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GEORGETOWN UNIVERSITY MEDICAL CENTER

Vincent T. Lombardi Cancer Research Center
School of Medicine
Department of Medicine
Division of Hematology/Oncology

October 6, 2006

VIA OVERNIGHT MAIL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mailstop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: CMS-1506-P; Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment Systems and CY 2007 Payment Rates

Dear CMS Administrator:

I serve as Director of the Comprehensive Hemophilia Treatment Center (HTC) at Georgetown University Hospital and the Lombardi Cancer Center in Washington, DC. I appreciate this opportunity to respond to the proposed changes to the Hospital Outpatient Prospective Payment System (HOPPS), and in particular, the proposed decrease in payment for clotting factor concentrate replacement products.

Our federally-funded facility is reimbursed for the care we provide to our Medicare patients under the Hospital Outpatient Prospective Payment System methodology. I, along with two nurses and a part-time social worker, serve approximately 100 patients with hemophilia, six of whom are Medicare beneficiaries.

Clotting factor concentrate products are absolutely essential in the treatment of hemophilia and other bleeding disorders. Many hemophiliacs suffer from debilitating and limb threatening bleeding events, which severely and negatively impact their quality and quantity of life. Prophylactic clotting factor treatment strategies can help to prevent this damage and other long-term and acute bleeding

3800 Reservoir Road NW Washington, DC 20007-2197
Faculty/Administration: 202-687-2198 FAX: 202-687-4429
Ambulatory Services: 202-687-2223 FAX: 202-687-3302

complications. When severe bleeds result in significant blood loss or occur in critical areas such as the brain, administration of clotting factors can be life-saving.

Although I am extremely pleased that CMS will continue to provide the clotting factor furnishing fee, updated based on the Consumer Price Index, I must express concern over the proposed decrease in clotting factor payment from the current ASP+6% to the proposed ASP+5%. In the proposed rule, CMS does not provide a rationale for the clotting factor payment decrease, as it does for other specified covered outpatient drugs. Even if the same rationale were to apply to commercial clotting factor concentrates, I would strongly encourage CMS to gather and analyze at least another year of data before taking this drastic 1% step.

Immediate access to clotting factor concentrate products is absolutely vital to the life and health of our patients. Although this 1% drop in payment may seem small, for our facility and most importantly, for our patients, the ramifications can be large. The treatment and care of individuals with congenital bleeding disorders are labor and time intensive and current reimbursement mechanisms through E and M codes are not adequate to cover the level of complexity and the time expended by physicians and specialized nurses for their medical issues. Overall, the care of such complicated patients is already being subsidized by the institution which houses our HTC. Any reduction in the reimbursement for hemophilia care will necessitate increased subsidization for our HTC by the hospital. This will possibly jeopardize the future of our HTC in the long-term and in the least will certainly result in reduction of services to our hemophilia patients in the short term.

Federal funding for our Hemophilia programs has not increased over the past ten years and has not even been adjusted for inflation. Any reduction in Medicare reimbursement for clotting factor concentrate therapy is tantamount to an additional reduction in support, which will greatly affect our HTC's ability to address our patients' medical needs.

Should you have questions or require additional information, please do not hesitate to contact me at (202) 444-8676. In fact, if you are interested in learning more about hemophilia care and the unique and comprehensive services provided by HTC's, which have actually been demonstrated to reduce the cost of health care for these patients, I would be very happy to invite you to visit and observe the activities of our HTC at Georgetown University Hospital. I thank you in advance for your time and consideration of this matter.

Sincerely,

Craig M. Kessler MD

Craig M. Kessler, MD
Professor of Medicine and Pathology
Director, Comprehensive Hemophilia Treatment Center and
Director, Division of Coagulation

Bard Urological Division
C.R. Bard, Inc.
13183 Harland Drive
Covington, GA 30014
(678) 342-4801

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BARD

Mark O. Downey
President

October 05, 2006

Via Overnight Mail

Honorable Mark 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, Maryland 21244-1850

Re: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; (CMS-1506-P)

Dear Dr. McClellan:

On behalf of C. R. Bard, Inc., I am pleased to offer the following comments on the Centers for Medicare and Medicaid Service's (CMS) Proposed Hospital Outpatient Prospective Payment System and 2007 Payment Rates (CMS-1506-P, *Federal Register*, Vol. 71, No. 163, Tuesday, August 23, 2006, p. 49505). C. R. Bard, Inc appreciates the considerable effort you and your staff have put into the development of the proposed Hospital Outpatient rule.

For almost 100 years, C. R. Bard, Inc. has committed its resources to creating innovative products and services that meet the needs of healthcare providers and patients. Today, Bard is a worldwide leader in products that focus on disease state management in three key areas: Vascular, Oncology, and Urology. Bard is committed to advancing the technology of diagnosis and intervention to help reduce healthcare costs and improve patient outcomes. Founded in 1907, C. R. Bard has facilities in eight U. S. locations and in 20 other countries around the world, and employs more than 8,100 people.

Bard's Urological Division is the worldwide market leader in Urological Diagnostic and Interventional Products with a focus on urological drainage, continence, and prostate disease management. The Division offers a wide range of brachytherapy products and services to service the brachytherapy market. It is the goal of the division to ensure that all interested clinicians may easily and cost-effectively become knowledgeable participants in this emerging therapy and patients have access to these emerging therapies.

Bard's comments, which are set forth in detail below, make the following points with respect to the 2007 Hospital Outpatient rule.

1. CMS should maintain 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 for 2007 and 2008.

2. CMS should establish two new HCPCS codes for stranded Iodine-125 and stranded Palladium-103 sources in 2007. In accordance with prior policies, CMS should extend the current payment policy (hospital's charges adjusted to cost) for these new brachytherapy devices, as no hospital claims-based data is available.

3. In line with Congressional intent, CMS should revise the proposed definition of brachytherapy devices to include all brachytherapy devices, without limitation.

4. CMS should provide clarification that the policy of billing all brachytherapy sources actually prescribed and ordered remains in force, notwithstanding the reference to "used" in the December 19, 2003 Program Transmittal.

Our detailed comments and recommendations follow.

CMS should maintain 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 for 2007 and 2008.

Prostate brachytherapy is a highly customized treatment (number, configuration, and radioactive intensity) that is unique to the individual patient's prostate size, geometry and disease involvement. The individual aspect of this procedure is amplified by individual physician (radiologists and urologists) techniques and clinical preferences necessary to perform the procedure. In total, these differences in physician techniques, clinical preferences with respect to the number and type of sources used per case, and individual patient prostate gland size and geometry lead to significant variations in individual hospital costs.

Due to the substantial cost variations of the sources and delivery systems used in prostate brachytherapy, the proposed prospectively set median payment for these sources would seriously underpay a number of hospitals for the costs they incur for a number of patient procedures. As a result, the proposed methodology would create incentives for hospitals to refrain from offering this medical procedure thus severely limiting or denying beneficiary access.

Congress has expressed longstanding concerns about beneficiary access to brachytherapy procedures. In 1999, Congress expressly included all existing brachytherapy devices within the pass-through methodology under the newly developed Hospital Outpatient Prospective

Payment System (HOPPS). Again, in 2003, Congress enacted legislation, Section 621(b) of the Medicare Modernization Act (MMA), requiring reimbursement for each brachytherapy device equal the hospital's charge adjusted to cost for 2004, 2005, and 2006, to protect beneficiary access.

As part of the MMA, Congress directed the Government Accountability Office to conduct and publish a study on brachytherapy device reimbursement by the end of 2004, giving Congress, CMS, and interested parties a two-year period to deliberate and develop the proper reimbursement methodology for the future. Unfortunately, the GAO study was not published until July 2006. This delay restricted Congress' ability to respond and prevented any discussion on the most proper reimbursement methodology for the future before the Congressional sunset date of 12/31/2006.

Additionally, the GAO Report itself is fundamentally flawed in its implementation.

- The GAO's data used for the report is significantly outdated (2002) and does not include important technological changes in clinical practice over the past several years. In recent years new clinical protocols have evolved, including the use of patient prescribed custom "stranded" brachytherapy devices. Stranded brachytherapy devices are distinct from traditional brachytherapy devices providing additional patient and physician treatment options, requiring separate FDA approvals and having substantial increased costs of production. These separate technologies are not reflected in the data.

- The GAO failed to collect usable data from its hospital survey. The GAO survey included tools to assess differences in seed intensity and configuration; however, they we unable to collect adequate data to include separate analysis in their report. Accordingly, their report does not reflect some current clinical protocols, including the use of prescription stranded products.

Because of the ongoing issues with properly identifying brachytherapy data, two public advisory groups (the APC Advisory Panel, and the Practicing Physicians Advisory Council) strongly recommended that CMS retain the current "charges adjusted to cost" methodology to all brachytherapy devices and not adopt the proposed prospective median payment methodology.

An example that accentuates this flaw in the CMS data is this absence of data for stranded brachytherapy devices. In this instance, HCPCS codes for brachytherapy devices have not kept pace with changes in clinical practice or technological/clinical advancements. In the MMA, Congress highlighted their intent for CMS to use separate codes to reflect clinically relevant distinctions among different types of brachytherapy devices. The creation of distinct codes for emerging brachytherapy technologies and the subsequent collection of two years of claims data will allow adequate time to establish a proper payment methodology for these technologies and allow interested parties to assess these methodologies. To establish

prospective payment rates for brachytherapy devices without this critical data is inconsistent with Congress' direction to CMS under the Social Security Act.

CMS should establish two new HCPCS codes for stranded Iodine-125 and stranded Palladium-103 sources in 2007. In accordance with prior policies, CMS should extend the current payment policy (hospital's charges adjusted to cost) for these new brachytherapy devices, as no hospital claims-based data is available.

In the MMA Congress recognized the need to resolve the long-standing brachytherapy data issues, and determined that CMS must create separate HCPCS codes for different, clinically relevant types of brachytherapy devices.

While we recognize that CMS has established new brachytherapy codes after the passage of the MMA that reflected differences in configurations of the same isotope (e.g. the establishment of the HCPCS code for linear Palladium-103), the 2005 CMS data does not reflect the important new clinical protocols that have emerged over the last decade. These new protocols have resulted in the development of stranded brachytherapy source devices. This special stranded device is manufactured prior to delivery to the customer and is not a process, which can be performed by a hospital. In the stranded brachytherapy device, sources are connected with stranded suture material (such as polyglactin) and the sources are separated at specified intervals. This ensures the initial and long-term position of each source when implanted in and around cancerous tumors.

One brachytherapy society who reviewed the data from the GAO survey recommended that any data used to establish reimbursement rates should reflect the increased clinical use of "more costly but considered clinically advantageous" stranded brachytherapy devices.

These stranded brachytherapy devices are distinct from other brachytherapy devices in a number of fundamental characteristics:

- Stranded Iodine-125 and Palladium-103 source devices require separate FDA clearances from traditional Iodine-125 and Palladium-103 sources.

- Stranded Iodine-125 and Palladium-103 source devices 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.

- Stranded sources can be placed at the periphery of the prostate or outside the prostate gland, permitting treatment of extra-prostatic extension of the disease without the potential for migration into another body organ.

- Stranded source devices may require increased radioactive intensity in comparison to traditional brachytherapy source devices, as such, stranded source devices fall within the meaning of the coding and reimbursement provisions in Section 621(b) of the MMA and meet CMS' definition of brachytherapy devices.

A review of available clinical literature demonstrates that stranded source devices improve patient safety and clinical outcomes in the treatment of prostate cancer, which has resulted in widespread clinical practice.

These new HCPCS codes are required to ensure beneficiary access to the most clinically effective and safest treatment now and in the future. These codes are also required to further refine the data collection and cost analysis necessary for the refinement of the HOPPS brachytherapy payment methodology.

In response to CMS' invitation to "submit recommendations for new codes to describe new brachytherapy source devices in a manner reflecting the number, isotope, and radioactive intensity of the sources", we recommend CMS implement two new HCPCS codes for stranded brachytherapy devices on January 1, 2007:

1.) C26XX Brachytherapy device, Stranded Iodine-125, per source
2.) C26XX Brachytherapy device, Stranded Palladium-103, per source

In line with Congressional intent, CMS should revise the proposed definition of brachytherapy devices to include all brachytherapy devices, without limitation.

The term, brachytherapy, comes from the Greek word "brachy" which translates to "near" and treatment (therapy). Brachytherapy is the type of treatment the patient receives; not the type of source. Many different types of sources, radioactive and non-radioactive may be appropriate to delivery brachytherapy.

In brachytherapy, radiation sources are carefully positioned inside the cancerous tissue in a manner that will attack the cancer most efficiently. In the treatment of cancer using brachytherapy, sources give off radiation that travels only a few millimeters to kill nearby cancer cells. The evolution of technology has shown that brachytherapy source devices do not have to be radioactive to deliver therapeutic radiation. Technological advances demonstrate that non-radioactive (electronic) source devices, for example, can generate a therapeutic radiation dose.

CMS proposes to limit the definition of a brachytherapy device as a "seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive, meaning that the sources contain a radioactive isotope."

Section 1833 (t)(6) of the Social Security Act states:

> *(A) IN GENERAL.—The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):*
> *(ii) CURRENT CANCER THERAPY DRUGS AND BIOLOGICALS AND BRACHYTHERAPY.—A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy or temperature monitored cryoablation, if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.*

This passage clearly states "but not limited to", indicating Congress' clear intent for the definition of brachytherapy devices to be inclusive, not restrictive.

Also, Section 1833(t)(2)(H) states:

> *"with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices.*

It is clear that Congress sees the definition of a "device" as completely different, and independent from the definition of a "source/seed", and that a radioactive source does not have to be inherently radioactive, but has to be able to deliver prescriptive, therapeutic radiation.

New innovative, non-radioactive brachytherapy devices meet the criteria required by the legislation and are approved as brachytherapy devices by the Food and Drug Administration (FDA). By narrowing the definition of a brachytherapy device to devices that contain a radioactive isotope only, CMS would not only limit access to new technology, but also eliminate Medicare beneficiary access to FDA-approved cancer care.

CMS should provide clarification that the policy of billing <u>all</u> brachytherapy sources actually prescribed and ordered remains in force, notwithstanding the reference to "used" in the December 19, 2003 Program Transmittal.

In December 19, 2003, CMS published Medicare Program Transmittal (Transmittal 32, Change Request 3007, Publication 100-20, R320TN), in which it appeared to instruct hospitals to bill for prostate brachytherapy sources used, rather than billing for the number of sources prescribed by the physician and ordered by the hospital. This language has caused considerable confusion among hospitals and concern about being properly reimbursed for purchased sources prescribed/ordered by their physicians.

CMS policy since the inception of HOPPS has been consistently clear that hospitals were to bill for sources prescribed by the physician.

In January 2001, in a letter to Gordon B. Schatz of Reed Smith LLP, Marjorie D. Baldo, HCFA, stated:

> With the issue of billing for brachytherapy seeds, the Health Care Financing Administration (HCFA) understands that physicians may at times order more brachytherapy seeds than needed by the patient during a procedure. Brachytherapy seeds contain radioactive isotopes with short half-lives that quickly eliminates their clinical potency, thus making them ineligible for reuse. In this instance, hospitals may bill for the number of brachytherapy seeds ordered by the physician and purchased by the hospital, even if during the procedure the physician has determined that not all seeds should be used for the patient. This is consistent with our policy regarding drugs that are ordered by physicians whose full amount is not administered to the patient.

Later in 2001, HCFA published on its website, in the Medlearn Frequently Asked Questions section,

Question 114:

> Q. 114 Can hospitals bill for all brachytherapy seeds ordered by the physician even if the physician does not use all of the brachytherapy seeds?
>
> A. 114 Yes. There may be times when a physician orders more brachytherapy seeds than necessary since the physician may not know the exact amount of brachytherapy seeds needed for one patient. In this case, the hospital may bill for all of the brachytherapy seeds ordered.

In addition, the American Society for Therapeutic Radiation Oncology (ASTRO) has a coding corner Q & A guidance for its members which states:

> CODING QUESTION: An ASTRO member attended the 2004 ASTRO Socioeconomic Lunch and has the following question:
>
> For prostate seed implants, the member typically orders 6 extra seeds in addition to the preplan count. There was an ACR Bulletin back in December 2001 that said, "Therefore, it is valid that the hospital charge the "ordered seed" inventory for each patient, accounting for the seeds ordered only once." Is that still true? Should they bill for the number of seeds ordered or the number of seeds implanted in 2005?
>
> "The ASTRO Code Utilization and Application Subcommittee (CUAS) is not aware of anything that has changed in 2005 on this issue. It is presumed in the ACR statement on the seed inventory, that these extra seeds are either used, returned, or wasted--never

transferred to another patient. Thus, it is appropriate for all seeds to be charged for, not just the ones that the doctor uses."

It is not uncommon for a treatment plan to be modified slightly in the operating room on the day of the implant. Physicians typically order extra sources for implant procedures in case the treatment plan must be altered during the course of treatment. This may result from the physician determining a few extra sources are necessary to treat the patient, due to changes in the size or shape of the prostate. In most cases, all ordered seeds are implanted leaving few that are left to decay. In the event that these extra seeds are not required for treatment, the hospital is required to absorb the cost of all the sources ordered.

Hospitals should not be penalized for following a physician's prescriptive order. We urge CMS to alleviate the confusion among hospitals by re-affirming that brachytherapy sources are a patient prescribed, once-used, non-transferable device, and hospitals should bill for sources prescribed regardless of whether all sources were actually implanted.

In conclusion, if the proposed payment for prostate brachytherapy that is set forth in the proposed rule were finalized, many hospitals would receive inadequate reimbursement for the costs they incur, likely resulting in hospitals limiting access to this procedure for many Medicare beneficiaries.

Thank you for your consideration of these comments and recommendations. We at C. R. Bard's Urological Division stand ready to assist you should you have any questions with respect to these comments or prostate brachytherapy therapy. We encourage you to contact George Clark, who manages our reimbursement efforts, if you have specific questions about these comments. He can be reached by phone (678-342-4850) or e-mail (george.clark@crbard.com).

Respectfully yours,

Mark O. Downey

Mark O. Downey
President
Bard Urological Division

Nucletron

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October 5, 2006

The Honorable Mark 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: Medicare Hospital Outpatient Prospective Payment System and CY07 Payment Rates

Dear Dr. McClellan:

Nucletron Corporation (Nucletron) 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.

Nucletron, located in Columbia, Maryland, is a medical device company established in 1975 specializing in the development, manufacture, sales, service & support of innovative products used today for cancer treatment. Nucletron has over 110 employees in the United States and is acknowledged as the world's leading supplier of High Dose Rate (HDR) Afterloading Brachytherapy Systems including HDR Iridium-192 sources, a wide range of needles and catheters, NRC licensed repair service and source exchange technical service. Nucletron is also a supplier of radiation therapy treatment planning systems, conventional radiation therapy simulators, Low Dose Rate Permanent Seeds and automated seed delivery systems. Nucletron is a member of AAPM, ASTRO, ABS, ACRO, CAB, SROA, and AAMD.

Nucletron thanks CMS for scheduling time during the comment period to meet and discuss the proposed changes for HDR Brachytherapy and brachytherapy sources. As requested, we are submitting comments in writing per the Federal Register guidelines.

Payment Methodology for Brachytherapy Sources

We believe that it would be inappropriate to implement a new payment system for 2007 that would establish set payment rates for brachytherapy sources based upon median costs. The variations in cost of each source require a unique payment methodology for radioactive sources. One source may have a cost variation of over 10 times based upon the intensity of the source. HDR sources vary significantly from hospital to hospital based upon the number of fractions used during a period of time.

The CMS claims data shows large variations in per unit cost reported (see table below) on claims across hospitals, which further validates the concerns regarding the data that CMS proposes to use to set brachytherapy device payments in 2007.

HCPCS and Description	Variation of Cost per Unit (2005 Hospital Claims)
C1716 Gold-198	$3 - 943
C1717 HDR Iridium-192	$0 – 4,746
C1718 Iodine-125	$0 - 14,632
C1719 Non-HDR Iridium-192	$3 – 1,761
C1720 Palladium-103	$0 - 20,825
C2616 Yttrium-90	$1,676 - 62,071
C2632 Iodine-125 solution	$0 – 7,253
C2633 Cesium-131	$28 - 15,797
C2634 High Activity Iodine-125	$2 – 4,526
C2635 High Activity Pd-103	$3 – 5,212
C2636 Linear Palladium-103	$0 -1,690

The recommended payment methodology will not appropriately capture the variation of brachytherapy source configurations. We urge CMS to continue the current payment methodology for brachytherapy sources based on hospital charges adjusted to cost for each brachytherapy device.

Nucletron recommends that CMS continue the current HOPPS payment methodology of hospital charges adjusted to cost for all brachytherapy devices. This recommendation also was made by the APC panel at the August 24, 2006 meeting and PPAC at the August 26, 2006 meeting.

High Dose Rate (HDR) Brachytherapy Sources (C1717)

High Dose Rate brachytherapy is a unique brachytherapy source that requires allocation of the quarterly source cost by each hospital. The actual cost of the source is based upon the number of treatments or fractions that are administered to patients over the life of the source.

CMS claims data shows a huge variation in cost per unit reported on claims data across hospitals for the source:

APC	Number of Hospitals	Number of Claims	Variation of Cost per Unit
1717	283	4740	$0-4,746

In addition to the large variation of cost per unit across the hospitals and claims in the CMS data, the highest utilization hospital should have the lowest cost for the HDR source and hospital cost from there should increase in numeric succession. The analysis of the top five volume hospitals, per CMS claims data, indicates significant anomalies in the data. Clearly this information should cause CMS to question the accuracy of the data when considering payment based upon the claims data.

HCPCS	Hospitals	Median	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5
C1717	283	$135	$3	$9	$479	$118	$95

In addition, there were over 100 diagnosis codes reported on claims with C1717 (Ir-192) and each treatment with Ir-192 requires a different protocol. This adds to the claims data confusion as well.

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Treatment Site	Average treatments (fractions)	Average HDR Source Runs	Average Treatment Days	Average Number of Catheters per Treatment
Breast	10-12	18-36	5-6	1-36
Uterine	3-5	3-18	5	1-18
Prostate	3-4	16-18	2	24-36
Vaginal	3-5	1-3	3-5	1-2
Lung	2-4	1-3	3-5	2-5

To further validate the variation in cost per unit, a survey of eighty hospitals was conducted by The Pinnacle Health Group to determine the actual cost of the HDR source to the hospital. This survey was originally conducted using 2002 hospital data and was updated using 2005 hospital specific costs and actual source runs. The findings indicated that the variation in cost per unit among these 80 hospitals range from $4-5,775. These findings validate the CMS claims data that indicate variation in cost per unit of ($0-4,746).

Number of Hospitals	Total ACUTAL Source Runs	Average Quarterly Unit Cost	Average Quarterly Source Service Cost	Average Quarterly Source Cost	Variation of Cost per Unit
80	47,050	$17,500	$7,150	$10,000	$4-5,775

In addition to the variation in HDR source cost in the CMS claims data and the actual hospital survey, the GAO had an opportunity to review the HDR source cost as part of the report published by the agency this year. The GAO stated "data from 8 hospitals was determined to be usable to evaluate Ir-192 causing the GAO to recognize there was too much variability in Ir-192 source cost and therefore no recommendations could be made."

The cost of the HDR source is a fixed cost. Hospitals must purchase the source and have it available to treat cancer patients at any time. HDR cost varies from other diagnostic imaging technologies that may also have associated fixed costs. The HDR source must be on hand at all times so the hospital incurs the cost on a daily basis. For imaging services, the cost of the imaging agent is only incurred by the hospital if a study is performed or ordered by the physician. The cost of the source is incurred by the hospital even if patients are not treated.

Based upon the variability in the data, validation by the GAO report and recommendations from the APC panel and PPAC, Nucletron recommends that CMS continue to reimburse hospitals for HDR brachytherapy sources based upon charges reduced to cost.

<u>Reporting High Dose Rate (HDR) Brachytherapy Sources (C1717)</u>

In addition to the proposed payment methodology for HDR source, CMS requested recommendations regarding the reporting methodology for HDR sources on a per fraction or per day basis. The HDR source is ordered by the physician and used by the hospital based upon a 'per fraction' basis. The source runs from the afterloader into each catheter on a per fraction treatment basis.

The CMS claims data in 2002 indicated that only a very small number of hospitals reported the use of the HDR source. The primary reason for this low reporting by hospitals was due to confusion regarding the reporting of the source use and cost. Claims data now indicates that over 60% of hospitals are reporting the HDR source on the claim form with HDR procedures.

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This would indicate that hospitals are beginning to understand the methodology required to report the HDR source accurately. A change in the methodology for reporting the source at this point may cause confusion in reporting requirements and lead to more confusion in the CMS claims data.

HDR treatment protocols vary significantly from daily to weekly protocols. Due to the significant treatment variations in patient protocols, payment for the HDR source should remain on a per treatment basis and not be changed to per treatment day. Continued changes in hospital reporting requirements will confuse providers and will lead to inconsistency in claims data making future payment rates unstable.

Nucletron recommends that CMS continue to require hospitals to report the use of HDR sources (C1717) per fraction and NOT per day.

Ytterbium-169 (C2637)

Ytterbium-169 (Yb-169) is a High Dose Rate (HDR) brachytherapy source was approved by the FDA in 2005. As required by the MMA, CMS assigned a HCPCS code for Ytterbium so hospitals could appropriately report the cost of the source to CMS. This source will be available in 2007 and we understand that CMS does not have hospital claims data to determine an appropriate cost for Yb-169.

CMS considered four (4) options in establishing payment for Yb-169. CMS proposes to assign Yb-169 to its own APC with a payment rate set at or near the lowest proposed payment rate for any brachytherapy source paid on a per source basis (Option 2).

Yb-169 is a HDR source with unique characteristics and differences in application than other sources. Yb-169 has a shorter half-life than HDR Iridium-192 (C1717) and requires source replacement every 32 days vs. 90 days for HDR Iridium-192. In addition, Yb-169 requires different shielding and has a unique target activity compared to HDR Iridium-192.

Since there are no other sources that are comparable to this new brachytherapy source, the most appropriate payment methodology for Yb-169, and any new brachytherapy source, would be to establish a charge reduced to cost (CCR) methodology in order to collect cost data from hospitals. This option would be similar to the CMS policy for New Technology APCs.

Nucletron recommends that CMS adopt Option 1 proposed by CMS and reimburse Ytterbium-169 (C2637) at charges adjusted to cost, consistent with the payment methodology that should be used for all brachytherapy sources.

Payment for NEW Brachytherapy Sources

In the proposed rule, CMS solicited comments regarding establishing payment amounts for new brachytherapy sources eligible for separate payment when no hospital claims-based cost data is available. The only effective way for CMS to capture cost data regarding new brachytherapy sources is for CMS to establish payment to hospitals for new brachytherapy sources at hospital charges reduced to cost when no hospital claims-based cost data is available.

Nucletron recommends that CMS implement a three year payment policy for new brachytherapy sources at hospital's charges adjusted to cost.

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Proposed Definition of Brachytherapy Source

CMS has proposed to define a device of brachytherapy eligible for separate payment under the HOPPS as a "seed or seeds (or radioactive source) as indicated in section 1833(t)(2)(H) of the Social Security Act which refers to sources that are themselves radioactive."

Brachytherapy is derived from ancient Greek words for short distance (brachy) and treatment (therapy). The procedure is most often an outpatient procedure used in the treatment of different kinds of cancer. Brachytherapy sources are carefully placed inside of the cancerous tissue and positioned in a manner that will attack the cancer most efficiently. Brachytherapy has now been used for over a century to treat prostate cancer, cervical cancer, breast cancer, endometrial cancer, and coronary artery disease. Brachytherapy has been proven to be very effective and safe, providing a good alternative to surgical removal of the prostate, breast, and cervix, while reducing the risk of certain long-term side effects.

In the treatment of cancer using brachytherapy, sources give off radiation that travels only a few millimeters to kill nearby cancer cells. There are two types of brachytherapy, permanent, when the source remains inside of the body, and temporary, when the source is inside of the body and then removed. Brachytherapy is not defined by the type of source used to treat the cancer, but by the treatment that is delivered to the patient.

Nucletron recommends that CMS reconsider their definition of brachytherapy sources as consisting of a radioactive or non-radioactive source or seed.

Summary of Recommendations

Brachytherapy offers important cancer therapies to Medicare beneficiaries. Appropriate payment for brachytherapy sources is required to ensure that hospitals can continue to offer Medicare beneficiaries the highest quality of cancer care.

In summary, Nucletron recommends that CMS:

- **continue the current HOPPS payment methodology of hospital charges adjusted to cost for all brachytherapy devices**
- **continue to reimburse hospitals for HDR sources at charges adjusted to cost**
- **continue to require hospitals to report the use of HDR sources per fraction**
- **reimburse Ytterbium-169 (C2637) at charges adjusted to cost**
- **implement a three year payment policy for NEW brachytherapy sources at hospital's charges adjusted to cost**
- **reconsider the proposed definition of brachytherapy sources**

Thank you for your consideration of these important issues.

Sincerely,
NUCLETRON CORPORATION

Jeroen Cammeraat
President

Nucletron Corporation • 8671 Robert Fulton Drive • Columbia, MD 21046 • 800-336-2249

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R. MARCUS VENNART, M.D.

F.A.C.S., F.A.C.O.G.
500 SOUTH RANCHO DRIVE
QUAIL ORIENT, SUITE A-3
LAS VEGAS, NEVADA 89106
FAX (702) 870-2826 TEL. (702) 870-2939

OBSTETRICS AND GYNECOLOGY

August 22, 2006

Senator Harry Reid
528 Hart Senate Office Building
Washington, D. C. 20510

Dear Senator Reid:

Your support is necessary to help preserve patient access in Nevada and elsewhere in the U.S. for women suffering from tumors or fibroids in their uterus which cause pain, infertility, abnormal bleeding and urinary complications. Some 30% of women 25-55 years old have these fibroids. This results in 250,000 women annually undergoing surgery such as a hysterectomy with the attendant emotional distress, lost time at work, and decreased productivity, all having a significant impact on our economy.

There is an alternative option available to avoid these invasive procedures (hysterectomy) but we need your help to make this option available. A technology utilizing magnetic resonance guidance and focused ultrasound (MRgFUS) was approved by the FDA in October of 2004. This technology is used to destroy tumors with no incision and no blood loss. Patients are returning to work within 1-2 days, compared with 7-42 days for the invasive alternatives such as hysterectomy.

Currently, the Medicare Hospital Outpatient Prospective Payment System (HOPPS), through CMS, lists the MRgFUS procedure as a covered service for beneficiaries. However, CMS has placed the MRgFUS procedure into an APC that will not allow healthcare providers to cover the cost of the procedure. Because the providers cannot cover the cost of the MRgFUS procedure, this adversely impacts patient access to this noninvasive treatment. CMS must correct this APC assignment immediately and place the MRgFUS procedure into a clinically and resource appropriate APC.

Despite calling this issue to the attention of administrators at CMS through direct meetings, conference calls and through members of Congress, CMS has continued to overlook this misclassification for the past two years.

We are requesting that you contact CMS and urge them to promptly address this issue and assign the MRgFUS procedure to a clinically and resource appropriate APC for the final 2007 HOPPS rule. The procedure is currently classified into APCs 195 and 202 and should be appropriately assigned to APC 127, as the other procedures in APC 127 have a similar cost and require similar clinical resources.

Beneficiaries in the State of Nevada and across the country will greatly appreciate your support and interest in this important issue for women.

Sincerely,

R. Marcus Vennart, M.D.

The Cyberknife Service of BroMenn Healthcare at The Community Cancer Center

70-0
(3)

October 5, 2006

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

Re: New Technology APCs – Section c. Pages 49553 and 49554

We appreciate the opportunity to submit comments on the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule published August 23, 2006 in the Federal Register Volume 71, No. 183 Part II 42 CFR Parts 410, 414, 416, 419, 421, 485, and 488 [CMS-1506-P; CMS-4125-P] RIN 0938-AO15, pages 49553 and 49544 – New Technology APCs, Section c. Stereotactic Radiosurgery (SRS) Treatment Delivery Services.

New Technology APCs

The Proposed Rule includes changes to the Ambulatory Payment Classifications (APCs) for G0339 (image-guided robotic stereotactic radiosurgery complete or first treatment) and G0340 (image-guided robotic stereotactic radiosurgery fractionated – treatments 2 through 5). Specifically the proposal is to move G0339 from APC 1528 to APC 0067 resulting in a reduction of ($1,190.39) per treatment. It is also proposed to move G0340 from APC 1525 to APC 0066 resulting in a reduction of ($833.32). These proposed revisions would result in a reduction in payment averaging ($2,857.03) per patient (based on the average treatment of three fractions per patient). A reduction of this magnitude for these codes would make it financially prohibitive for institutions to make this technology available to their patients. The proposed reductions were made based on the Center for Medicare and Medicaid Services (CMS) review of the Identifiable Data Set Hospital OPPS file for Calendar Years (CY) 2004 and 2005. We have serious concerns about this review, which we will enumerate in these comments. It is our hope that CMS will modify its proposed changes to payment codes and rates for both staged and single session image-guided robotic stereotactic radiosurgery, effective CY 2007. We request your assistance in setting reasonable Medicare rates for image-guided robotic stereotactic radiosurgery technology.

407 East Vernon Avenue, Suite 110, Normal, Illinois 61761 • 309-451-2288 • Toll Free: 1-888-292-7564
www.cyberknifeillinois.org

We want to acknowledge and applaud CMS' efforts over the past several years to continually improve its understanding of image-guided robotic stereotactic radiosurgery and maintain a process that allows for tracking of new technology claims. We would like to take this opportunity to further assist CMS in its efforts to establish appropriate payment rates for this technology and clarify the descriptor related to image-guided robotic stereotactic radiosurgery. To that end, we are supplying a brief overview of the development of the relevant codes and rates.

History of Medicare Coding and Payment for Image-Guided Robotic Stereotactic Radiosurgery (r-SRS)

CY 2002

In the November 30, 2001 Federal Register, CMS acknowledged that, "the APC assignment of (these) G codes and their payment rate was based on the understanding that stereotactic radiosurgery was generally performed on an inpatient basis and delivered a complete course of treatment in a single session..."[1] Robotic radiosurgery treatment with the CyberKnife is, in fact, just the opposite – predominantly an outpatient staged treatment.

CMS also acknowledged that, "We did not clearly understand either the relationship of IMRT to stereotactic radiosurgery or the various types of equipment used to perform these services."[2]

Accordingly, in the November 30, 2001 Federal Register, CMS substantially altered the codes available for stereotactic radiosurgery and modified the then-existing code descriptors. The HCPCS Code used in CY 2001 for reporting stereotactic radiosurgery (for both Gamma Knife® and linear accelerator-based radiosurgery) was HCPCS Code G0173. In the November 30, 2001 Federal Register, CMS announced a modified descriptor for Code G0173 to limit its use to linear accelerator-based stereotactic radiosurgery. However, CMS did not distinguish between gantry-based and image-guided robotic radiosurgery systems because it did not have any data regarding the relative costs of image-guided stereotactic radiosurgery (e.g., the CyberKnife) and non-robotic LINAC-based stereotactic radiosurgery using more conventional technology. CMS assigned HCPCS Code G0173 to New Technology APC 0721 for CY 2002.

In the November 30, 2001 Federal Register CMS also indicated that it was planning to adopt a new HCPCS code for fractionated (i.e. staged) radiosurgery procedures, which was introduced in a March 28, 2002 Program Memorandum[3]. While CMS eventually adopted the new HCPCS code - G0251 - this code did not specify that it be used only for image-guided treatment with robotics. (The descriptor for this code was "linear accelerator-based stereotactic radiosurgery, fractionated treatment, per session, maximum 5 sessions per course of treatment."). This code only became effective July 1, 2002.

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[1] Federal Register, November 30, 2001, page 59865.
[2] Federal Register, November 30, 2001, page 59866.
[3] CMS Program Memorandum A-02-026, 2002 Update of the Hospital Outpatient Prospective Payment System (OPPS), March 28, 2002.

CMS acknowledged in its Final Rule, published November 1, 2002, that there are significant fixed costs for all stereotactic radiosurgery, but they did not have enough cost data showing the current APC assignment for G0251 (APC 713) as inappropriate. In response, Georgetown University Hospital submitted cost data for CyberKnife treatment in December 2002. Stanford University Hospital submitted its cost data in January 2003. University of Southern California Keck School of Medicine submitted its cost data in February 2003.

CMS designated G0251 for treatment completed in stages, and priced the treatment using the payment for a single stage treatment (G0173), dividing the payment by 5, and allowing up to five payments. Under the payment methodology, each staged treatment was set at the national rate of $1,125, which did not reflect the consistent use and cost of resources for each treatment.[4] As a result of this initial payment rate calculation methodology, CyberKnife centers continued to be underpaid for treatments 2-5.

CY 2003

CMS agreed to revisit the APC assignments for all stereotactic radiosurgery procedures in 2003 when it had 2002 claims data available. The APC classification for G0173 was based on claims submitted in Calendar Year 2001, before the CyberKnife was used in any substantial way for clinical purposes in the United States. In CY 2001, there was only one HCPCS Code – G0173 – for stereotactic radiosurgery (complete course of treatment in one session), regardless of whether the treatment was provided using a LINAC or cobalt-based system (Gamma Knife®) and regardless of whether the treatment was performed in stages.

CY 2004

For 2004, CMS made certain changes to the HCPCS codes and APCs applicable to robotic stereotactic radiosurgery. CMS recognized new HCPCS codes for robotic stereotactic radiosurgery to distinguish these services from other linear accelerator-based (LINAC-based) SRS services that are substantially less resource-intensive. CMS established HCPCS G0339, which describes image-guided robotic LINAC-based SRS completed in one session (or the first of multiple sessions), and assigned this new code to New Technology APC 1528 -- the same APC used for other forms of SRS. CMS also established HCPCS G0340, which describes the second and any subsequent sessions of r-SRS (up to five sessions), and assigned this new code to New Technology APC 1525, with a rate that was approximately 70% of the rate for the first treatment or session. These decisions were made after a review of the available clinical, cost and other data. **We believe that the decisions that were made were – and are -- correct.**

CY 2005

For CY 2005, no changes were made to G0339 and G0340. In the OPPS final rule (69 FR 65711) CMS stated that ***"any SRS code changes would be premature without cost data to support a code restructuring"***. (CMS-1506-P, page 156).

[4] Federal Register November 30, 2001, page 59868

CY 2006

At the August, 2005 APC Panel meeting, stereotactic radiosurgery codes including G0339 and G0340 were discussed. The Data Subcommittee reported its analysis of the CY 2004 Identifiable Data Set Hospital OPPS file for all SRS codes. The data reflected significant cost differences among institutions billing the G0339 and G0340 codes, and resulted in the median costs of the procedures being lower than the current APC assignments warranted. The APC Panel's recommendation to CMS was to continue to reimburse G0339 and G0340 at their current APCs because of a lack of adequate and accurate data to assign a permanent APC. At the conclusion of the August, 2005 APC Panel meeting, the Panel recommended to CMS that no changes be made to SRS treatment delivery codes G0173. . . G0339, and G0340 (CMS-1506-P, page 157).

Proposed CY 2007 APC Changes

The Hospital Outpatient Prospective Payment System (OPPS) was intended by Congress to be resource-based, as reflected in hospital cost and charge data. The question is ***whether the APC rates adopted by CMS for a covered service for which there is inadequate and inconsistent claims history appropriately reflect the relative clinical utility and whether the rate established by CMS reflects a reasonable estimate of the resources involved.***

There is no question that image-guided robotic stereotactic radiosurgery is substantially more resource-intensive than other forms of LINAC-based SRS. In fact, it was for this reason that ***CMS created separate HCPCS codes to distinguish these two technologies in CY 2004. And yet for CY 2007 CMS proposes to place r-SRS and LINAC-based SRS back into the same APC.***

It is our understanding from the CyberKnife Coalition that CMS is required to have a minimum of two years of claims data before moving a HCPCS code from a new technology to a clinical APC. Like the Coalition, we also believe that CMS does not have meaningful two-year data upon which to base the proposed changes to the APC placement of G0339 and G0340. We support the CyberKnife Coalition's assertions that:

1. The proposed APC classifications and rates are based on claims submitted in Calendar Years 2004 and 2005, before the CyberKnife® (the only true image-guided robotic stereotactic radiosurgery system on the market) was used in any substantial way for clinical purposes in the United States. In the beginning of CY 2004, there were only twelve (12) operational CyberKnife centers in the United States, with eight (8) of these centers (67%) beginning operations during the calendar year and submitting claims to CMS for less than a full year.

   By the end of CY 2005, there were thirty-five (35) centers operating: fifteen (15) of those centers began operations during that year. Forty-three percent (43%) of all operational CyberKnife centers submitted claims for less than a full calendar year.

   Thus, although CMS looked at data from the years 2004 and 2005, they do not have claims data of two years' duration.

2. Further, the CyberKnife Coalition's analysis of the CY 2004 Identifiable Data Set Hospital OPPS file raises serious questions about the reliability of the claims as reported.

   The basis for determining the proposed APC rate for CY 2007 for image-guided robotic stereotactic radiosurgery was a review of claims data for G0339 and G0340. Of the 486 claims analyzed for 2004, 15% of the claims came from centers using the G0339 code which did not have an image-guided robotic stereotactic radiosurgery system. As a result, inclusion of their data in the calculation of the appropriate APC results in a lower median cost. The average cost, as indicated in the Identifiable Data Set Hospital OPPS file for CY 2004 for true image-guided robotic stereotactic centers (CyberKnife) is reported at $6,203.27 per unit. For non-CyberKnife centers, the average cost is $3,479.65. The range in costs and charges is not surprising since the code has been used by centers that do not provide image-guided robotic stereotactic radiosurgery services.

3. In addition, the 2004 Identifiable Data Set Hospital OPPS file does not include data for several of the most productive CyberKnife centers in the country which are also in large urban areas: Georgetown University Hospital had the 2nd highest procedure volume in the United States; Sinai Hospital in Baltimore, 6th highest procedure volume in the United States, and Miami CyberKnife Center with the 7th highest procedure volume in the United States. Other smaller, less urban centers are also not included.

   The total number of claims for both G0339 and G0340 in the CY 2004 Identifiable Data Set Hospital OPPS file is 1,311. The total CY 2004 Medicare claims for Georgetown University Hospital (an institution not included in the Identifiable Data Set Hospital OPPS file) was 282; Miami CyberKnife Center submitted 196 claims to Medicare in CY 2004. ***Georgetown and Miami's claims along with the other centers whose data was not included in the 2004 Identifiable Data Set Hospital OPPS file total, at a minimum, more than thirty-six percent (36%) of the total number of claims that were included in the 2004 Identifiable Data Set Hospital OPPS file for G0339 and G340 together.***

The CY 2004 Identifiable Data Set Hospital OPPS file clearly does not provide a sound basis for modifying the APC classification in light of the relatively low number of appropriate claims, the high number of centers contributing data for less than a full year for both CY 2004 and 2005, the number of claims not included in the Identifiable Data Set Hospital OPPS file that are nonetheless relevant when establishing median cost, and the extraordinary variation in costs caused by a mix of centers utilizing the G0339 and G0340 codes for all types of SRS procedures instead of exclusively for r-SRS procedures.

Historical Precedent – Gamma Knife New Technology Codes

We also note that CMS is proposing to assign the Gamma Knife to a higher APC, while reclassifying image-guided robotic radiosurgery to a lower APC. CMS noted that ***it is a "mature technology [with] stable median costs"*** (CMS-1506-P, p 157). This would be an accurate reflection of the Gamma Knife, a technology in existence for 30 years with significant and mature data with which to establish an appropriate median cost.

Since the clinical process-of-care, resources utilized and related costs involved in providing intra- and extracranial image-guided robotic stereotactic radiosurgery using CyberKnife are at least as great as, if not greater than, the clinical process-of-care, resources utilized and related costs involved in the provision of intracranial radiosurgery using the Gamma Knife, the APC assignment should reflect a similar reimbursement. Gamma Knife was maintained in temporary APC status for nearly 30 years while data was collected for review and determination of final rate setting. The proposed APC assignment for image-guided robotic radiosurgery for CY 2007 is based on less than two full years of data as well as a small number of claims (a total of 486 single billed claims for G0339 and 940 billed claims for G0340 for CY 2004). The CY 2005 Identifiable Data Set Hospital OPPS file is not yet available to us for purchase and therefore has not been analyzed. However, we expect that these trends will be evident proportionally, and possibly exclude even more centers from the "common working file".

CY 2004 and CY 2005 Data Variability Summary

In 2004, 12 r-SRS centers were operating and 8 new centers started operation that that year. This was the first operational year for 67% of centers who had no established costs on which to set charges.

	# centers operating Jan 1st	**New centers treating during year**	**% of centers in first year**
2004 CY 2004	12	8	67%
2005 CY 2005	20	15	43%

Of the 25 centers reported in the 2004 Identifiable Data Set Hospital OPPS file using G0339 / G0340 – only 16 centers or 64% of those listed have dedicated image-guided robotic SRS equipment. The CY 2004 data is a mixture of data from all kinds of stereotactic radiosurgery procedures using various treatment modalities with vastly differing resource requirements. A clearer distinction among SRS codes through continued code descriptor refinement will help facilitate the collection of data for all types of SRS services and the eventual establishment of appropriate permanent rates for each, respectively.

Further, the CY 2004 Identifiable Data Set Hospital OPPS file for code G0339 for example, consists of only 486 claims with cost data ranging from $3,479.65 (non-robotic SRS centers) to $6,203.27 (for image-guided r-SRS centers).

We believe that this analysis establishes that the CY 2004 claims data available for image-guided robotic stereotactic radiosurgery do not currently provide a sound basis for modifying the APC classifications or the proposed CY 2007 payment rates for codes G0339 and G0340.

It was our hope to have received the Coalition's analysis of the CY 2005 Identifiable Data Set Hospital OPPS file, which was to be released at the beginning of September. It was, however, recalled by CMS. We regret that the comment period was not adjusted to allow interested parties to review this important data in the preparation of their comments. As we have indicated,

however, we expect the same problems will be evident in the CY 2005 Identifiable Data Set Hospital OPPS file and we urge CMS to review the 2005 data with our comments in mind.

Conclusion

The purpose of new technology HCPCS codes is to allow for collection of a comprehensive, stable data set with which to effect an analysis of the charges and costs associated with the new technology. We understand that two years is the statutory minimum amount of time for which CMS must have data before moving a covered service from a new technology code to a clinical code. In the case of CyberKnife, the minimum is insufficient. An analysis of two years of data is not enough due to the large number of new centers submitting less than a full year of data for 2004 and 2005 and the large number of centers with non-robotic equipment using the image-guided robotic stereotactic radiosurgery codes. Thus, while G0339 and G0340 are a vast improvement over the original SRS codes, they are still unclear and potentially misleading, resulting in a lower median cost as non-robotic SRS procedures are being billed using the image-guided robotic SRS codes. There is clear precedent for maintaining new technology codes well beyond the minimum two years. Gamma Knife, for example, was maintained in temporary new technology codes for the first thirty years of its use.

Image-guided robotic stereotactic radiosurgery is still developing, with the CyberKnife the only dedicated r-SRS system in use at this time. The majority of the centers are new, in full operation for one year or less. ***Thus the 2004 and 2005 Identifiable Data Set Hospital OPPS files result in an analysis of less than two full years of data. The data are not stable and do not accurately capture the resources used in r-SRS as is CMS's charge.*** We join the many stakeholders who urge you to look at external data in making your classification decisions. We have shared with you the analysis the CyberKnife Coalition undertook, which we believe demonstrates the insufficiency of the CY 2004 and 2005 CMS data relative to SRS codes.

Recommendations

►No changes should be made in the APCs or payment rates for G0339 (APC 1528) and G0340 (APC 1525) for CY 2007.

►CMS continue to work with CyberKnife centers to establish accurate and adequate reimbursement for image-guided robotic stereotactic radiosurgery (r-SRS).

Sincerely,

Penny Cermak

Penny Cermak
VP and Chief Financial Officer
BroMenn Healthcare

cc: CoalitionNews@CKCoalition.org

71

S. Gerald Sandler, MD, FACP, FCAP
Professor of Medicine and Pathology
Director, Transfusion Medicine

Department of Laboratory Medicine

Georgetown
University
Hospital

October 5, 2006 **VIA OVERNIGHT MAIL**

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mailstop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: CMS-1506-P; Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment Systems and CY 2007 Payment Rates

Dear Dr. McClellan:

I am pleased to have the opportunity to submit this comment letter in response to the CY 2007 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule. I am writing regarding the dangerous precedent CMS proposes to set by lowering payment for clotting factors, which would not only affect hospital outpatients but has the potential to affect the inpatient setting in 2008 if not before.

Board certified in both internal medicine and transfusion medicine, I am proud to serve as the Director of Transfusion Medicine, Department of Laboratory Medicine, at Georgetown University Hospital in Washington, DC. Our hospital is a 609-bed, not-for-profit, acute care teaching and research facility with a medical staff of more than 1,100 physicians providing patient care throughout our community. Our patient population includes 23.5% Medicare and 7.8% Medicare beneficiaries. This year, we had 16,208 in-patient admissions and 28,800 outpatient visits. In FY 2006, our Hemophilia Treatment Center and related clinical services infused more than 730,000 IU of recombinant or plasma-derived coagulation factors VII and IX and more than 610,000 μg of activated recombinant coagulation factor VIIa.Georgetown University Hospital is in partnership with MedStar Health, a non-profit, community-based health system serving the greater Washington-Baltimore region. MedStar's seven hospitals and associated providers have in excess of 145,000 inpatient admissions and more than one million outpatient visits each year.

MedStar Health
3800 Reservoir Road, NW - Room M1306, Washington DC, 20007-2113
phone: 202 444 8520 • *fax:* 202 444 2440 • *e mail:* sandlerg@gunet.georgetown.edu

In my role as Director of Transfusion Medicine, I am responsible for ensuring that blood products are used in an efficient and cost-effective manner. We evaluate each patient's needs individually and make certain that all our inpatients receive the most effective blood product to treat his/her specific medical problem or condition. Like other blood products, all clotting factors are inventoried in the blood bank and are, therefore, my responsibility. As a member of the U.S. Department of Health and Human Services Advisory Committee on Blood Safety and Availability, I am extremely sensitive to the intent of the proposed rule.

In the proposed rule, CMS outlines a decrease in payment for clotting factors from the current ASP+6% to ASP+5%.[1] CMS has expressed intent to pay for clotting factors similarly in both the inpatient and outpatient settings in previous proposed and final rules applicable to the inpatient setting.[2] Recently, the FY 2007 Hospital Inpatient Prospective Payment System final rule stated that, "Medicare will be making consistent payments for blood clotting factor provided to inpatients and outpatients" by the Medicare Part A fiscal intermediaries' use of the Medicare Part B Drug Pricing File.[3] Given this, it is unclear as to whether CMS plans to apply the ASP+5% methodology to the inpatient setting for FY 2007, although it seems impractical to do so given that the final CY 2007 outpatient rule will not be released until after the final FY 2007 inpatient rule has become effective, and I ask CMS to assure hospitals that no such intention exists for this year.

However, CMS has been quite clear that it intends to pay consistently for clotting factors in both the inpatient and outpatient setting. Should CMS decrease payment for CY 2007 in the outpatient setting, I am extremely concerned that this stated policy of consistent payment will result in a similar decrease being applied to the inpatient setting in future years without the setting-specific analysis necessary to ensure access to the most appropriate factor products and course of treatment for Medicare beneficiaries. By retaining the current ASP+6% payment in the hospital outpatient setting, CMS will be adhering to this policy for 2007, and I strongly urge CMS to do so.

I appreciate your consideration of my comments and can be reached at (202) 444-8520 or sandlerg@gunet.georgetown.edu should you have questions regarding my comments.

Sincerely,

S. Gerald Sandler, MD

[1] CY 2007 Hospital Outpatient Prospective Payment System, Proposed Rule. Federal Register, Vol. 71, No. 163, p. 49586 (August 23, 2006).

[2] FY 2006 Hospital Inpatient Prospective Payment System, Proposed Rule. Federal Register, Vol. 70, No. 85 pp. 23453-4, 23482 (May 4, 2005); and FY 2006 Hospital Inpatient Prospective Payment System, Final Rule. Federal Register, Vol. 70, No. 155, pp. 47473 and 47506 (August 12, 2005).

[3] FY 2007 Hospital Inpatient Prospective Payment System, Final Rule. Federal Register, Vol. 71, No. 160, p. 48125 and 48165 (August 18, 2006).