except for clinic services or the absolute number these services made up, as we do not believe such an analysis would accurately and comparably reflect potential differences between hospitals for all outpatient services they perform.

The industry representatives also made technical comments, which we incorporated where appropriate.

We are sending a copy of this report to the Administrator of CMS. The report is available at no charge on GAO's Web site at <http://www.gao.gov>. We will also make copies available to others on request.

If you or your staff have any questions, please call me at (202) 512-7119. Another contact and key contributors to this report appear in appendix IV.

Sincerely yours,



A. Bruce Steinwald
Director, Health Care—Economic
and Payment Issues

Scope and Methodology

We analyzed Medicare claims data used by the Centers for Medicare & Medicaid Services (CMS) to set the 2003 outpatient prospective payment system (OPPS) payment rates. In addition, we analyzed drug average wholesale prices (AWPs), drug sources (sole-source, multi-source, or generic), and OPPS payment rates obtained from CMS. We interviewed officials at CMS and representatives from the American Hospital Association, Association of American Medical Colleges, Association of Community Cancer Centers (ACCC), Federation of American Hospitals, Greater New York Hospital Association, as well as from one large hospital system, one large hospital alliance, and five individual hospitals. In addition, we spoke with representatives from the Advanced Medical Technology Association, Biotechnology Industry Organization, California Healthcare Institute, Pharmaceutical Research and Manufacturers of America, as well as from seven drug manufacturers and three device manufacturers. We also spoke with consultants that advise hospitals on setting their charges.

To compare payment for drugs to previous pass-through payments, we relied on information provided by CMS on drug sources and 2003 and 2004 drug payment rates, and on CMS's calculations of the AWPs for these drugs, which we supplemented with our own calculations. From CMS, we obtained the drug source and the payment rate for the 115 drugs and the 7 drugs whose pass-through eligibility expired as of January 1, 2003 and January 1, 2004, respectively, that were assigned to separate ambulatory payment classification (APC) groups. We used Medicare's January 2003 and January 2004 Single Drug Pricer files to determine the 2003 and 2004 AWPs, respectively, for most of the drugs. For the 37 drugs that were not included in the 2003 Single Drug Pricer file, we used the *2002 Drug Topics Red Book*, published by Thomson Medical Economics, to calculate their AWPs. For the 2 drugs that were not in the 2004 Single Drug Pricer file, we used the *2003 Drug Topics Red Book*, published by Thomson PDR, to calculate their AWPs. We calculated payment rates as a percentage of AWP for all drugs in 2003 and 2004. From our 2003 analysis, we excluded 1 multi-source drug for which we calculated an AWP from the *2002 Drug Topics Red Book* that was inconsistent with the 2002 AWP CMS provided to us and another multi-source drug with an AWP of \$0.34, but a payment rate of almost 29,000 percent of that amount.

To determine whether a particular type or types of hospitals provide a disproportionate number of outpatient services associated with drugs and devices, we used the outpatient claims file that CMS used to calculate the

2003 OPPS payment rates.¹ To perform our own data reliability check of this file, we examined selected services to determine the reasonableness of their frequency in the data set, given the population of the beneficiaries receiving services and the setting in which they are delivered. We determined the data were reasonable for our purposes.

Using the claims, we determined which outpatient services were most often associated with drugs and devices and found that drugs were most often associated with chemotherapy administration services and devices were most often associated with cardiac services. Then, also using the claims, we compared proportions of chemotherapy administration and cardiac services for all hospitals, as well as for cancer center and noncancer center hospitals, major teaching and other hospitals, urban and rural hospitals, and hospitals with different outpatient service volumes.² We included only those hospitals identified in CMS's 2003 OPPS impact file, a data file CMS constructs to analyze projected effects of policy changes on various hospital groups, such as urban and rural hospitals. We excluded hospitals with fewer than 1,100 total outpatient services, or approximately 3 outpatient services per day, as we believe such hospitals are not representative of most hospitals with outpatient departments. We defined cancer center hospitals as those hospitals that were members of ACCC as of February 28, 2003, the latest data available when we performed this analysis. We obtained the membership list from the ACCC. Using the September 2002 Medicare Provider of Services file and information obtained directly from the ACCC, we determined the Medicare provider numbers of ACCC members to identify claims billed by these hospitals. We defined major teaching hospitals as those hospitals having an intern/resident-to-bed ratio of 0.25 or more. We defined the urban or rural location of a hospital based on the urban/rural location indicator in the Medicare hospital OPPS impact file from calendar year 2003. We defined volume based on the number of services a hospital provided, also as

¹ This data file contains claims for services performed from April 1, 2001 through March 31, 2002.

² For both chemotherapy administration and cardiac services, we included in our analysis the procedure or administration codes associated with those services. We also included any chemotherapy or cardiac drugs that were assigned to their own APC for payment in 2003. We identified only separately paid drugs, and did not include packaged drugs, because the structure of the data file would have counted the packaged codes twice in our analysis – once with the procedure code and again if they were also listed separately on the claim. For the same reason we excluded all of the device codes from our analysis, as all devices that lost pass-through eligibility were packaged in 2003.

indicated in the impact file. Small volume hospitals were those with fewer than 11,000 services, medium volume hospitals were those with at least 11,000 services but fewer than 43,000 services, and large volume hospitals were those with at least 43,000 services.

We interviewed representatives from hospitals, hospital associations, and drug and device manufacturers and the associations that represent them to obtain information about hospital charging practices. We received information on charge-setting practices from 5 hospitals whose officials we interviewed. We indirectly received information from 50 other hospitals through association and industry representatives with whom we spoke. Finally, we contacted seven state hospital associations in geographically diverse areas not well represented in our previous sample to identify their members' charging practices. Some hospitals responded directly to us and others responded to their state association, which forwarded the responses to us. We received responses from 58 hospitals. The 113 hospitals from which we received information are not a statistically representative sample of all hospitals.

We conducted our work from March 2003 through August 2004 in accordance with generally accepted government auditing standards.

Summary of Hospital Charge-Setting Methodologies

We received information from 113 hospitals, although not all hospitals responded to each question. Hospitals reported using a variety of methods to set the base charges for their clinic visit services (see table 3). To set the base charges for drugs, 25 of 57 hospitals responding reported that they used acquisition cost, 30 used the drug's average wholesale price (AWP), and 2 used a combination of acquisition cost and AWP. To set the base charges for devices, 55 of 57 hospitals responding reported that they used acquisition cost. After setting base charges, 29 of 45 hospitals responding reported that they marked up all of their clinic visit services by the same percentage increase, although they reported using a variety of other methods as well. To mark up base charges for drugs and devices, most hospitals responding used either the same percentage for all drugs and for all devices, or used a graduated percentage markup, marking up low-cost items by a higher percentage (see table 4).

Table 3: Number and Percentage of Hospitals that Reported Methods for Setting Base Charges for Clinic Visit Services, 2003

	Number	Percentage
Cost of visit	13	29
Comparable charges in market	10	22
Medicare physician fee schedule	8	18
Cost of visit and comparable charges in market	4	9
Unspecified Medicare payment	3	7
Outpatient prospective payment system amount with an adjustment	1	2
Cost of visit and Medicare physician fee schedule	1	2
Unspecified Medicare payment and comparable charges	1	2
Other	4	9

Source: GAO.

Table 4: Number and Percentage of Hospitals that Reported Methods to Mark Up Drug and Device Charges, 2003

	Drugs		Devices	
	Number	Percentage	Number	Percentage ^a
Same percentage for all items	40	43	39	46
Graduated percentage, higher for low-cost items	33	36	39	46
Graduated percentage, lower for low-cost items	6	7	4	5
Other	13	14	3	4

Source: GAO.

^aPercentage of total hospitals responding does not total 100 percent due to rounding.

In addition, 24 of the 57 hospitals responding reported that they include nonproduct costs as a portion of their drug charges, and 25 of 57 responding reported that they include nonproduct costs as a portion of their device charges. The most common nonproduct costs included were administrative and overhead costs. Of the 24 including nonproduct costs in drug charges, 12 reported that they do so by adding an additional percentage of the drug acquisition cost to the drug charge. Of the 25 including nonproduct costs in device charges, 16 reported that they do so by adding an additional percentage of the device acquisition cost to the device charge. However, the amount of the nonproduct costs as a percentage of the charges varied widely among hospitals. Of the 24 hospitals including nonproduct costs in drug charges, 16 reported that the amount varied by the route of administration for the drug, such as intravenous or intramuscular administration.

Of the 58 hospitals responding, all reported that they update their charges for inflation; 40 reported they did so annually, 12 did so at other times, and 6 did so both annually and at other times. While many used a standard across-the-board percentage increase to update their charges, the majority used other methods. In addition, 33 of the 57 hospitals responding reported that they exclude certain charges from these updates. The types of services whose charges they excluded, such as drug, laboratory, and room charges, varied widely. Finally, 49 of 58 hospitals responding reported that they periodically review all their charges.

Comments from the Centers for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: AUG 19 2004

TO: A. Bruce Steinwald
Director, Health Care – Economic
and Payment Issues

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator *MM*

SUBJECT: Government Accountability Office (GAO) Draft Report: *MEDICARE: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services (GAO-04-772)*

Thank you for the opportunity to review and comment on the draft report. We appreciate the interest of the House of Representatives Subcommittee and the efforts of GAO in the methodology used to set rates under the Medicare Outpatient Prospective Payment System (OPPS).

As required by the Balanced Budget Act of 1997, the Centers for Medicare & Medicaid Services (CMS) implemented in August 2000 a new prospective payment system to pay for most types of Medicare services provided in hospital outpatient departments. The new system is based on ambulatory payment classifications (APCs) that are groupings of clinically similar services that require similar resources. The relative weights and payments assigned to the APCs for the first several years of the OPPS were based on an analysis of hospital outpatient claims under the prior reasonable cost-based methodology.

Beginning with the update for calendar year 2003, the relative weights for most APCs have been based on hospital claims submitted and paid under the new system. The CMS establishes a median cost for each APC by applying a cost-to-charge ratio derived from hospital cost reports to the charges on the claims. The median cost for each APC is then compared to the median cost for the mid-level clinic visit, one of the most frequently performed OPPS services, in order to establish the relative weight for each APC. Excluded from payment under the OPPS, and, therefore, excluded from consideration in setting OPPS rates are such services as services provided under Medicare's physician fee schedule, and clinical laboratory services paid under the clinical laboratory fee schedule.

Since the implementation of the OPPS, CMS has continued to review and refine its data collection and analysis. For example, in the first year, CMS did not have the capability to analyze multiple procedure claims. As a result, 40 percent of outpatient claims were excluded

Appendix III
Comments from the Centers for Medicare &
Medicaid Services

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from the weight-setting process. In the past 2 years, CMS has made significant improvements in the use of multiple procedure claims.

Meanwhile, payment rates for certain items, such as drugs (and for 2003, devices of brachytherapy) that have been priced using claims data and paid separately were calculated from 100 percent of the line items in usable claims for those products. As a result, there was no packaging for those products and use of multiple claims for such items is not a problem. Overall, for the 2004 update, CMS used at least some portion of the 82 percent of claims for services that fell under the OPPS.

It is in this context that we address the recommendations in the GAO report.

Attachment

Appendix III
Comments from the Centers for Medicare &
Medicaid Services

Centers for Medicare & Medicaid Services' Comments to the GAO
Draft Report: *MEDICARE: Information Needed to Assess Adequacy*
of Rate-Setting Methodology for Payments for Hospital Outpatient Services
(GAO-04-772)

GAO Recommendation

That CMS gather the necessary data and perform an analysis that compares the types and costs of services on single-service claims to those on multiple-service claims.

CMS Response

The CMS is searching for ways to use the data from all valid claims for OPSS services, including multiple procedure claims. We have moved to line item date of service segregation to attempt to associate revenue code charges submitted without Healthcare Common Procedure Coding System (HCPCS) codes with charges for the related, separately paid HCPCS codes. We have also established criteria for bypassing charges for separately paid HCPCS codes in determining whether a claim may be treated as a single procedure claim. This has allowed us to use significantly more claims data for 2004 OPSS than for 2002 or 2003 OPSS. We expect to further refine the methodology for 2005 OPSS. We are also exploring ways of allocating line item charges among multiple separately paid HCPCS codes on a claim. However, we note that any methodology we use will allocate such charges generally but not specifically.

When we have spoken to hospitals about this issue, they describe the difficulties in allocating line item charges for packaged services among the separately paid services, and that is why they bill charges without HCPCS codes. For example, when there is a charge for administration of an anesthetic during a surgery in which two procedures are performed, the hospital cannot allocate the charge for the anesthetic between the two procedures. Similarly, when a patient incurs charges in an operating room and recovery room for two procedures that were performed in the same operative session, hospitals are unable to split the charges between the two separately paid procedures as would be necessary to secure an accurate allocation of the total charge for the use of those spaces.

An allocation of charges to use in multiple procedure claims would require use of assumptions in an algorithm, rather than an actual split based on the amount of the drug or the amount of operating room or recovery room time that relates to each procedure separately. The result of such a process may, in fact, create more distortion in relative weights than would occur if we continue to set weights based on single procedure claims. Moreover, there would be no way to confirm that there is more or less distortion unless hospitals can provide the data needed to create a "gold standard" against which to compare both methodologies. Again, the cost to hospitals of providing, and to Medicare of collecting and analyzing, such data needs to be considered.

As we have explained above, we have made and are continuing to make strides in the amount of data from multiple procedure claims we are able to use in rate setting. In our forthcoming proposed rule for 2005, we expect to discuss additional improvements to our processes for using data from multiple procedure claims.

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Comments from the Centers for Medicare &
Medicaid Services**

Page 2- Attachment

GAO Recommendation

That CMS analyze the effect that the variation in hospital charge-setting practices has on the OPPS rate-setting methodology.

CMS Response

The GAO says that “CMS assumed that to set charges, all hospitals mark up their costs by the same percentage.” We believe this statement is an overgeneralization. Our department-specific cost-to-charge ratios (CCRs) capture variability in charging practices by cost center. The CMS uses department (cost-center) specific, or absent them, hospital overall CCRs applied to the charges from that hospital by related revenue code in order to determine the relative costs of services for that hospital. The CCRs are determined from the cost and charge data provided by the hospital and therefore reflect the differential charging practices by department and by hospital. For example, for the 2004 final rule, median CCRs by department ranged from 0.12 for CAT Scan (3230) to 1.12 for Family Practice (4040).

Hence, the CMS methodology does not assume that “all hospitals mark up their charges by the same percentage.” However the methodology does assume that the CCR for the department or for the hospital reflects the markup practices of that hospital for all services within the department or within the hospital and therefore it determines costs on a basis that is broader than each specific item or service in the department. The CCRs are not available for specific items and services within the hospital.

While we recognize that the application of CCRs to the charges of a hospital does not result in precise costing for individual items and services, it has long been the recognized method of establishing reasonable costs for hospital services. It has been supported by hospital organizations in public comments as the best means of establishing relative costs for OPPS rate setting. The application of CCR to charges is a fundamental principle of cost reimbursement that was in effect in Medicare for many years, supported by the hospital industry as resulting in an appropriate reflection of the costs of services they furnished. Moreover, as recently as the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Congress specified that this methodology would be used to set payment amounts for brachytherapy sources at cost. In a budget neutral payment system, the relative costs serve as the means for distributing the payments relative to the costs of items and services paid under the system and the application of hospital reported CCR to hospital reported charges in order to determine relative cost is the best system we currently have on which to base the payment distribution.

The issue raised by manufacturers is whether the department-specific ratio can adequately capture the variation in mark-up between low and high cost services within the same cost center. This variability may reflect hospital pricing sensitivity to income elasticity on the part of beneficiaries, among other influences, such as competitive pricing. The CMS’ use of variable CCRs and the specific distinction of “within” department differences should be addressed. GAO might demonstrate that this was the issue raised in its interview guide. Further, GAO should

**Appendix III
Comments from the Centers for Medicare &
Medicaid Services**

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note that its acquisition cost survey required by the MMA will provide some evidence on variability in charges for drugs, assuming that sampling is by hospital.

GAO Recommendation

That CMS analyze whether the OPSS rate-setting methodology results in payment rates that uniformly reflect hospitals' costs of the services they provide to Medicare beneficiaries, and, if it does not, make appropriate changes in that methodology.

CMS Response

We will consider GAO's recommendations as we continue to assess and refine our rate-setting methodology. In that regard, we would welcome more specific recommendations from GAO based on the findings in this report and/or as part of the studies that GAO is undertaking pursuant to its mandate under the MMA on hospital costs for drugs, biologicals, radiopharmaceuticals, and brachytherapy sources. We also look forward to receiving the results of GAO's surveys on hospital acquisition costs of the items mandated by the MMA. However, we believe the GAO recommendations should take into account the costs to providers and to the Medicare program of gathering additional data for analysis and possible methodological changes.

We continue to welcome specific recommendations from GAO and others on additional ways to increase the percentage of data used from multiple procedure claims to update OPSS rates. In spite of the progress we have made, we recognize that there are some services that are very frequently performed with other services that may be underrepresented in our rate-setting data. However, we believe we have made great strides on this issue and we are continuing to pursue the analyses necessary to create means by which all claims can be used to set the OPSS relative payment weights and rates.

GAO Contact and Staff Acknowledgments

GAO Contact

Nancy A. Edwards, (202) 512-3340

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