

July 2006

MEDICARE OUTPATIENT PAYMENTS

Rates for Certain Radioactive Sources Used in Brachytherapy Could Be Set Prospectively





Highlights of [GAO-06-635](#), a report to congressional committees

Why GAO Did This Study

Generally, in paying for hospital outpatient procedures, Medicare makes prospectively set payments that are intended to cover the costs of all items and services delivered with the procedure. Medicare pays separately for some technologies that are too new to be represented in the claims data used to set rates. It also pays separately for certain technologies that are not new, such as radioactive sources used in brachytherapy, a cancer treatment. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required separate payment for the radioactive sources. It also directed GAO to make recommendations regarding future payment. GAO examined (1) how Medicare determines payment amounts for technologies that are not new but are separately paid and (2) how payment amounts for iodine, palladium, and iridium sources used in brachytherapy could be determined.

What GAO Recommends

GAO recommends that Medicare (1) in paying separately for iodine and palladium, use outpatient claims to set prospective rates, and (2) use claims data to evaluate the unit cost of iridium, so that a suitable separate payment methodology can be determined. In response, CMS stated that it will take GAO's recommendations into consideration.

www.gao.gov/cgi-bin/getrpt?GAO-06-635.

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

MEDICARE OUTPATIENT PAYMENTS

Rates for Certain Radioactive Sources Used in Brachytherapy Could Be Set Prospectively

What GAO Found

In paying separately for technologies that are not new, the Centers for Medicare & Medicaid Services (CMS) generally sets prospective rates based on the average unit cost of the technologies across hospitals. For example, CMS currently pays separate prospective rates for certain high-cost drugs based on the mean per-unit acquisition cost, as derived by CMS from data provided by drug manufacturers. A prospective rate is desirable because basing a rate on an average encourages those hospitals that provide the technology to minimize their acquisition costs. However, when CMS determines that the unit cost of a technology designated for separate payment varies substantially and unpredictably over time, or that reasonably accurate data are not available, it pays each hospital its cost for the technology. For example, CMS pays each hospital its cost for corneal transplant tissue, because it determined that the fees eye banks charge hospitals vary substantially and unpredictably.

GAO's analysis suggests that CMS could set prospective payment rates for iodine and palladium because their unit costs are generally stable and CMS can base the payments on reasonably accurate data. According to interviews GAO conducted with hospitals and manufacturers, iodine and palladium have an identifiable unit cost that does not vary unpredictably over time. In addition, the results of GAO's survey of hospital purchase prices suggest that the unit cost of iodine and palladium does not vary substantially. Furthermore, GAO found that Medicare claims would be a reasonably accurate source of data for setting prospective rates for these sources. GAO was not able to determine a suitable methodology for paying separately for iridium. In contrast with iodine and palladium, which are permanently implanted in patients, iridium is reused across multiple patients, making its unit cost more difficult to determine. Although GAO surveyed hospitals on the unit cost of iridium, it did not receive sufficient data to identify and evaluate an average unit cost across hospitals. However, CMS has outpatient claims data from all hospitals that have used iridium. In order to identify a suitable methodology for determining a separate payment amount, CMS would be able to use these data to establish an average cost and evaluate whether the cost varies substantially and unpredictably.

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Abbreviations

ABS	American Brachytherapy Society
ACCC	Association of Community Cancer Centers
ACRO	American College of Radiation Oncology
APC	ambulatory payment classification
ASP	average sales price
ASTRO	American Society for Therapeutic Radiation and Oncology
CAB	Coalition for the Advancement of Brachytherapy
CMS	Centers for Medicare & Medicaid Services
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
OPPS	outpatient prospective payment system

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Congressional Committees

Under Medicare’s hospital outpatient prospective payment system (OPPS), hospitals are paid a fixed, predetermined—that is, prospectively set—amount for each procedure they provide to Medicare beneficiaries.¹ Hospitals are expected to use this prospective payment to cover the costs of items and services, such as anesthesia and medical supplies, associated with the procedure. In creating one payment bundle for items and services associated with a procedure, Medicare provides hospitals with an incentive to operate efficiently, as they retain the difference if the payment exceeds the cost the hospital incurs in performing the procedure. Although bundled payment is a fundamental principle of the OPPS, Medicare pays separately for certain high-cost technologies because bundling them into a payment with their associated procedures could financially disadvantage hospitals even if they operate efficiently.² Some technologies are paid separately because they are new and their costs are not represented in the historical data used to set bundled payments for procedures. However, certain other technologies that are not new and have historical claims have also been designated for separate payment either by Congress or by the agency that administers Medicare, the Centers for Medicare & Medicaid Services (CMS) in the Department of Health and Human Services.

Brachytherapy is an example of a procedure involving a technology that is not new and is separately paid. During the procedure, radioactive materials, called sources, are implanted in or near a cancerous tumor. The three radioactive sources most commonly used in this treatment are iodine-125 and palladium-103, which provide a prolonged, low dose of radioactivity, and iridium-192, which provides a brief, high dose of

¹For purposes of this report, “procedure” can refer to a service that constitutes a clinical course of action, such as an outpatient surgery; a medical test; or another service, such as an office visit.

²In this report, we use “technologies” to refer to certain products that are used in outpatient procedures. These products include drugs; devices; biologicals, which are derived from living sources, including humans, animals, or microorganisms; and radiopharmaceuticals, which are radioactive chemical agents provided orally, injected, or provided through other means for diagnostic or therapeutic purposes.

radioactivity.³ In 2002, these three sources were billed on 98 percent of the claims for radioactive sources associated with brachytherapy. Medicare pays separately for these, as well as other radioactive sources associated with brachytherapy,⁴ at each hospital's cost.⁵ According to our estimates, payments in 2004 for iodine, palladium, and iridium sources represented less than one-half of 1 percent of the \$15.9 billion in OPPS spending.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required that all radioactive sources used in brachytherapy be paid separately rather than bundled into payment for their associated procedures.⁶ The MMA specified that these separate payments be made at each hospital's cost through December 31, 2006. While the MMA required separate payment after this date as well, it did not specify a methodology for determining the separate payment amounts. Rather, it directed us to conduct a study and make recommendations regarding future payment for radioactive sources. As discussed with the committees of jurisdiction, this report examines (1) how CMS determines payment amounts for technologies that are not new but are separately paid and (2) how payment amounts for iodine, palladium, and iridium sources used in brachytherapy could be determined.

To examine how CMS determines payment amounts for technologies that are not new but are separately paid, we reviewed federal law and regulation pertaining to the OPPS. We also interviewed officials at CMS. To examine how payment amounts for iodine, palladium, and iridium sources used in brachytherapy could be determined, we conducted a

³For the remainder of this report, we refer to iodine-125 as "iodine," palladium-103 as "palladium," and iridium-192 as "iridium." While iridium-192 can also be provided in low-dose form, this method of treatment is rare. Therefore, we refer to iridium in its high-dose form, unless otherwise specified.

⁴Medicare pays for 12 radioactive sources used in brachytherapy: high- and low-activity iodine, high- and low-activity palladium, gold-198, low-dose iridium, high-dose iridium, yttrium-90, cesium-131, liquid iodine-125, ytterbium-169, and linear palladium-103.

⁵Unless otherwise specified, paying "at each hospital's cost" refers to a particular methodology CMS uses to estimate a hospital's cost of providing a technology. This methodology relies on the charge a hospital identifies on its claim for reimbursement, which CMS converts to cost using the ratio of aggregate costs and charges from the hospital's most recent cost report. An alternative method of paying at each hospital's cost relies on the costs reported by the hospital on its most recent cost report.

⁶Pub. L. No. 108-173, § 621(b), 117 Stat. 2066, 2310 (to be codified at 42 U.S.C. § 1395l(t)(2)(H) and (16)(C)).

survey of purchase prices paid by 121 hospitals from July 1, 2003, through June 30, 2004.⁷ These hospitals were selected to be representative of all hospitals purchasing these sources in 2002, the most recent year from which data could be used to construct a sample.⁸ We assessed the reliability of the data we received from these hospitals. After excluding questionable data, we determined that the remaining data were suitable for our purposes. Our final results represented data from 62 hospitals, or slightly more than 50 percent of the hospitals in our sample. Our results can be generalized to the larger population of hospitals providing these sources in the outpatient setting that met our sampling criteria. (See app. I for more information on our hospital survey.) We also interviewed representatives from a trade association of radioactive source manufacturers, six radioactive source manufacturers, three associations representing physicians and other health professionals involved in brachytherapy, an association of cancer hospitals, and seven individual hospitals. We conducted a site visit to a hospital that provides brachytherapy. We also reviewed federal law and regulation pertaining to the OPDS and interviewed officials at CMS. We did our work in accordance with generally accepted government auditing standards from June 2004 through July 2006.

Results in Brief

When paying separately for technologies that are not new, CMS's general practice is to set prospective rates based on an average—that is, the mean or median—unit cost of the technologies across hospitals. For example, CMS currently pays separate prospective rates for certain high-cost drugs and biologicals⁹ based on the mean estimated per-unit acquisition cost, as derived by CMS from data provided by drug manufacturers. A prospective rate, even for technologies that are separately paid, is desirable because basing a rate on an average encourages those hospitals that provide the technology to minimize their acquisition costs. If CMS determines that a technology's unit cost varies substantially and unpredictably, or that reasonably accurate data on which to base an average unit cost are not available, CMS pays for the technology at each hospital's cost. When the

⁷Specifically, we asked hospitals to report the prices they paid for sources upon receiving the product. These prices are net of discounts, but they do not reflect rebates from manufacturers, which are not commonly provided for brachytherapy sources, nor any costs hospitals may incur in storing and handling the radioactive sources.

⁸These hospitals were Medicare providers as of July 2004.

⁹For the remainder of this report, we use "drugs" to refer to both drugs and biologicals.

cost of a technology varies substantially and unpredictably, a prospective rate based on a historical average may not adequately pay hospitals even if they operate efficiently. One example of such a technology is corneal transplant tissue. After analyzing data submitted by hospitals and other stakeholders, CMS determined that the fees eye banks charge hospitals for corneal transplant tissue vary substantially and unpredictably over time and across eye banks in a given year. The amount of the fee charged by an eye bank depends heavily on the level of charitable donations it receives, which it uses to subsidize the cost of providing the tissue to hospitals. As a result of the variation in fees hospitals pay, CMS pays for the tissue at each hospital's cost.

CMS could set prospective payment rates for iodine and palladium due to the general stability in their unit cost and the availability of reasonably accurate data. According to interviews we conducted with hospital and manufacturer officials, iodine and palladium have an identifiable unit cost, the price per source. When we surveyed hospitals on their purchase prices, we found that the prices do not vary substantially or unpredictably. Furthermore, we determined that a reasonably accurate source of data, historical OPPS claims, is available for setting prospective rates for iodine and palladium. We were unable to identify a methodology CMS could use to determine future payment amounts for iridium. In contrast to iodine and palladium, where multiple sources are permanently implanted in one patient, a single iridium source is temporarily implanted. Because an iridium source can be implanted in multiple patients over its 3-month life span,¹⁰ and each patient can receive multiple treatments with the source, the appropriate unit cost of an iridium source is the average cost of all treatments administered across all patients. Although we surveyed hospitals on the per-treatment costs of iridium, we did not receive sufficient data to estimate an average cost across hospitals. However, hospital claims data are available to CMS for estimating an average per-treatment cost across hospitals that have used iridium. Using these data, CMS would be able to evaluate whether the range of cost comprising the average is substantial and whether cost varies unpredictably over time. Such an analysis would help CMS identify a suitable methodology for determining a separate payment amount.

¹⁰We use "life span" to refer to the period of time iridium is sufficiently radioactive to be used for high-dose brachytherapy.

In this report, we make recommendations to the Secretary of Health and Human Services regarding payment for iodine, palladium, and iridium sources. Specifically, we recommend that the Secretary direct the Administrator of CMS to (1) set prospective payment rates for iodine and palladium sources, with each rate based on the source's mean or median cost across hospitals estimated from OPPS claims data, and (2) use claims data to evaluate the unit cost of iridium, so that a suitable, separate payment methodology can be determined. In response, CMS stated that it will take GAO's recommendations into consideration.

Background

Iodine, palladium, and iridium are the radioactive sources most commonly used in brachytherapy. The brachytherapy procedure is typically performed in the outpatient setting where, under the OPPS, costs associated with a procedure are generally bundled in order to promote hospital efficiency. However, since the OPPS was implemented in 2000, an increasing number of technologies have been paid separately. Except in 2003, the one year in which iodine and palladium used to treat prostate cancer and iridium were bundled into payment for brachytherapy procedures, all radioactive sources used in brachytherapy have been paid separately.

Radioactive Sources Used in Brachytherapy

Radioactive sources are used in brachytherapy to treat a variety of types of cancers. The most prevalent brachytherapy procedure is low-dose brachytherapy with iodine or palladium, which is typically provided for early-stage prostate cancer. During this procedure, approximately 20 to 200 tiny iodine or palladium sources are implanted in the prostate, deliver radiation over a period of months, and then remain permanently in the body. Generally, the choice between iodine and palladium is determined by the aggressiveness of the tumor, and the number of sources by the size of the prostate.¹¹

In recent years, utilization of the high-dose brachytherapy procedure, which typically uses iridium, has grown. Iridium can be used to treat a variety of advanced-stage cancers—most commonly gynecological cancers. In high-dose brachytherapy, a single, highly radioactive iridium

¹¹Although iodine and palladium both emit relatively low levels of radiation, palladium emits radiation at a higher rate, making it generally appropriate for more aggressive tumors.

source is implanted in the tumorous area for a brief period—a matter of minutes or hours—and then withdrawn. Depending on a patient’s clinical needs, the patient may receive one or more such treatments, also known as fractions, with the same source over the course of several days. Because an iridium source emits sufficient radiation for 3 months, the same source can be used to treat multiple patients.

Evolution of Medicare Payment for Outpatient Services

The payment methodology for outpatient services has varied in the degree to which it relies on bundled payments to promote hospital efficiency. Prior to OPSS implementation in 2000, payment for outpatient items and services was not bundled; rather, hospitals were paid under a complex array of cost-based reimbursement methods and fee schedules. Generally, neither of these payment methodologies provides a strong incentive to furnish services efficiently. Under a cost-based methodology, each hospital is paid its cost based on information it reports to CMS. Under a fee schedule methodology, all hospitals receive a prospectively determined rate for each item and service they provide, but little incentive exists for them to provide only the necessary items and services.

Under the Balanced Budget Act of 1997, CMS was required to implement the OPSS, which was designed to streamline the historically complex system of payment for outpatient care and better promote hospital efficiency.¹² CMS assigns each outpatient procedure to one of approximately 850 ambulatory payment classification (APC) groups. Each APC group includes procedures that share cost and clinical similarities and has one payment rate for all procedures in the group.¹³ To set an APC rate, CMS uses historical claims to calculate a median cost across a group’s procedures that includes the costs of the associated bundled services and supplies, which are known as “packaged” costs. A median, rather than a mean, gives less weight to extreme values. That median cost is then converted into a numeric weight, which determines the payment hospitals receive for all procedures assigned to the APC. Because the OPSS provides a single payment to cover the average total cost of a procedure, the incentive for each hospital to efficiently provide the necessary items and services associated with that procedure is greater

¹²Pub. L. No. 105-33, § 4523, 111 Stat. 251, 445-50.

¹³For example, APC 396, “Bone Imaging,” includes the following procedures: “bone imaging, limited area”; “bone imaging, multiple areas”; and “bone imaging, whole body.”

than when the hospital is paid its cost or a separate fee schedule payment for each item and service used in the procedure.

Although bundling is a fundamental principle of the OPPS, the number of technologies that are paid separately from their associated procedures has increased since the implementation of the payment system.¹⁴ Beginning in 2000, the first year of the OPPS, CMS was required to make temporary, separate payments—referred to as “transitional pass-through payments”—for technologies that it determines to meet specified criteria for being new and high cost.¹⁵ These payments supplement the bundled payments for outpatient procedures associated with the technologies, and are designed to compensate hospitals for the additional cost. A new technology is eligible for pass-through payments for 2 to 3 years, after which time the technology is no longer considered new and CMS can include the technology in the payment bundle for the associated procedure. Over time, other high-cost technologies that are not new—mainly certain drugs and radiopharmaceuticals—have also been designated for separate payment either by Congress or by CMS.

OPPS Payment for Radioactive Sources

The payment methodology for radioactive sources associated with brachytherapy has changed several times since the inception of the OPPS. CMS was required to make separate pass-through payments for all radioactive sources associated with brachytherapy beginning in 2000. In 2003, these technologies were no longer eligible for pass-through payments. Because they are considered devices by Medicare, and devices are typically bundled into payment for their associated procedures, CMS bundled iodine and palladium into the payment bundle for the low-dose brachytherapy procedure for prostate cancer, and iridium into the payment bundle for the high-dose brachytherapy procedure, regardless of cancer type. For iodine and palladium sources provided for conditions other than prostate cancer, CMS continued to pay separately. Instead of paying separately for these radioactive sources at each hospital’s cost, CMS set prospective rates for 2003 based on the median cost of each

¹⁴See Medicare Payment Advisory Commission, *Report to the Congress: Selected Medicare Issues* (Washington, D.C.: June 2000), and Barbara O. Wynn, *Medicare Payment for Hospital Outpatient Services: A Historical Review of Policy Options*, a working paper prepared for the Medicare Payment Advisory Commission by RAND Health, June 2005.

¹⁵The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-13, app. F, § 201(b), 113 Stat. 1501, 1501A-337—1501A-339.

source across hospitals. The MMA mandated that all brachytherapy sources be paid separately after 2003 and specified that from January 1, 2004, through December 31, 2006, separate payments for the sources be at each hospital's cost. The MMA did not specify a methodology for paying separately after this date.

When Paying Separately for Technologies That Are Not New, CMS's General Practice Is to Set a Rate Based on an Average Cost across Hospitals

When paying separately for technologies that are not new, CMS's general practice is to set a prospective rate for all hospitals, based on an average unit cost across hospitals. However, certain technologies may vary in cost substantially and unpredictably or there may not be reasonably accurate data on which to base an average cost across hospitals. In either case, CMS pays for these technologies at each hospital's cost.

When Paying Separately for Technologies That Are Not New, CMS's General Practice Is to Set Prospective Rates

Although CMS does not use published criteria to determine payment amounts for separately paid technologies that are not new, we found that its general practice is to pay prospectively based on the average historical cost of each technology across hospitals. A prospective rate, even for technologies that are separately paid, is desirable because basing a rate on an average encourages those hospitals that provide the technology to minimize their acquisition costs.¹⁶

To set prospective rates for these separately paid technologies, CMS currently uses two sources of historical data: manufacturer data and OPPS claims. For example, CMS pays for certain high-cost drugs prospectively based on average per-unit acquisition cost.¹⁷ To calculate hospital acquisition cost, CMS relies on per-unit average sales price (ASP) data, which manufacturers are required to submit to CMS and are used in

¹⁶For example, if two manufacturers sell the same technology, and there is not a discernable difference in quality between the two products, then the hospital would have the incentive to purchase the technology from the manufacturer offering the lower purchase price.

¹⁷These include certain drugs known as specified covered outpatient drugs and other drugs with per-day costs of \$50 or more.

making payments for physician-administered drugs.¹⁸ CMS also uses ASP data to pay a per-unit rate for particular orphan drugs, which are drugs used to treat patients with rare conditions and are typically high in cost. For drugs where CMS does not have ASP data, CMS pays based on the mean cost calculated from OPPS claims.

Certain Technologies That Are Not New and Are Not Suitable for Prospective Payment Are Paid at Cost

When a technology's unit cost varies substantially and unpredictably, or when reasonably accurate cost data are not available, CMS pays for the technology at each hospital's cost. If the cost varies substantially and unpredictably, a prospective rate based on a historical average may not adequately pay hospitals even if they operate efficiently. CMS pays each hospital's cost, for example, for corneal transplant tissue and certain vaccines, including those for flu and pneumonia.¹⁹ CMS uses this methodology for corneal transplant tissue because, after analyzing data submitted by hospitals and other stakeholders, the agency determined that the fees eye banks charge hospitals for this tissue can vary substantially and unpredictably over time and across eye banks in a given year. The amount of the fee charged by an eye bank depends heavily on the level of charitable donations it receives, which it uses to subsidize the cost of providing the tissue. The cost to hospitals of providing vaccines also varies substantially and unpredictably due to instability in the nation's vaccine supply.

In other cases, CMS makes cost-based payments for technologies when it determines that reasonably accurate historical data on unit cost are not available. For example, the MMA mandated separate payment for certain radiopharmaceuticals. As we discussed in our 2006 report on OPPS

¹⁸The MMA required manufacturers to report quarterly ASPs for drugs sold, with certain exceptions, to all purchasers. MMA § 303(i)(4)(B)(iii), 117 Stat. 2254. An ASP must be net of volume discounts, prompt-pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and all rebates but those owed to Medicaid. MMA § 303(c), 117 Stat. 2240-41.

¹⁹CMS pays hospitals at cost for corneal transplant tissue somewhat differently than it pays hospitals at cost for other separately paid technologies. Specifically, CMS instructs hospitals to record the acquisition cost on the claim instead of a charge and pays them for this amount. CMS later conducts a reconciliation of these payments with the costs indicated on the hospital's annual cost report to ensure that the payments were based on reasonable costs.

payment for certain drugs and radiopharmaceuticals,²⁰ differences among hospitals in how these technologies are purchased make it difficult for CMS to set a prospective rate based on an average cost across hospitals. As a result, payment for these radiopharmaceuticals is based on each hospital's cost.

When Paying Separately for Iodine and Palladium, CMS Could Set Prospective Rates, but Suitable Payment Methodology for Iridium Is Unclear

Based on our analysis, the absence of wide variability in the unit costs of iodine and palladium and the availability of reasonably accurate historical data makes these radioactive sources suitable for prospective payment rates. We were unable to establish a unit cost for iridium and, as a result, could not identify a suitable payment methodology. CMS has OPPS claims data from hospitals that provided iridium, and would be able to use these data to calculate an average unit cost across hospitals and to identify which methodology is suitable for determining a separate payment amount.

CMS Could Set Prospective Payment Rates for Iodine and Palladium

Our analysis suggests that CMS would be able to develop prospective rates for iodine and palladium beginning in 2007. Based on interviews we conducted with hospital and manufacturer officials, and the results of our hospital survey, we determined that iodine and palladium have identifiable unit costs and that these costs do not appear to vary substantially and unpredictably across hospital purchases at a given point in time or from year to year. Both hospitals and manufacturers told us that hospitals generally purchase iodine and palladium sources at a per-source price, making the calculation of a unit cost straightforward. According to our survey of 121 hospitals on the prices they paid during 1 year—specifically, from July 2003 through June 2004—the range of iodine and palladium prices is not wide.²¹ This is indicated by the relative level of precision—technically, the coefficient of variation—achieved for our estimated mean

²⁰GAO, *Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS*, [GAO-06-372](#) (Washington, D.C.: Apr. 28, 2006).

²¹Our survey requested per-source purchase prices from hospitals. These prices do not reflect storage and handling costs associated with the radioactive sources. Prior to April 1, 2004, CMS had not articulated a policy specifically on reimbursement for these costs. Effective on that date, CMS provided several avenues for hospitals to identify the costs associated with the storage and handling of radioactive sources, so that these costs might be recognized in the payment system.

price.²² (See table 1.) We also note that iodine and palladium are not subject to the same supply and demand conditions as corneal transplant tissue and flu and pneumonia vaccines—conditions that lead to substantial and unpredictable cost variation from year to year.

Table 1: Reported Iodine and Palladium Purchase Prices, July 2003-June 2004

Type of source	Number of reported purchases ^a	Number of hospitals reporting purchases	Estimated mean price per source ^b	Coefficient of variation for the mean estimate ^c
Iodine	1,926	52	\$29.54	1.59%
Palladium	941	40	\$45.35	0.68%

Source: GAO survey of purchase prices from July 2003 through June 2004.

^aA reported purchase refers to an individual hospital's purchase of a given quantity of the radioactive source at a particular price on a specific date.

^bThe estimated mean price per source is weighted according to the methodology described in app. I.

^cThe coefficient of variation measures the magnitude of dispersion around the mean. In statistical terms, a coefficient of variation below 10 percent is considered to be low. (See Morris H. Hansen, William N. Hurwitz, and William G. Madow, *Sample Survey Methods and Theory* (New York: John Wiley & Sons, 1953), 124,129-130.)

Although CMS uses ASP data to set a prospective rate for certain high-cost drugs, CMS currently does not have ASP data for radioactive sources used in brachytherapy. However, we found that OPPS claims provide a reasonably accurate source of data for setting a prospective rate for iodine and palladium sources. To determine if claims could be used as a reasonable data source, we compared the payment rates for 2003 and the proposed payment rates for 2004,²³ which were based on median costs

²²To the extent that variation exists across either palladium or iodine prices, it could be attributed to differential pricing by specific source characteristics, such as radioactivity level or the configuration in which they are purchased—that is, whether they are stranded together for insertion or are individual, “loose” sources. We did not receive enough data from hospitals to reliably identify any price differences by source characteristic. However, we instructed hospitals to report all their purchases during the survey period. Therefore, any price variation due to source characteristic should be reflected in our data. Regarding activity level, we note that the MMA required CMS to establish payments that account for the radioactive intensity of sources. As a result, in 2005, CMS established separate billing codes for high- and low-activity iodine and palladium sources. CMS is therefore expected to have the data available to set separate rates for high- and low-activity iodine and palladium in 2007.

²³These rates were proposed for 2004; however, they were not implemented due to the MMA requirement to pay for the sources based on each hospital's cost.

calculated from historical claims, with the median of the per-source purchase prices reported directly to us by hospitals. Although the payment rates applied only to sources used in non-prostate brachytherapy, CMS officials told us that they were calculated using prostate and non-prostate brachytherapy claims with iodine and palladium sources. We found that for iodine the prospectively set rate for 2003 and proposed rate for 2004 were \$31.33 and \$36.35, respectively, and the median of reported purchase prices was \$25.37.²⁴ For palladium, the prospectively set rate for 2003 and proposed rate for 2004 were \$43.96 and \$44.00, respectively, and the median reported purchase price was \$45.46.

Since 2004, when CMS was required to pay separately for all iodine and palladium sources, the agency has been accumulating claims data that include separate charges for these sources. As a result, CMS will have data from 2005 for the 2007 payment year.²⁵ These data could be used to set prospective payment rates, either based on a mean—as is currently done with certain high-cost drugs—or based on a median—which CMS used to set the 2003 and proposed 2004 rates for iodine and palladium sources.

Suitable Methodology for Determining Separate Payment Amount for Iridium Is Unclear

Due to the reusable nature of the iridium source, identifying its unit cost is not as straightforward as identifying the unit cost of iodine and palladium. Over the course of its 3-month life span, an iridium source can be temporarily implanted in multiple patients and each of those patients can receive about 1 to 10 such treatments with the same source. Therefore, the appropriate unit cost of an iridium source is the per-treatment cost—the average cost of all treatments administered across all patients over a 3-month period. When hospitals purchase an iridium source, they may not know the exact number of patients they will treat or the number of treatments each of those patients will receive. Therefore, hospitals must bill Medicare based on projections of their unit cost, and will only be able to identify their actual unit cost retrospectively.

We asked hospitals to provide the per-treatment cost of iridium sources they purchased over a previous 12-month period in order to identify a unit cost. However, we did not receive enough data to identify the per-treatment cost. Of 121 total hospitals surveyed, 19 responded with data on iridium, and the majority of these 19 hospitals did not provide data we

²⁴The median reported price is weighted according to the methodology described in app. I.

²⁵All payment rates for a given year are based on claims for services provided 2 years prior.

could use to estimate the cost per treatment. Specifically, 11 either did not provide the number of treatments, reported a questionable source price, or both. Eight hospitals reported a source price and the number of treatments from which a unit cost could be calculated. However, among these 8 hospitals there were inconsistencies in the data provided. Some hospitals reported the total price of their iridium contracts,²⁶ while other hospitals isolated the price of the radioactive source within their contracts and reported that price. Because we could not establish a unit cost, we could not assess if the unit cost of iridium varies substantially and unpredictably over time.

Although we could not identify an average per-treatment cost from our survey data, CMS has OPPS claims data from hospitals that provided iridium. Using these data, CMS would be able to evaluate whether the range of costs comprising the average is substantial and whether the cost varied unpredictably. Such an analysis would help CMS identify a suitable methodology for determining a separate payment amount.

Conclusions

Under the OPPS, an increasing number of technologies have been designated for separate payment, either by Congress or by CMS. Pursuant to the MMA, radioactive sources used in brachytherapy, including iodine, palladium, and iridium, are among those technologies. Based on our analysis, CMS can pay separately for iodine and palladium sources using prospective rates because the unit cost of the sources does not vary substantially and unpredictably. In addition, CMS has data available to identify reliable average costs across hospitals to set prospective payment rates beginning in 2007. Paying prospectively in this manner would help encourage hospital efficiency. However, we were not able to identify a suitable methodology for determining a separate payment amount for iridium sources because we did not receive sufficient information from hospitals to estimate an average per-treatment cost across hospitals. In order to identify a suitable methodology for determining a separate payment amount, CMS would be able to use OPPS claims data to evaluate whether the range of costs comprising the average is substantial and whether the average per-treatment cost varies unpredictably over time.

²⁶Most hospitals purchase the iridium source as part of an annual contract that covers the cost of four sources—one for each quarter—and the cost of maintaining the sources.

Recommendations for Executive Action

In order to promote the efficient delivery of radioactive sources associated with outpatient brachytherapy, we recommend that the Secretary of Health and Human Services direct the Administrator of CMS to take the following two actions:

- Set prospective payment rates for iodine and palladium sources with each rate based on the source's average—that is, the mean or median—unit cost across hospitals estimated from OPPS claims data.
- Use claims data to evaluate the unit cost of iridium so that a suitable, separate payment methodology can be determined.

Agency and External Reviewer Comments and Our Evaluation

We received written comments on a draft of this report from CMS (see app. II). We also received oral comments from individuals at five organizations representing manufacturers of radioactive sources used in brachytherapy and providers of brachytherapy. These included the Coalition for the Advancement of Brachytherapy, which represents manufacturers of radioactive sources; the Association of Community Cancer Centers (ACCC), which represents hospitals that provide cancer treatment; and three organizations representing physicians and others involved in providing brachytherapy: the American College of Radiation Oncology (ACRO), the American Brachytherapy Society (ABS), and the American Society for Therapeutic Radiation and Oncology (ASTRO). We also received technical comments from CMS and the external reviewers, which we incorporated as appropriate.

CMS Comments and Our Evaluation

In reviewing our draft report, CMS stated that it appreciated our analysis and will consider our recommendations on iodine, palladium, and iridium as it develops payment policy for 2007. CMS also noted that we did not make recommendations on payment for other radioactive sources associated with brachytherapy that may be separately payable in 2007.

As stated in our draft report, we examined how payment amounts for iodine, palladium, and iridium could be determined. In 2002, these three sources were billed on 98 percent of the claims for radioactive sources associated with brachytherapy. Medicare pays for seven other radioactive sources used in brachytherapy—gold-198, low-dose iridium, yttrium-90, cesium-131, liquid iodine-125, ytterbium-169, and linear palladium-102. We did not examine how payment for those sources could be determined because sufficient data on those sources were not available in the 2002 claims used to construct the sample of hospitals for our survey. Medicare did not pay for cesium-131, ytterbium-169, and linear palladium-102 in

2002, and gold-198, low-dose iridium, liquid iodine-125, and yttrium-90 together appeared on 2 percent of the approximately 22,000 claims for radioactive sources in that year. Although we did not examine how payment amounts could be determined for these seven sources, the analytical framework we used may apply to them as well.

Manufacturer and Provider Comments and Our Evaluation

Comments from external reviewers representing manufacturers of radioactive sources and providers of brachytherapy centered on three different areas: our recommendation to pay prospectively for iodine and palladium sources; our recommendation that CMS evaluate the unit cost of iridium; and payment for radioactive sources other than iodine, palladium, and iridium.

Representatives from CAB disagreed with our recommendation to set prospective rates for iodine and palladium using OPPS claims data. They asserted that price variation due to the range of available iodine and palladium products makes it inappropriate to pay for sources prospectively based on averages. In their opinion, our finding that the unit costs of iodine and palladium sources are generally stable was compromised by limitations in our hospital survey—specifically, our exclusion of outlier data and the absence of source configuration information in many of the surveys we received from hospitals. ACCC stated that OPPS claims data are flawed and that prospective rates may be appropriate but only when a more accurate data source is available. They also noted, as did ACRO representatives, that costs incurred by hospitals for storing and handling radioactive sources were not represented in our survey results. Representatives from ASTRO, ABS, and ACRO agreed with our recommendation that payment can be based on an average. ACRO representatives cautioned that the data used to set the payment must be representative of different types of hospitals, and ABS representatives suggested that the data should reflect the increased use of stranded sources, which they stated are more costly but considered clinically advantageous by many physicians.

Regarding our recommendation that CMS use OPPS claims data to evaluate the unit cost of iridium in order to determine a suitable separate payment methodology, representatives from CAB said the report accurately conveys the difficulties of identifying a per-unit cost for iridium. However, they disagreed with our recommendation because they said it would not be possible for CMS to fully evaluate a unit cost using OPPS claims data, which they asserted to be flawed. They stated that the cost of iridium varies substantially and unpredictably and would not be

appropriate for prospective payment based on an average. Representatives from ASTRO, ABS, and ACRO agreed with our recommendation, although they expressed confidence that the unit cost of iridium would be found to vary substantially and unpredictably and would therefore be inappropriate for prospective payment based on an average cost calculated across hospitals.

Finally, other comments focused on payment for radioactive sources other than iodine, palladium, and iridium. Representatives of ASTRO and CAB noted that we did not specifically address payment for the other radioactive sources used in brachytherapy—gold-198, low-dose iridium, yttrium-90, cesium-131, liquid iodine-125, ytterbium-169, and linear palladium-102—and ASTRO asked whether we would be making recommendations on payment for these other radioactive sources.

Concerning the comments that variation in source price makes it inappropriate to pay prospectively for sources, as noted in the draft report, we based our finding on the low coefficient of variation we calculated from surveys received from our representative sample of hospitals. We do not believe that our exclusion of outlier data masked the true degree of price variation. We used standard statistical trimming principles, which resulted in the exclusion of only 2 percent of reported purchases of iodine and none of the reported purchases of palladium. Although many of the responding hospitals did not indicate on the survey the configuration of the sources purchased, we instructed hospitals to list prices for all sources purchased during the survey period. Therefore, the variation we calculated from hospital responses can be expected to reflect the range of products purchased by hospitals at the time. Representatives from ACRO and ABS stated that they believed the average prices presented in the draft report were consistent with prices for the types of sources—loose, low-activity sources—commonly used during the survey period. If costlier stranded sources have become more frequently used since the survey period of July 1, 2003 through June 30, 2004, as stated by representatives of ACRO and ABS, the use of those sources would be captured in OPSS claims data from subsequent years and reflected in future prospectively set rates. Regarding the concerns about basing prospectively set rates for iodine and palladium on OPSS claims data, as noted in the draft report, we based our recommendation on our comparison of average purchase prices for those sources from our hospital survey with CMS payment rates for 2003 and proposed payment rates for 2004, which CMS derived from OPSS claims data. Concerning the comments about the cost of storing and handling radioactive sources, CMS has provided guidance to hospitals on how they can receive reimbursement for those costs.

With respect to our recommendation on payment for iridium, as noted in the draft report, we are recommending that CMS use its claims data to evaluate whether the range of costs comprising the average for a given year is substantial across hospitals and whether this average unit cost varied unpredictably over time. Consistent with its general practice for paying separately for technologies that are not new, CMS could pay for iridium at each hospital's cost if OPPS claims did not prove to be a reasonable source of data or if CMS determined that the unit cost varies substantially and unpredictably over time.

As we noted in our response to comments received from CMS, we limited our examination of payment for radioactive sources to iodine, palladium, and iridium because sufficient data on the other sources were unavailable in the 2002 claims used to construct the sample of hospitals for our survey, and these three sources were billed on 98 percent of the claims for radioactive sources associated with brachytherapy.

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

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



A. Bruce Steinwald
Director, Health Care

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Appendix I: GAO Survey of Hospital Purchase Prices for Iodine, Palladium, and Iridium Sources Used in Brachytherapy

This appendix summarizes the sample design, methods for collecting and processing the data, and methods for estimating mean and median purchase prices for iodine and palladium sources used in brachytherapy.¹ Though we were not able to estimate mean and median purchase prices for iridium, this appendix also includes a discussion of the data we received.

Sample Design

We developed a random sample of hospitals to survey for the purchase prices of iodine, palladium, and iridium sources used in brachytherapy. The sample frame consisted of 949 hospitals that (1) had charged Medicare for radioactive sources during 2002, the most recent year for which usable data were available;² (2) were still Medicare providers on July 1, 2004; and (3) were a subset of sample hospitals drawn for a survey we conducted of hospital outpatient drug prices.³ The sampling frame contained 98 percent of the 968 hospitals that submitted Medicare claims for the three brachytherapy sources in 2002. We drew a sample of 121 hospitals from the sample frame, on the basis of an expected response rate of 50 percent. Our results can be generalized to the larger population of hospitals providing iodine and palladium in the outpatient setting and meeting the above criteria.

To improve the precision of our estimates of mean and median purchase price, we stratified the sample of hospitals. The objective was to obtain a sample of hospitals that mirrored the distribution of hospitals billing Medicare for these sources. Because we did not have a measure of purchase price of radioactive sources at the time we selected the sample, we used total hospital outpatient drug charges to Medicare as a proxy for purchase price variation. We used a regression model to identify stratification factors (such as teaching hospital status) that would maximize the difference in mean purchase price (as proxied by Medicare drug charges) among strata. We grouped hospitals into major teaching

¹Radioactive sources commonly used in brachytherapy include iodine and palladium, which provide a prolonged, low dose of radioactivity, and iridium, which provides a brief, high dose of radioactivity.

²Although 2003 data were available at the time the sample was constructed, there was neither a separate billing code for iridium sources nor separate billing codes for iodine and palladium sources used in prostate brachytherapy.

³GAO, *Medicare: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting*, [GAO-05-733R](#) (Washington, D.C.: June 30, 2005).

hospital, nonmajor teaching hospital, urban nonteaching hospital, and rural nonteaching hospital strata. We placed small hospitals in a separate stratum to ensure that hospitals with no or minimal charges for drugs during the first 6 months of 2003 were appropriately represented.

In our sample design, we defined a major teaching hospital as a hospital for which the ratio of residents to the average daily number of patients was at least 1 to 4 and a nonmajor teaching hospital as one having a ratio of residents to patients of less than 1 to 4. We defined a hospital as urban if it was located in a county considered a metropolitan statistical area (as defined by the Office of Management and Budget) and rural if it was located in a county not considered a metropolitan statistical area. We defined a small hospital as a hospital with total Medicare drug charges of less than \$10,000 during the first 6 months of 2003.

Data Collection and Data Processing

To develop our survey of hospital purchase prices for radioactive sources, we interviewed representatives from the Coalition for the Advancement of Brachytherapy (CAB). CAB reports that it represents manufacturers of 90 percent of all brachytherapy sources and 100 percent of high-dose rate brachytherapy sources in the United States. We also interviewed representatives of the American Brachytherapy Society, the American College of Radiation Oncology, the American Society for Therapeutic Radiology and Oncology, and the Association of Community Cancer Centers. We also interviewed representatives from six radioactive source manufacturers and seven hospitals and officials at the Centers for Medicare & Medicaid Services. In developing the survey, we obtained information from these associations and individual hospitals and pilot tested the survey with 5 hospitals prior to sending it to the entire sample of 121 hospitals. As a result, we clarified certain protocols and procedures but did not substantially change the survey instrument.

The survey instrument was five pages long with one page for each radioactive source, one page for rebate data, and one page defining the terms in the previous pages. We collected data by reported purchase—that is, the purchase of a given quantity of a radioactive source at a particular price on a specific date. For iodine and palladium sources, we asked hospitals to provide the name of the manufacturer; the number of sources; the price per source; and certain characteristics of the sources purchased, such as radioactivity level. For iridium, we asked hospitals to provide the

name of the manufacturer, the number of treatments delivered,⁴ the source price, and the rebate eligibility. We also asked hospitals to report information on any rebates they received for these purchases.

We contracted with Westat to administer the survey. Westat began data collection on September 27, 2004. Key components of the data collection protocol were

- a first mailing to the chief executive officer or chief financial officer of each hospital explaining the survey, followed by a telephone call to identify the main point of contact;
- a second mailing to the main contact outlining the data that were needed and describing the options for submitting the data;
- a follow-up telephone call to facilitate the main contact's understanding of the data collection, provide technical assistance as needed, and obtain some basic information about the hospital; and
- telephone calls at regular intervals to remind the hospitals to submit their data and to provide assistance as needed.

Hospitals could submit data in one of three ways: by uploading electronic files through the study Web site, by sending an e-mail to the study address with data attached, or by sending electronic media or paper submissions through the mail. When our contractor received a brachytherapy survey from a hospital, it forwarded the survey to us for processing and analysis.

Of the 121 hospitals surveyed, 62 hospitals submitted usable data, resulting in an overall response rate of 51 percent. We considered iodine and palladium data usable if we were able to identify the price per source and the number of sources purchased. We considered iridium data usable if we were able to identify the price per source and the number of fractions provided with the source. Of the 62 hospitals, 52 hospitals submitted usable data for iodine and 40 hospitals submitted usable data for palladium, with some providing data for both radioactive sources. Sixty-five percent of hospitals providing data for iodine and 63 percent of hospitals providing data for palladium were teaching hospitals.

Our data were not sufficient to measure overall price differences by radioactivity level and other characteristics across each of the two types of sources. Specifically, hospitals did not indicate activity level for

⁴The survey asked for number of fractions, which refers to the number of individual treatments provided.

37 percent of their reported purchases of iodine and 47 percent of their reported purchases of palladium. They did not indicate source configuration for 43 percent of their reported purchases of iodine and 51 percent of their reported purchases of palladium.⁵ Although we did not receive enough data from hospitals to reliably identify any price differences by source characteristic, we instructed hospitals to report all their purchases during the survey period. Therefore, any price variation due to source characteristic should be reflected in our data.

We applied statistical trimming rules to eliminate outliers in the data. Accordingly, 2 percent of the reported purchases of iodine were trimmed, and none of the reported purchases of palladium were trimmed. The resulting data allowed us to calculate the mean and median price per source for iodine and palladium.

Few hospitals reported receiving rebates. This is consistent with information we received from hospitals during interviews—that manufacturer rebates were not commonly provided for radioactive sources. Therefore, we did not factor rebates into our mean and median purchase prices.

We determined that there were insufficient data to estimate the price of iridium. Of the 19 hospitals submitting iridium data, 11 either did not provide number of treatments, reported a questionable iridium source price, or both. Eight hospitals reported an iridium source price and the number of treatments from which a unit cost could be calculated. However, among these 8 hospitals there were inconsistencies in the data provided. Some hospitals reported the total price of their iridium contracts, which includes the cost of maintaining the iridium source, while other hospitals isolated the price of the iridium source within the contracts and reported that price.

⁵Of the iodine and palladium purchases that contained information on activity level, about 90 percent were identified as low activity. Of the iodine and palladium purchases that contained information on source configuration, 86 percent of the iodine purchases and 95 percent of the palladium purchases were identified as loose.

Estimates of Mean and Median Purchase Prices for Iodine and Palladium Sources

This section describes the rationale and method for weighting the hospital sample, calculating mean purchase price, calculating median purchase price, and calculating the associated coefficients of variation—or standard error reflecting sample design and weights.

Weighting the Hospital Sample

To estimate hospitals' mean and median purchase prices for iodine and palladium sources, the sample hospitals' purchase price data were weighted to make them representative of the sample frame of hospitals from which the sample was drawn. The less likely that a hospital was sampled, the larger its weight. For example, if each hospital had a 1 in 10 probability of being sampled, its sample weight was 10. That is, each hospital in the sample represents 10 hospitals in the sample frame. Consequently, if 5 hospitals in a sample bought a particular radioactive source, and the sample weight was 10, we estimate that 50 hospitals in the frame bought that radioactive source. In this report, we refer to sample weights as "hospital weights." Our sample was stratified, so all hospitals in a particular stratum (for example, major teaching hospitals) had the same weight. Since in our sample the probability of a hospital's being selected varied by stratum, hospitals in different strata had different weights.

We calculated the hospital weight as

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

where

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

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

Mean Purchase Price
 Using Volume and Hospital
 Weights

To summarize hospitals' purchase prices for iodine and palladium sources—reflecting purchases made, in many cases, at different prices and in different quantities—we calculated a mean purchase price for each radioactive source. This mean purchase price for a particular radioactive source is, in effect, a weighted mean. To reflect the differences among hospitals in purchase prices and purchase volumes, we used both the hospital weights and purchase volume as weighting variables in estimating the mean purchase price. All calculations were done at the individual purchase level but reflect the hospital and purchase volume weighting variables.

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

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

where

- N_h represents the total number of hospitals in the h^{th} stratum;
- n_h represents the size of the sample of hospitals in the h^{th} stratum;
- $y_{jhi}^* = \sum_k y_{jhik}$, which represents the total dollar amount for the j^{th} radioactive source listed on the k^{th} invoice for the i^{th} hospital in the h^{th} stratum; and
- $x_{jhi}^* = \sum_k x_{jhik}$, which represents the total number of units for the j^{th} radioactive source listed on the k^{th} invoice for the i^{th} hospital in the h^{th} stratum.

The equation estimates the mean purchase price of a radioactive source as the ratio of the total amount purchased in dollars to the total number of units purchased.

Median Purchase Price
 Using Volume and Hospital
 Weights

In addition to the mean purchase price, we calculated the estimated median of each radioactive source's purchase price. To calculate this median, we first applied volume and hospital weights to each hospital's purchases of a given radioactive source; we then ranked the weighted hospitals' purchase prices from lowest to highest and selected the midpoint of these prices. More precisely, the estimated median—based on the population cumulative density function F for hospital purchase prices—is given by

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

where

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

$$F(x) = \frac{\sum_h N_h}{\sum_h \sum_i \sum_k n_{hik}} \sum_i \sum_k I(y_{jhik} \leq x) / \frac{\sum_h N_h}{\sum_h \sum_i \sum_k n_{hik}}$$

Coefficients of Variation for Mean Purchase Price

To assess the precision of our estimates of the mean purchase price, we calculated coefficients of variation for the estimated mean purchase price. We also used the coefficients of variations as an indicator of price variability across hospitals. We estimated the mean purchase prices, median purchase prices, and the coefficients of variation for the means using specialized software for survey data analysis—SUDAAN[®].⁶

⁶B.V. Shah, B.B. Barnwell, and G.S. Bieler, *SUDAAN: User's Manual Release 7.5*, vols. 1 and 2 (Research Triangle Park, N.C.: Research Triangle Institute, 1997). SUDAAN[®] is a registered trademark of the Research Triangle Institute.

Appendix II: Comments from the Centers for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

JUN - 8 2006

200 Independence Avenue SW
Washington, DC 20201

TO: A. Bruce Steinwald
Director, Health Care

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

SUBJECT: Government Accountability Office's (GAO) Draft Report: "MEDICARE
OUTPATIENT PAYMENTS: Rates for Certain Radioactive Sources Used in
Brachytherapy Could Be Set Prospectively" (GAO-06-635)

Thank you for the opportunity to review and comment on the GAO draft report entitled "MEDICARE OUTPATIENT PAYMENTS: Rates for Certain Radioactive Sources Used in Brachytherapy Could Be Set Prospectively." The report summarizes GAO's position regarding the payment rates for brachytherapy sources in the Outpatient Prospective Payment System (OPPS).

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) instructed the Centers for Medicare & Medicaid Services (CMS) to pay hospitals for outpatient brachytherapy sources based on charges reduced to cost beginning January 1, 2004 through December 31, 2006. The MMA also mandated the creation of separate groups of covered hospital outpatient services that classify brachytherapy devices (seeds or radioactive sources) separately from other services or groups of services. The additional groups are to be created in a manner reflecting the number, isotope, and radioactive intensity of the devices of brachytherapy furnished, including separate groups for Palladium-103 and Iodine-125.

One further MMA provision requires the GAO to conduct a study to determine appropriate payment amounts for devices of brachytherapy, and to submit a report on its study with recommendations to Congress and the Secretary. This report presents the GAO's analysis on the three brachytherapy sources that are most commonly used for malignant tumors, Iodine-125, Palladium-103, and high dose rate Iridium-192. The GAO's analysis suggests that prospective payment rates could be set for Iodine-125 and Palladium-103 because the unit costs are generally stable and reasonably accurate data is available. The GAO report states that it was not able to determine a suitable payment methodology for Iridium-192.

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The GAO recommends that CMS:

- (1) Set prospective rates for Iodine-125 and Palladium-103 sources, with each rate based on the respective mean or median cost, across hospitals, estimated from OPPS claims data.
- (2) Use claims data to evaluate the unit cost of Iridium-192, so that a suitable separate payment methodology can be determined.

The GAO made no recommendations for the remaining nine brachytherapy sources that may be separately payable in the OPPS as of January 1, 2007.

The CMS has not yet proposed a methodology to pay for brachytherapy sources as of January 1, 2007. The OPPS proposed rule for CY 2007 payment is expected to be published in July 2006. We appreciate the GAO's analysis and will consider their recommendations as we develop our policies for the proposed rule.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

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

Acknowledgments

In addition to the contact above, Maria Martino, Assistant Director; Shamonda Braithwaite; Melanie Anne Egorin; Hannah Fein; Nora Hoban; Dae Park; Dan Ries; Anna Theisen-Olson; Yorick F. Uzes; and Craig Winslow made contributions to this report.

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