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OPPS

Coalition For The Advancement Of Brachytherapy

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September 29, 2006

Via Overnight Delivery

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The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1506-P Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule -- Brachytherapy (Letter 2 of 2)

Dear Dr. McClellan:

The Coalition for the Advancement of Brachytherapy (CAB) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 23, 2006 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule.

Please note that this is CAB's second comment letter regarding the HOPPS proposed rule for your consideration and this letter focuses solely on CAB's primary recommendation.

CAB's Primary Recommendation:

CMS should continue the current payment methodology for brachytherapy devices in the hospital outpatient setting (hospital's charges adjusted to cost for each device provided on a patient-by-patient basis) for all brachytherapy devices in 2007 and 2008.

CAB's additional recommendations on the proposed rule are addressed in detail in a separate comment letter sent by CAB dated September 25, 2006.

CAB was organized in 2001 and is composed of the leading developers, manufacturers, and suppliers of brachytherapy devices, sources, and supplies. CAB's mission is to work for improved patient care by assisting federal and state agencies in developing reimbursement and regulatory policies to accurately reflect the important clinical benefits of brachytherapy. Such reimbursement policies will support high quality and cost-effective care. Over 90% of brachytherapy procedures performed in the United States are done with products developed by CAB members and it is our mission to work for improved care for patients with cancer (see Attachment 1).

We would like to thank CMS for the opportunity to meet with staff during the past several years, most recently on May 1 and September 18, 2006, to discuss brachytherapy source

reimbursement. CAB is committed to working with CMS to identify an appropriate, fair and consistent payment methodology for brachytherapy devices (also known as sources or seeds) while preserving Medicare beneficiary access to high quality brachytherapy in the hospital outpatient setting.

Discussion:

CMS should continue the current payment methodology for brachytherapy devices in the hospital outpatient setting (hospital's charges adjusted to cost for each device provided on a patient-by-patient basis) for all brachytherapy devices in 2007 and 2008.

There is significant variability in the number, radioactive intensities and types (configurations) of brachytherapy devices needed to treat individual cancer patients. Given this unique patient-to-patient variability, the use of prospectively-set average reimbursement runs the risk of creating significant barriers to access for individual cancer patients and placing financial pressures on hospitals to take shortcuts in the use of brachytherapy devices. Maintaining patient access to brachytherapy is critical, given that in many instances brachytherapy devices provide the safest and most effective treatment for prostate and other forms of cancer.

Barriers to patient access are accentuated by the ongoing problems with CMS' data for brachytherapy devices. Further, CMS' codes for brachytherapy devices are not keeping pace with changes in clinical practice. Brachytherapy is a complex medical treatment that requires the implantation or application of devices that vary in numerous, clinically-important ways. These important clinical nuances must be factored into codes and payment to ensure that Medicare's policies reflect clinical treatment and patient access.

The proposed rule would change the way that brachytherapy devices are reimbursed by adopting prospectively-set average payment rates. As discussed below, the CMS proposal is based on data that are inaccurate, outdated and insufficiently detailed. In addition, CMS should continue the current reimbursement methodology for brachytherapy devices to satisfy the plain meaning and intent of Section 621(b) of the Medicare Modernization Act.

A. CMS Should Adhere to the Recommendations of Two Congressionally-Created Advisory Panels, Which Urged CMS to Abandon the Proposed Rule and Instead Continue the Current Reimbursement Methodology for Brachytherapy Devices

Shortly after CMS posted the proposed rule, two separate Congressionally-created public advisory groups recommended against proceeding with CMS' proposal to set fixed rates for brachytherapy devices.

- First, on August 24, 2006, the APC Advisory Panel recommended that CMS continue the current "charges adjusted to cost" reimbursement methodology for all brachytherapy devices in 2007 (instead of implementing CMS' proposal to begin prospectively-set payment rates in 2007).[1] The APC Advisory Panel based this recommendation on

[1] Advisory Panel on Ambulatory Payment Classification (APC) Groups, *Panel Recommendations* (Aug. 23-24, 2006), available at: http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

concerns about the validity of the data that CMS is using to calculate prospective payments for brachytherapy devices.

- Second, on August 28, 2006, the Practicing Physicians Advisory Council (PPAC) recommended that CMS "abandon" its proposed payment methodology for all brachytherapy devices under the hospital outpatient prospective payment system.[2] The PPAC also based its decision on concerns regarding CMS' data.

There are several additional points worth highlighting:

- These advisory panels, especially the APC Advisory Panel, are accustomed to working with imperfect data in establishing payment rates under Medicare. However, in this instance, the advisory panels identified the problems with CMS' brachytherapy device data as being so significant that CMS should not proceed with its August 23, 2006 proposal.

- Both advisory panels recommended continuation of the current "charges adjusted to cost" reimbursement methodology for **all** brachytherapy devices. CMS should not take a piecemeal approach to reimbursement for brachytherapy devices. Specifically, CMS should not attempt to apply prospective payment rates to a few (or any) types of brachytherapy devices. In the past, when CMS has taken a piecemeal approach to brachytherapy device reimbursement (applying one reimbursement methodology to some sources, but not others), tremendous and unnecessary confusion arose in the hospital community.

B. CMS Should Continue the Current Reimbursement Methodology for Brachytherapy Devices for At Least Two More Years to Fulfill the Brachytherapy Provisions of the Medicare Modernization Act

In response to similar concerns regarding flawed data for brachytherapy devices and the need to protect patient access, Congress established a plan to address Medicare's data and coding problems involving brachytherapy devices in 2003. Unfortunately, this plan has not yet been implemented in full.

In 2003, Congress enacted Section 621(b) of the Medicare Modernization Act (MMA) to protect access to brachytherapy for a vulnerable patient population in the hospital outpatient setting.[3] As a result of CMS's policies in place prior to enactment of the MMA, under-reimbursement for medically necessary brachytherapy devices was having a chilling effect on access.

By enacting Section 621(b) in 2003, Congress established a plan designed to prevent the implementation of new pricing policies for prostate brachytherapy devices in the absence of credible data. Specifically, Section 621(b) addressed the following issues:

- Congress established permanent safeguards from bundling by prohibiting CMS from bundling payment for brachytherapy devices with the implantation procedures.[4]

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2 CMS, Practicing Physicians Advisory Council, available at: http://www.cms.hhs.gov/FACA/03_ppac.asp#TopOfPage.

3 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, § 621(b) (2003).

4 Id. at § 621(b)(2).

- Congress created safeguards by directing CMS to refrain from setting prospective average payment rates for brachytherapy devices (as CMS planned under its November 2003 final rule) at least until the end of 2006. Specifically, Congress directed CMS to reimburse hospitals for the cost of each brachytherapy device prescribed to treat each patient (calculated from each hospital's charges adjusted to costs) through December 31, 2006.[5]

- Recognizing the need for more accurate data and an in-depth analysis, Congress directed the GAO to complete a study on brachytherapy devices no later than December 31, 2004.[6]

Congress established the 2004 deadline for the GAO report to allow at least two years for Congress, CMS and the public to digest, debate and further analyze brachytherapy device reimbursement data and access issues before the sunset of the "charges adjusted to costs" reimbursement provision. Importantly, the two-year period established under the statute was not established only to facilitate CMS' review of the study

Unfortunately, the GAO failed to complete its study within the timeframe established by Congress, and in addition, the GAO report reflects fundamental flaws in its implementation. The GAO did not publish its report until July 25, 2006 – over 1½ years after Congress' deadline.[7] By publishing the study so late, the GAO effectively eliminated the two-year period established in the MMA for debate and consideration of the GAO report. In fact, CMS stated that there was insufficient time for CMS to review the GAO report before publishing the recent proposed rule.[8]

We believe that the delay in publishing the GAO report is a direct result of the problems with the GAO's hospital survey. Ultimately, the GAO determined that a great deal of the information requested in the initial survey was not usable in the final report. The GAO's struggle to use a poor data sample may have caused or contributed to the delay.

The GAO concluded that CMS could set prospective payment rates for brachytherapy devices, but the GAO made this recommendation without reportable data about the types of devices used in clinical practice, without reportable data on the radioactive intensities of brachytherapy devices used in clinical practice and without consideration of the potential impacts on patient access. In fact, one of the striking features of the GAO report is the lack of data presented in the study.

In fact, there are a number of fundamental flaws in the GAO report, including the following:

- The GAO's data are significantly outdated and fail to reflect important changes in clinical practice over the past several years. In fact, both CMS's data and the GAO's data fail to reflect the new clinical protocols that have evolved over the past few years, including the increased use of prescriptions for "stranded" and "custom-stranded" brachytherapy devices for prostate cancer. These devices, which improve patient safety and clinical outcomes, are

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5 Id. at § 621(b)(1).
6 Id. at § 621(b)(3).
7 U.S. Gov't Accountability Office, *Rates for Certain Radioactive Sources Used in Brachytherapy Could Be Set Prospectively* (GAO-06-635, July 2006) [hereinafter *GAO Report*], available at: http://www.gao.gov/new.items/d06635.pdf.
8 71 Fed. Reg. 49506 (Aug. 23, 2006).

distinct from traditional brachytherapy devices (requiring separate FDA approvals and having increased costs of production).

- The importance of studying the clinical use of such new configurations of brachytherapy devices is evident from the GAO report in several ways. First, at the end of the report, the GAO notes that a professional society highlighted the need for the data to reflect the increased clinical use of stranded brachytherapy devices, which are "more costly but considered clinically advantageous."[9] Second, the GAO validated the importance of considering this information because the GAO attempted to collect data on the configurations of brachytherapy sources used in clinical practice. As noted in an appendix, the GAO did not collect adequate samples to report any information regarding the configurations or radiation intensities.[10]

- Although the GAO recognized the importance of collecting data from rural areas, the GAO secured data from only one rural hospital. This is not stated in the report, but the GAO staff acknowledged this important point verbally.[11] There is virtually no meaningful data in the report regarding the participation of different types of hospitals in the survey. At the end of the report, the GAO also noted that a professional society reviewed a draft of the report and cautioned the GAO that data used for payments must be representative of different hospital types.[12]

C. CMS Should Continue the Current Reimbursement Methodology for Brachytherapy Devices Because of the Flaws in CMS' Current Data on These Devices

CAB continues to have significant concerns regarding the accuracy of hospital reported brachytherapy data on which CMS is basing the proposed payment for brachytherapy sources in 2007. The Coalition engaged Christopher Hogan, Ph.D. of Direct Research LLC to perform an independent analysis of the 2005 hospital claims data that formed the basis for the 2007 payment rates. Dr. Hogan's analysis of the claims data appears throughout our correspondence and is presented in the following tables. (See attachment 2 for methodological information.)

At the outset, one of the fundamental problems with CMS' current data for brachytherapy devices involves the lack of separate data reflecting the use of stranded Iodine-125 and stranded Palladium-103 in clinical practice. As Congress highlighted in the MMA, one critical step in resolving the data problems facing CMS in the area of brachytherapy devices is for CMS to use separate codes that reflect clinically-relevant distinctions among different types of brachytherapy devices. These codes should evolve over time.

However, CMS's current 2005 data do not reflect the important new clinical protocols that have emerged over the past few years resulting in increased clinical use of "stranded" and "custom-stranded" brachytherapy devices for the treatment of prostate cancer. As described above, the GAO noted that one brachytherapy professional society reported that stranded brachytherapy devices are "more costly but considered clinically advantageous."[13]

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9 *GAO Report*, *supra* note 10, at 15.
10 *GAO Report*, *supra* note 10, at 22.
11 Meeting with GAO staff and representatives from the Coalition to Advance Brachytherapy, Washington, D.C. (May 17, 2006).
12 *GAO Report*, *supra* note 10, at 15.
13 GAO Report, note 10, at 15.

Stranded sources are distinct from traditional brachytherapy devices in a number of fundamental ways. As demonstrated in the clinical literature and widespread clinical practice, stranded Iodine-125 and Palladium-103 sources improve patient safety and clinical outcomes in the treatment of prostate cancer. In addition, Stranded Iodine-125 and Palladium-103 sources have increased costs of production arising from a number of factors, including the cost of using increased radioactivity due to the additional preparation time, along with the material and labor costs associated with "stranding" the sources with spacing that is consistent with the treating physician's specific prescription for a particular patient.

The absence of data or information about stranded brachytherapy devices is a significant flaw in CMS's current data. Blindly establishing prospective payment rates for brachytherapy devices without taking steps to protect patient access to these devices, which result in improved safety and efficacy, is ill-advised and inconsistent with Congress' direction to CMS under the Social Security Act. In contrast, CMS can easily address this issue (see recommendation to establish separate codes for stranded sources in separate comment letter from CAB dated September 25, 2006).

There are a number of additional, important flaws in CMS' data on brachytherapy devices. These flaws include – but certainly not limited to – the issues identified below from the initial analysis that Dr. Hogan performed.

1. The data continue to show a huge variation in per unit cost reported on claims across hospitals, which further validates our concerns regarding the data that CMS proposes to use to set brachytherapy device payments in 2007 (see Tables 1 & 2).

Table 1

HCPCS Code & Descriptor	**Type of Brachytherapy Device**	**Variation of Cost per Unit (2005 Hospital Claims)**
C1716 Gold-198	Seed	$3 - $943
C1717 HDR Iridium-192	reusable source	$0 - $4,746
C1718 Iodine-125	Seed	$0 - $14,632
C1719 Non-HDR Iridium-192	reusable source	$3 - $1,761
C1720 Palladium-103	Seed	$0 - $20,825
C2616 Yttrium-90	microsphere	$1,676 - $62,071
C2632 Iodine-125 solution	Solution	$0 - $7,253
C2633 Cesium-131	Seed	$28 - $15,797
C2634 High Activity Iodine-125	Seed	$2 - $4,526
C2635 High Activity Palladium-103	Seed	$3 - $5,212
C2636 Linear Palladium-103	Rod	$0 -$1,690

Table 2

HCPCS Code & Descriptor	**Min** (cost per unit)	**25th Percentile** (cost per unit)	**50th Percentile** (cost per unit)	**75th Percentile** (cost per unit)	**Max** (cost per unit)
C1717 HDR Iridium-192	$0	$61	$135	$286	$4,746
C1719 Non-HDR Iridium-192	$3	$15	$32	$110	$1,761
C2634 High Activity Iodine-125	$2	$16	$26	$41	$4,526

Further, we examined claims from the top 5 hospitals that perform High Dose Rate brachytherapy using the HDR Iridium-192 reusable source (C1717). Since these five institutions report the most HDR brachytherapy one would assume that the median costs would be similar and would increase from hospital 1 to hospital 5 based on the volume of services that should yield increasing costs per fraction as less procedures are performed (see Table 3).

Table 3

HCPCS Code & Descriptor	Total Hospitals	Median All Claims	Hosp 1 Median	Hosp 2 Median	Hosp 3 Median	Hosp 4 Median	Hosp 5 Median
C1717 HDR Iridium-192	283	$135	$3	$9	$479	$118	$95

2. The number of claims used to determine proposed payment for several brachytherapy devices are inadequate (see Table 4).

Table 4

HCPCS Code & Descriptor	Total Count of 2005 HOPPS Claims
C2633 Cesium-131	23
C2636 Linear Palladium-103	51
C2632 Iodine–125 solution	79
C1716 Gold-198	100
C1719 Non-HDR Iridium-192	144

3. Two-thirds of the current brachytherapy device APCs have proposed payment rates with 50 or fewer hospitals reporting cost data (see Table 5).

Table 5

HCPCS Code & Descriptor	Hospitals Reporting 2005 HOPPS Claims
C2637 Ytterbium-169	0
C2636 Linear Palladium-103	7
C2633 Cesium-131	8
C1716 Gold-198	14
C2635 High Activity Palladium-103	20
C1719 Non-HDR Iridium-192	27
C2632 Iodine–125 solution	31
C2634 High Activity Iodine-125	50

4. Rank order anomalies exist in proposed payments for brachytherapy devices. For example, High Activity Iodine-125 sources (C2634) always cost more than "low activity" Iodine-125 sources (C1718). In practice, High Activity sources typically are 2 to 10 times more expensive than loose Iodine-125 sources. However, CMS' data do not reflect this fact, which indicates that CMS' data are inaccurate (see Table 6).

Table 6

HCPCS Code & Descriptor	Median Cost (2005 Hospital Claims)
C1718 Iodine-125	$35.54
C2634 High Activity Iodine-125	$25.77

Another example involves Palladium. In practice, High Activity Palladium-103 (C2635) source cost is always significantly higher than "low activity" Palladium-103 sources (C1720). Further, the Linear Palladium-103 (C2636) cost should be higher than "low activity" Palladium-103 sources (C1720) (see Table 7). As a result, it is clear that CMS' data are inaccurate.

Table 7

HCPCS Code & Descriptor	Median Cost (2005 Hospital Claims)
C1720 Palladium-103	$49.07
C2636 Linear Palladium-103	$39.28
C2635 High Activity Palladium-103	$54.48

5. The use of a unit-weighted median can result in a single claim or a single hospital being the primary determinate of the median cost, if that claim or hospital accounts for a large number of reported units. For example, one hospital reporting data for Linear Palladium-103 (C2636) accounts for 88% of the claims data used to determine median cost for the source. This is particularly troublesome because we know that some hospitals are still not reporting accurate charges and yet the payment for a brachytherapy source might be determined by erroneous data. Fifty percent of the current brachytherapy device APCs have their median cost being determined by only a few hospitals that report data (see Table 8).

Table 8

HCPCS Code & Descriptor	Top Hospital (% total units)	Top 5 Hospitals (% total units)	Top 10 Hospitals (% total units)
C1716 Gold-198	27%	87%	99%
C1719 Non-HDR Iridium-192	27%	78%	94%
C2632 Iodine-125 solution	22%	68%	93%
C2633 Cesium-131	40%	99%	100%
C2635 High Activity Palladium-103	28%	72%	93%
C2636 Linear Palladium-103	88%	100%	100%

6. Brachytherapy always requires the use of a brachytherapy device(s). Every hospital claim for brachytherapy treatment should include at least one unit of a brachytherapy source HCPCS code ("C" code). While claims data may be improving over time, the majority of hospitals still do not include a brachytherapy source code with the procedure claims (see Table 9).

Table 9

Brachytherapy Procedure APC	Percentage of 2005 Hospital Claims with a Brachytherapy Source "C" Code
312 Radioelement Applications	29.6%
313 Brachytherapy	59.6%
651 Complex Interstitial Radiation Source Application	36.4%

Proposed 2007 prospective payment rates for brachytherapy sources are based on flawed and erroneous data as are supported by the Direct Research LLC 2005 outpatient claims data analysis. **CAB recommends that CMS continue the current HOPPS payment methodology of hospital charges adjusted to cost for all brachytherapy devices in 2007 and 2008.**

Conclusion

CAB agrees with the Advisory Panels that maintaining the current reimbursement policy is the best course of action at this time, and we urge CMS to continue the current "charges adjusted to costs" (CCR) reimbursement methodology during 2007 and 2008.

- Continuing the current reimbursement methodology will ensure that Congress, CMS and the public will have the time envisioned under the Medicare Modernization Act (MMA) for consideration and discussion regarding the GAO's report on brachytherapy pricing and the possible development a new proposed payment methodology by CMS. Although Congress instructed the GAO to complete its report before the end of 2004, the final report was not released until July 25, 2006, more than 18 months after the statutorily set deadline of December 31, 2004.

- The current reimbursement methodology reflects much of the congressional direction from the MMA, especially in terms of a payment methodology that properly accommodates the variation in the configurations and radioactive/radiation intensities of the brachytherapy devices prescribed for each patient.

- The current reimbursement methodology ensures that no inadvertent barriers to access exist for the vulnerable population of cancer patients who require brachytherapy. For example, the current payment methodology reflects the evolving nature of brachytherapy devices in clinical practice, including the trends toward use of stranded, coiled, linked and echogenic devices, as well as use of an expanding range of radioactive intensities. There are additional emerging brachytherapy technologies, including new isotopes and new non-isotopic (electronic) radiation sources.

- The current methodology addresses the ongoing concerns regarding CMS' data on brachytherapy devices, especially during a period of evolution in the configurations and intensities used in clinical practice. Maintaining the current payment methodology will help physicians prescribe the most appropriate source and configuration for each patient.

- The current payment policy has been in place for more than two years and is working well for beneficiaries, hospitals and the Medicare program, ensuring patient access and allowing Medicare to be a prudent purchaser.

Brachytherapy offers important cancer therapies to Medicare beneficiaries. Appropriate payment for brachytherapy sources is necessary to ensure that Medicare beneficiaries will continue to have full access to high quality cancer treatment in the hospital outpatient setting.

We hope that CMS will take these issues under consideration during the development of the 2007 Hospital Outpatient Final Rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH, at (703) 534-7979 or Gordon Schatz, Esq., at (202) 414-9259.

Thank you for your consideration.

Sincerely,

Lisa Hayden
Chair

Janet Zeman
Vice-Chair

cc: Carol M. Bazell, M.D.

Attachment 1

Coalition for the Advancement of Brachytherapy (CAB)

The Coalition for the Advancement of Brachytherapy (CAB) is a national non-profit association composed of manufacturers and developers of sources, needles and other brachytherapy devices and ancillary products used in the fields of medicine and life sciences. CAB members have dedicated significant resources to the research, development and clinical use of brachytherapy, including the treatment of prostate cancer and other types of cancers as well as vascular disease. Over 90% of brachytherapy procedures performed in the United States are done with products developed by CAB members.

Member Companies

BrachySciences
C.R. Bard, Inc.
Cytyc Corporation
IsoRay
MDS Nordion
Mentor Corporation
Nucletron Corporation
Oncura
SIRTeX Medical, Inc.
Theragenics Corporation
Varian Medical Systems
Xoft, Inc.

CAB Advisory Board

American Brachytherapy Society
American College of Radiation Oncology
Association for Freestanding Radiation Oncology Centers
Society for Radiation Oncology Administrators

Attachment 2

Christopher Hogan, Ph.D., Direct Research LLC
2005 Outpatient Claims Data Analysis of Brachytherapy APCs
Background and General Methods

Currently there are 12 brachytherapy source codes (C1716, C1717, C1718, C1719, C1720, C2616, C2632, C2633, C2634, C2635, C2636 & C2637), although CMS does not have claims data for Ytterbium-169 (C2637) in the 2005 claims data set.

In prior years CMS paid these as a cost-based pass-through. Each hospital's payment reflected CMS's estimate of cost, based on charges and cost report data. Starting in 2007, however, CMS intends to pay a prospectively-set payment per unit for these sources, as it does for most other HOPPS items.

The 2007 proposed rule does not describe any details of the method used to calculate median costs for the brachytherapy sources. The rule does, however, describe brachytherapy sources in the same terms that (historically) were used to describe HOPPS-paid drugs. We can infer from this that CMS proposes to use the same methodology for brachytherapy sources that it used historically for drugs. And, empirically, I in fact get the exact CMS-calculated medians when I apply that method. (Drugs are no longer paid based on CMS-estimated "costs" from OPPS claims, but instead are now paid on the basis of average sales price (ASP) data.)

To calculate the rate, CMS takes the relevant OPPS claims and does the following:

- Calculates the "cost" on each claim line as charges times cost-to-charge ratio (CCR). CMS calculates the CCRs separately for each department in each hospital using the hospital's cost reports.
- Standardizes those costs for variations in hospital wage indices, to put all hospitals' data on a more nearly level playing field. So, the standardization reduces the costs for high-wage hospitals, and increases them for low-wage hospitals.
- Calculates a cost per unit as cost divided by reported units. Records with zero reported units are ignored. In the 2007 file a negligible number of brachytherapy source records had zero units.
- Trims statistical outliers using three standard deviations around the geometric mean. In practice, this means taking the (natural) log of cost per unit and dropping claims where the log cost is outside the range of plus or minus three standard deviations of log cost. In practice, this drops a nearly-negligible fraction of records (perhaps one-half percent). This calculation is done on a unit-weighted basis: claims with high number of reported units count more than claims with a lower number of units.
- Take the median cost per unit on the remaining records, weighted by the number of units on the record. Again, claims with large numbers of units count more than claims with low numbers of units.
- The median cost, as calculated, becomes the basis for setting the relative weight and payment amount. As of the 2007 proposed rule, the proposed 2007 payments appear very close to estimated 2005 median costs.

Drugs

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CORAR

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September 29, 2006

Via Overnight Delivery

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Attn: CMS 1506-P

Re: CORAR Comments on Radiopharmaceutical Payment in CMS Proposed Rule on Hospital Outpatient Prospective Payment System CY 2007

OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals

Dear Dr. McClellan:

The Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) is pleased to submit these comments and recommendations to the Centers for Medicare and Medicaid Services (CMS) in response to the proposed rule on the Medicare hospital outpatient prospective payment system for CY 2007 (71 Fed. Reg. 49,506, Aug. 23, 2006). CORAR has worked with CMS since the inception of the HOPPS to develop payment policies for radiopharmaceuticals that support high quality care for Medicare patients. Most recently, we appreciated meeting at CMS on September 21, 2006 with Doctors Bazell, Hambrick, Simon, Bowman and Rebecca Kane to discuss our initial recommendations. CORAR is an association comprised of companies in the United States who manufacture and distribute radiopharmaceuticals, sealed sources, and radionuclides primarily used in clinical care, medicine and life science research. Also, CORAR is a member of the Nuclear Medicine APC Task Force.

I. Executive Summary

A. CMS' proposes to set fixed payments in 2007 for all radiopharmaceuticals, with some severe reductions, after only one transition year under the cost to charge ratio method (CCR).

B. The proposed change in payment methodology, using data from 2005 does not include key changes that CMS instructed hospitals to make in radiopharmaceutical (RP) data charges. There have been significant coding changes in 2006. The 2006 data base will much better enable CMS to determine payment consistent with CMS' own instructions.

C. CORAR recommends that CMS continue the current CCR payment (using the overall hospital CCR) for all radiopharmaceuticals for one more year to ensure that the data used to set prospective rates reflects the changes in codes for 2006 and CMS instructions to hospitals to adjust charges in 2006.

D. When CMS sets prospective payment rates for radiopharmaceuticals, critical adjustments or refinements must be made, including:

1. Adjustment in payment for all radiopharmaceuticals to accurately reflect unique overhead costs of radioactive isotopes, either based on a fixed adjustment amount ($35) or a fixed percentage amount (10%) with a ceiling of $50.

2. Adjustments to cost (if or when made) should be calculated using the overall hospital CCR rather than the department CCR. The overall hospital CCR better reflects the reasonable costs of radiopharmaceuticals and related overhead.

3. Certain radiopharmaceuticals, especially diagnostic/therapeutic cancer related radiopharmaceuticals, require new or distinct methodologies to ensure payment based on average acquisition costs and prevent severe payment reductions that would undermine hospitals' ability to provide these products to patients.

E. When CMS moves to a fixed payment system, CORAR strongly recommends that CMS adopt a buffering mechanism so that the payment rates for some RPs do not experience rapid reductions which could adversely affect beneficiary access to services utilizing radiopharmaceuticals.

F. CMS should eliminate the proposed $55 threshold and allow separate payment for all radiopharmaceuticals.

II. CORAR Analysis, Discussion, and Recommendations

A. Background

The Medicare statute requires that payment for drugs and radiopharmaceuticals under HOPPS be based on the drug's or RP's "average acquisition cost" and subject to any adjustment for overhead costs and other adjustments determined to be necessary by the Secretary of Health and Human Services (see Social Security Act, section 1833(t)(14). CMS determined for CY2006 that the cost to charge ratio was a reasonable interim method to pay for radiopharmaceuticals. This was based on a number of factors including the exemption of radiopharmaceuticals from payment based on average sales price. See section 303(h) of Pub.L. 108-173.

CORAR supported CMS' position for CCR based payment of radiopharmaceuticals in 2006 and believes one more year is critical to stabilize hospital data and achieve, for most radiopharmaceuticals, a reliable data source to calculate average acquisition costs, or a reasonable proxy for average acquisition costs. As discussed below, CORAR encourages the continued assessment of all methodologies, including fixed payment based on "mean" costs as a starting point for payment for CY 2008.

B. Rationale for Continuation of CCR through 2007

1. Proposed payment levels do not reflect average acquisition costs

Proposed 2007 payment levels for some radiopharmaceuticals are severely flawed and fail to reflect the average acquisition costs. For example, payment reductions compared to 2005 rates exceed 40% - 48% for several radiopharmaceuticals. For example:

Radiopharmaceutical	2005 Payment	Proposed 2007 Payment
A9542 Zevalin	$2,419	$1,344
A9543 Zevalin	$20,948	$12,130
A9544 Bexxar	$2,200	$1,368
A9545 Bexxar	$19,422	$11,868
A9507 ProstaScint	$1,915	$928.

The attached chart documents all proposed radiopharmaceutical payment changes including the most severe ones.

CMS has typically been alert to radical payment reductions and has made various adjustments to protect hospitals from extreme payment reductions (including the use of external data and establishing a payment floor during 2007, based on a percentage of the APC payment rate). CMS' authority should be exercised here.

Additionally, there are 15 radiopharmaceuticals whose proposed payment rate based on "mean" cost is lower than actual cost. Therefore, on its face, the proposed application of mean cost to pay for these products would contravene the statutory requirement to pay based on average acquisition cost.

The underlying 2005 claims data used to set payment for CY2007 fails to accurately capture reasonable charges plus overhead and handling for many radiopharmaceuticals. These charges need to reflect the reasonable and necessary costs of patient and professional protections against exposure to radioactivity, as well as safe handling and disposal costs, along with the costs of complying with federal (Nuclear Regulatory Commission) and state regulations on radioactive materials. One more year could significantly improve the underlying data as hospitals will be responding in 2006 to CMS instructions.

For CY 2006, CMS instructed hospitals that, if necessary, the hospitals should appropriately adjust their charges for radiopharmaceuticals to more accurately reflect all costs associated with the acquisition, preparation, and handling of these products. See 70 Fed. Reg. 68654 (Nov. 10, 2005). This would create hospital charges that enabled CMS to determine payment under OPPS using the hospital overall CCR to accurately reflect all of the acquisition costs associated with providing these products to hospital outpatients. This is especially critical to high cost radiopharmaceuticals. Maintaining payment for radiopharmaceuticals based on the temporary methodology of charges adjusted to cost using the hospital overall CCR for one more year will stabilize coding and enable CMS to evaluate the data and determine fixed payment rates which serve as an appropriate proxy for average acquisition costs.

Only claims data from 2006 and beyond should be used to establish a future prospective payment methodology so that CMS does not negate the work done in CY 2006 to accurately capture radiopharmaceutical costs. CMS should evaluate the use of 2006 claims data to set prospective payments for radiopharmaceuticals in 2008, and then continue to use claims data from 2 years prior to set payments in 2009 and beyond. CMS should continue to use the hospital–specific overall CCR when setting future prospective payments to maintain consistency.

CMS' efforts to cross-walk certain products and recent changes in HCPCS descriptors further support the need for one more year of consistent codes to help hospitals generate accurate radiopharmaceutical data.

2. APC Advisory Panel, GAO and MedPAC support continuation of CCR

There is support from a number of sources for CMS to continue CCR for one more year. Most recently, on August 24, 2006, the APC Advisory Panel recommended that CMS continue CCR for radiopharmaceuticals for one more year through 2007. In a similar vein, the GAO report acknowledged the distinctive nature of radiopharmaceuticals which posed special challenges for collecting and interpreting hospital cost data. The recent GAO report recommended new data acquisition in recognition that hospital charge data, at that time, was not reliable. With recent code changes and payment methodologies, this is still true. Further, MedPAC in its report on overhead costs for drugs in the hospital outpatient setting found that radiopharmaceuticals had the highest overhead costs of any class of drugs.

Taken as a whole, the APC Advisory Panel recommendations, along with the recent GAO and MedPAC reports strongly support the continuation of CCR for radiopharmaceuticals for one more year.

C. Methodologies for Paying Radiopharmaceuticals - 2008

CORAR recommends that CMS enable full discussion on refined and new payment methodologies for 2008. CMS' proposal to use mean costs is a valuable starting point for some radiopharmaceuticals if appropriate adjustments for pharmacy overhead and handling are considered and can be made. For some products, however, even use of the mean cost fails to translate into a meaningful average acquisition cost.

1. Adjustments to better reflect unique overhead costs

CMS proposes to use the mean costs derived from 2005 claims data, where costs are determined using CMS' standard method of applying the hospital specific departmental CCR to radiopharmaceutical charges. As noted above, we expect 2006 data to reflect hospital responses to CMS' instructions in November 2005. Further, departmental CCRs have been flawed as a basis for converting radiopharmaceutical charges to costs, as the departmental CCR typically fails to reflect the unique overhead costs and charge practices for most radiopharmaceuticals. Hospital overall CCRs have served as a more accurate method to capture these costs.

CORAR recommends that for most radiopharmaceuticals, if a fixed payment has to be established for CY 2008, CMS use all the following factors:

a. Mean costs

b. Overall hospital CCR

c. Radiopharmaceutical overhead adjustment factor

($35 per radiopharmaceutical added to the mean cost, or 10% added to the mean cost) (See attached chart depicting related overhead costs)

2. Special considerations for high cost radiopharmaceuticals

The proposed 2007 payment levels for some higher cost (diagnostic and therapeutic) radiopharmaceuticals are so severely flawed that alternate methodologies need to be developed to ensure payment based on average acquisition costs. Charge compression in the 2005 claims data prevents the accurate capture of reasonable charges plus overhead and handling costs. Products paid in 2005 near $20,000 have proposed 2007 rates near $11,000. Proposed payment reductions in the range of 30-40% when comparing the proposed 2007 payment to 2005 payment levels could severely disadvantage hospitals from using these products. In November 2005, CMS instructed hospitals that, if necessary, they could appropriately adjust their charges for radiopharmaceuticals based on all costs associated with the acquisition, preparation, and handling of these products. Payments under OPPS using the hospital-specific overall CCR would then accurately reflect all of the actual costs associated with providing these products to hospital outpatients. Maintaining payment for these higher cost radiopharmaceuticals based on the temporary methodology of charges adjusted to costs using the hospital-specific overall CCR for one more year is expected to stabilize payment and enable CMS to determine fixed payment rates which may more accurately reflect hospital costs.

Only claims data from 2006 and beyond should be used to set prospective payments so that CMS doesn't negate the work done in CY 2006 to accurately capture the costs of these higher priced radiopharmaceuticals. CMS should use the 2006 claims data to set prospective payments for radiopharmaceuticals in 2008, and then continue to use claims data from 2 years prior to set payments in 2009 and beyond. CMS should continue to use the hospital–specific overall CCR when setting future prospective payments to maintain consistency in payment for radiopharmaceuticals.

There may also be a need for a distinct data trimming standard for the highest cost radiopharmaceuticals to eliminate the data, which arising from charge compression, results in severe underpayment.

D. Separate Payment for All Radiopharmaceuticals – No $55 Threshold

CMS is proposing to raise the threshold for separate payment for drugs from $50 to $55. CORAR recommends that all radiopharmaceuticals be paid separately, and that the proposed threshold of $55 should be eliminated. This will ensure that payment within the related nuclear medicine procedure APCs will be more homogeneous, and that hospitals are accurately reporting all radiopharmaceuticals and that payment levels for radiopharmaceuticals can be more equitably determined and paid across the spectrum of products.

III. Recommendations and Conclusions

CORAR recommends the following:

1. Continue CCR through 2007

2. Explore alternate methods to refine and set prospective rates for 2008

   a. Use mean costs plus an adjustment (either a fixed amount per radiopharmaceutical or a percentage of costs) to account for the unique overhead costs associated with radiopharmaceuticals.

   b. Develop methods to correct for charge compression for high cost radiopharmaceuticals

3. Pay for all radiopharmaceuticals separately and eliminate the proposed $55 threshold.

4. When CMS moves to a fixed payment system for RPs, CORAR strongly recommends that CMS adopt a buffering mechanism so that hospitals do not sustain extreme payment reductions for some RPs which could adversely affect beneficiary access to needed diagnostic or therapeutic services.

* * *

CORAR renews its offer to continue collaborating directly with CMS and through the Nuclear Medicine APC Task Force to develop workable alternate methodologies for payment of radiopharmaceuticals.

CORAR thanks CMS for its consideration of these recommendations. We look forward to working with CMS and the Nuclear Medicine APC Task Force to refine payment methods for radiopharmaceuticals, in support of high quality care for Medicare patients and equitable payment for hospitals.

Sincerely,

Lisa Saake/agw

Lisa Saake, R.N., MBA
CORAR Co-Chair – Clinical Practice and Reimbursement Committee

cc: Carol M. Bazell, M.D., CMS
Edith Hambrick, M.D., CMS
Kenneth Simon, M.D., CMS
Kenneth G. McKusick, M.D. (Nuclear Medicine APC Task Force)

Attachments:

1. Radiopharmaceutical payment chart – comparison of 2005 to proposed 2007 payment

2. Initial assessment and support for additional radiopharmaceutical overhead costs

Comparison of Medicare 2005 and Proposed 2007 HOPPS Payment for Radiopharmaceuticals

	Code	Description	2005 Payment	Proposed Payment
1	A9530-C9405	Th I-131 iodide sol mCi	$9.73	$12.60
2	A9517	I-131 sodium capsule /per mCi	$6.57	$14.54
3	A9528-C9403	Dx I-131 iodide cap mCi	$6.57	$24.86
4	A9505	TL 201 per mCi	$18.29	$27.18
5	A9516	123 sodium iodide capsule per 100 uCi	--	$27.44
6	A9524	Iodinated I-131 albumin per 5 uCi	--	$36.78
7	A9539-A9515	Tc 99m pentetate per dose revised from per mCi to per dose up to 25 mCi		$56.77
8	A9536-A9511	Tc 99m depreotide revised from per mCi to per dose	$37.79	$67.91
9	A9560- Q3010	Tc99m labeled RBC revised from per mCi to per dose up to 30 mCi		$132.95
10	A9553	Cr51 chromate revised from per 0.25 mCi to per dose up to 250 uCi		$167.62
11	A9562-Q3005	Tc99m mertiatide revised from per mCi to dose in 2006	$31.13	$180.08
12	A9564-Q3011	P32 chromic phosphate per mCi	$147.25	$222.35
13	A9526	Ammonia N-13, per dose	109.86	$230.77
14	A9563-Q3007	P32 Na phosphate per mCi	$94.98	$117.11
15	A9550- Q3006	Tc99m gluceptate per dose revised from per 5 mCi to per dose up to 25 mCi		$236.53
16	A9555-Q3000	Rb82 rubidium	$153.39	$239.83
17	A9548-C1092	In111 pentetate per 0.5mCi	$224.10	$262.81
18	A9605	Sm153 lexidronam per 50 mCi	$907.33	$1,316.41
19	A9502	Tc 99m tetrofosmin per dose	$104.58	$73.81
20	A9556-Q3002	Ga67 gallium per mCi	$27.10	$22.73
21	A9500	Tc 99m sestamibi per dose	$106.32	$82.58
22	A9551-C1201	Tc99m succimer per dose revised from per vial to per dose up to 10 mCi	$118.52	$84.79
23	A9546-C1079	Co57/58 revised from 0.5 uCi to per dose up to 1 uCi	$221.78	$149.44
24	A9565-Q3008	In111 pentetreotide revised from 3 mCi to 1 mCi	$1,079	$185.60
25	A9557-Q3003	Tc99m bicisate	$370.60	$254.46
26	A9549-C1122	Tc99m arcitumomab revised from per vial to per dose	$1,079.00	$255.95
27	A9547-C1091	In111 oxyquinoline	$373.50	$306.51
28	A9521	Tc-99m exametazine per dose	$778.13	$317.07

	Code	Description	2005 Payment	Proposed Payment
29	A9508	Iobenguane sulfate I-131/0.5 mCi	$996.00	$429.55
30	A9566-C1093	Tc99m fanolesomab per dose	$1,045.80	$527.31
31	A9600-C9401	Strontium-89 chloride per mCi	$406.16	$533.58
32	A9507	In-111 capromab pendetide per dose	$1,915.23	$928.19
33	A9542-C1082	In111 ibritumomab, dx	$2,419.78	$1,344.34
34	A9544-C1080	I131 tositumomab, dx	$2,241.00	$1,368.17
35	A9545-C1081	I131 tositumomab, tx	$19,422.00	$11,868.78
36	A9543-C1083	Y90 ibritumomab, rx	$20,948.25	$12,130.20
37	A4642	In111 satumomab pendetide, per dose (revised code in 2006)	$1,390.25	$192.12
38	A9529-C9404	Dx I-131 iodide sol mCi	$9.73	--
39	A9504	Tc99m apcitide per dose	$415.00	--
40	A9503	Tc 99m medronate per dose	--	--
42	A9510	Technetium TC99m disofenin per dose	--	--
43	A9512	Technetium TC99m pertechnetate	--	--
45	A9531	Dx I-131 so iodide microcurie	--	--
46	**A9532**	I-125 serum albumin per 5 uCi (should be paid separately - see current status indicator)	--	--
47	A9540-A9519	Tc MAA per dose		--
48	A9541-A9520	Tc 99m sulfur colloid per dose		--
49	A9554	I125 iothalamate, dx		--
50	A9558	Xe133 xenon per 10 mCi		--
51	A9561- Q3009	Tc99m oxidronate		--
52	A9567	Technetium TC-99m aerosol		--

September 20, 2006

RADIOPHARMACEUTICAL OVERHEAD COSTS FOR HOPPS

I. RADIOPHARMACEUTICALS - GENERAL

A. Unique technological features as radioactive isotopes
B. Clinical use in diagnostic and therapeutic nuclear medicine imaging procedures
C. Every nuclear medicine procedure requires at least one radiopharmaceutical (RP)
D. Hospital overhead and handling costs for RPs
    1. Important in ensuring safety of patient and protecting hospital staff from exposure to radiation
    2. Two or three different models
        a) Hospital operates nuclear pharmacy on site, prepares RPs from kits, or
        b) Hospital purchases all RPs from external nuclear pharmacy, or
        c) Hospital prepares some RPs from kits and purchases some RPs from external nuclear pharmacy.

II. SPECIAL HANDLING OF RPS (From Delivery to Hospital to Patient)

1. Radiation safety precautions - compliance for delivery and handling.
2. Technologist must check in RPs (15 mins) using radiation detection materials and survey meters.

Radiologic Technologist @0.41 / minute	= $6.15 per check-in, per RP
Survey meters average cost	= $800 to $1,000
Dose calibrator (5 year life)	= $5,496.67

3. Whole body dosimeters - exchanged on a monthly basis. 300 bed hospital 6-7 employees would be wearing badges

$25/per employee per month	= $162.50 per month

4. Radioactive materials license:
    - Annual license costs and licenses will vary depending on scope of services, diagnostic, therapeutic, sealed sources, generators, etc.

III. TRANSPORT WITHIN HOSPITAL AND STORAGE OF RPS

1. Transport container (lead pig), radiation storage area.
2. Time and materials to assay RP and/or calibrate/confirm dose of RP just prior to administration.
3. Syringe shield for preparation and administration = $200 - $300 ea.

IV. HOSPITAL DISPOSAL – ALSO REQUIRES SEPARATE STORAGE

1. Store and disposal of partial or remainder of RP dose required for 10 half lives of product (could be days to weeks).

2. Materials and supplies exposed to radioactive patient (inpatient) require special waste storage area before disposal.
3. Used needles, syringes, tubing, etc that have come into contact with patient receiving RPs and could include bedding, patient gowns.
4. Most hospitals must maintain radioactive holding area - segregated storage areas for (1) radioactive products and (2) needles and supplies.

V. SPECIAL EQUIPMENT/SUPPLIES FOR HOSPITALS THAT PREPARE RPS

1. Lead shield used in preparation of RP dose = $725 - $800 ea
2. Syringes
3. Lead storage box (life 10 – 15 years) = $3,850 ea
4. Survey monitors that detect exposure during mixing/preparation
5. Dose Calibrators for quality control and check activity levels prior to administration (Cost is between $5000 and $6800 depending on model).
6. Gamma counter – automatic = $17,665 ea.

VI. HOSPITAL RECORDKEEPING/SURVEY COSTS

1. Department record-keeping and hospital record-keeping
2. Daily radiation exposure, disposal surveys, Radiation survey meters (8 years) = $756.25 ea.
3. Weekly radiation exposure, disposal surveys
4. Quarterly, semi-annual and annual reports regarding use of RPs, safety and licensure

VII. SPECIAL STAFFING AND SOFTWARE - OVERHEAD

1. Staff time – Radiation Technologist time to document delivery/receipt of RPs
2. Radiation Safety Officer – Responsible for compliance / hospital employee annual salary = $80,000
3. Nuclear pharmacy management, hardware and software (5 years) = $13,400 - $15,000
4. Computer workstation, nuclear medicine analysis – viewing (5 years) = $55,097

VIII. COMMENTS AND RECOMMENDATIONS

1. CMS instructed hospitals to adjust RP charges to reflect overhead costs – Nov. 2005
2. Hospitals have begun to make adjustments during 2006
3. CORAR initially projects that the above overhead costs may add, at minimum, $35 to each radiopharmaceutical.
4. CORAR recommends that initially payment for all radiopharmaceuticals be adjusted to reflect overhead costs by adding $35.

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48
OPPS

APC
Visits

Tamar (2)
Dana (2)
Joan
Carol
Alberta

1

September 26, 2006

Attention: CMS-1506-P
Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
PO Box 8011
Baltimore, MD 21244-1850

RE: Medication Therapy Management Services

Dear Sir or Madam:

Could you please provide additional guidance with regard to your statement,

"We have no need to distinguish medication therapy management services provided by a pharmacist in a hospital from medication therapy management services provided by other hospital staff, as the OPPS only makes payments for services provided incident to physicians' services."

In a recent CMS Q&A on the CMS website, CMS identifies the services that qualify as an "incident to." One of the requirements is that the physician must provide direct supervision by being present in the office suite to assist if necessary. However, from the CMS Medicare Benefit Policy Manual (Pub 100-02) Chapter 6, Hospital Services Covered Under Part B, Section 20.4 Outpatient Therapeutic Services, "the physician supervision requirement is generally assumed to be met where the services are performed on hospital premises." Would the services of a pharmacist fall under Section 20.4?

In regard to pharmacists employed in hospitals providing medication therapy management services, these services are provided similar to cardiac rehab. The primary care physician who has referred the patient to the hospital for services is not physically present at the hospital at the time medication therapy management services are rendered. In most cases, the referring physician is a physician in the Community and their only relationship with the hospital is that of being a member of the medical staff. One of the most common medication therapy management services provided by a pharmacist in a hospital is anticoagulation therapy. The patient may come to the hospital weekly to receive lab work and see the pharmacist. The pharmacist would call the referring physician to make recommendations regarding medication management, as necessary. Is supervision assumed because the service is provided in a hospital?

The physician medical director would not have direct contact with the patient but would be available for consultation with the pharmacist if necessary. The medical director would be responsible for setting policies and procedures, but would not see any patients and would often not be physically present in the hospital at the time services are rendered.

Would you please comment on how it would be appropriate to bill for this service? Would it be appropriate to bill this as a clinic visit in the range (99211- 99215)? Would the service be limited to billing under 99211 as a "nurse visit" type of service?

Comments on this service would be very much appreciated as hospitals that either have services such as this, or are considering such services, would appreciate knowing if these services are appropriately reimbursable. If these services, provided by a non-directly supervised pharmacist, are not reimbursable as provided, it is appropriate to notify providers of that and avoid the conflict that occurred with cardiac rehab.

"Visits"

In reviewing the "Guidelines Based on the Time Staff Spent with the Patient" and "Guidelines Based on Patient Complexity," CMS commented that these two models both have the "potential for upcoding and gaming." In fact for the Patient Complexity model, the words "significant potential for upcoding and gaming" are used. However, later in this same section, it is stated, "we are proposing that hospitals may continue to use their existing internal guidelines to determine the visit levels to be reported with these codes."

Given all of that, if a hospital is using either of the two "Guidelines" above, may they continue to determine the visit levels based on this current methodology until CMS has implemented national guidelines? Does it matter if the distribution of codes does not result in "a normal curve?" Most facilities have a strong desire to be in compliance with CMS standards and appreciate clear guidance to avoid any potential fraud and abuse allegations in the future.

Sincerely,

R. Elizabeth Hickman

R. Elizabeth Hickman
Regional Director
Corporate Compliance