ASTRO
American Society for Therapeutic Radiology and Oncology

January 22, 2007

The Honorable Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1506–FC
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: Medicare Program; Revisions to Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Final Rule: CMS–1506–FC

Dear Administrator Norwalk:

The American Society for Therapeutic Radiology and Oncology (ASTRO)[1] appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2007 Payment Rates published in the *Federal Register* on November 24, 2006. Our comments focus on: (1) stereotactic radiosurgery (SRS) treatment delivery; (2) breast brachytherapy; and, (3) proposed use of single and multiple procedure claims – CPT® code 77421; *Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy.*

1. Stereotactic Radiosurgery (SRS) Treatment Delivery Services (APCs 0065, 0066, and 0067)

For Calendar Year (CY) 2007, CMS proposed to create several new SRS clinical Ambulatory Payment Classifications (APCs) of different levels to assign the HCPCS codes describing linear accelerator-based SRS treatment (HCPCS codes G0173, G0251, G0339, G0340 and G0243). It was explained by CMS that these assignments would be based on their clinical and hospital resource similarities and differences.

CMS proposed to assign HCPCS codes G0339 and G0173 to the same Level III SRS APC. The HCPCS codes describing subsequent fractions of image-guided, robotic (G0340) and non-image

[1] *ASTRO is the largest radiation oncology society in the world, with more than 8,500 members who specialize in treating patients with radiation therapies. As a leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing socioeconomic healthcare environment.*

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guided, non-robotic SRS treatments (G0251) would each be assigned to their own clinical APCs. Finally, CMS proposed to continue the assignment of HCPCS code G0243 for multi-source photon (Cobalt 60-based) SRS treatment delivery to clinical APC 0127, renamed Level IV Stereotactic Radiosurgery. A table listing the HCPCS code descriptions and payments is provided below.

HCPCS Code	Short Descriptor	CY 2006 APC	CY 2006 Payment Rate	Proposed CY 2007 APC	Proposed 2007 Payment Rate
G0173	Complete course of non-image guided, non-robotic linear accelerator-based SRS treatment	1528	$5,250	67	$4,045
G0251	Fractionated non-image guided, non-robotic linear accelerator-based SRS treatment	1513	$1,150	65	$1,381
G0339	Complete course of therapy in one session or first fraction of image-guided, robotic linear accelerator-based SRS	1528	$5,250	67	$4,045
G0340	Second through fifth sessions of image-guided, robotic linear accelerator-based SRS treatment	1525	$3,750	66	$2,907
G0243	Complete course of multi-source photon SRS	127	$7,305	127	$7,305

In our comments on the OPPS proposed rule, we did not oppose these potential APC assignments, although we were concerned by the extent of the payment reductions for some services. At our request, CMS re-checked the cost calculations for all the SRS services using the most current claims data available to determine the payment rates for the final rule. We appreciate the care with which CMS analyzed the available data in setting the final payment rates.

Also in our OPPS proposed rule comments, we noted that new CPT® codes for the services described by the above mentioned HCPCS codes, had been successfully presented to the American Medical Association's (AMA) CPT Editorial Panel and RVS Update Committee (RUC), and would become effective January 1, 2007. Furthermore, we requested the opportunity to work with CMS to ensure an appropriate transition to the new CPT codes, including their assignment to APCs with payment rates consistent with the resource costs required to provide the services.

We were pleased to note that in the OPPS final rule, CMS deleted HCPCS code G0243 and crosswalked the existing cost data to new CPT code 77371; *Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cerebral lesion(s) consisting of*

1 session; multi-source Cobalt 60 based. However, we were disappointed that CMS did not delete the other HCPCS codes for SRS. ASTRO feels that the new AMA approved CPT® codes fully describe the services' and the process of care for stereotactic radiation therapy, and therefore should replace the existing HCPCS codes. The following table lists the appropriate crosswalk between the existing HCPCS codes and the new CPT codes:

Current HCPCS Code	HCPCS Code Description	New CPT® Code	2007 CPT® Code Description
G0173	Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session	77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cerebral lesion(s) consisting of 1 session; linear accelerator based
G0251	Linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment	77373	Stereotactic body radiation therapy, treatment delivery, per fraction to one or more lesions, including image guidance, entire course not to exceed 5 fractions
G0339	Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment	77373	Stereotactic body radiation therapy, treatment delivery, per fraction to one or more lesions, including image guidance, entire course not to exceed 5 fractions
G0340	Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment	77373	Stereotactic body radiation therapy, treatment delivery, per fraction to one or more lesions, including image guidance, entire course not to exceed 5 fractions
G0243	Multi-source photon stereotactic radiosurgery, delivery including collimator changes and custom plugging, complete course of treatment, all lesions	77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cerebral lesion(s) consisting of 1 session; multi-source Cobalt 60 based

We recognize that it is too late for changes to be made for the 2007 OPPS. However, we believe that changes in 2008 will be essential since the co-existence of HCPCS codes and CPT codes

that describe the same services is extremely problematic for hospitals, as well as for payers, since not all payers recognize Medicare's temporary HCPCS codes.

We ask that CMS consider our recommendation to replace the temporary HCPCS codes with the permanent CPT® codes in 2008, and invite CMS to work with ASTRO to ensure an appropriate transition to the new CPT codes and in drafting a billing clarification directive to ensure that providers understand the new coding schema. Additionally, if CMS has any questions or concerns, we ask that they be brought to our attention prior to the development of the 2008 OPPS proposed rule. Finally, we recommend that the proposed rule for 2008 specifically recommend the elimination of the HCPCS codes for SRS and propose their replacement with the new CPT codes for SRS that are described above.

2. Breast Brachytherapy

For CY 2007, CMS proposed to reassign CPT code 19296; *Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy,* from New Technology APC 1524 (New Technology Level XIV— ($3000-$3500)) to clinical APC 0030 (Level III Breast Surgery) with a proposed median cost of $2,516.94. CMS also proposed to reassign CPT code 19297; *Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy,* from New Technology APC 1523 (New Technology Level XXIII—($2500– $3000)) to clinical APC 0029 (Level II Breast Surgery), with a proposed median cost of $1,738.75.

After full consideration of the comments submitted by ASTRO and others, CMS decided to assign both services to clinical APC 0648 with an APC title of "Level IV Breast Surgery" and a final median cost of $3,130.45. We greatly appreciate this decision which will help to ensure continued access to this important breast cancer treatment option.

3. Proposed Use of Single and Multiple Procedure Claims: CPT® Code 77421

We support the methodological changes to increase the number of single bills which could be used to calculate the relative weights. These changes include refinement of the policy for determining which HCPCS codes could be bypassed for purposes of creating single bills from multiple bills. In the proposed rule, CMS requests comments on the list of codes that the agency is proposing to add to the existing bypass list for creation of "pseudo" singles for CY 2007.

The current bypass list includes CPT code 76950; *Ultrasonic guidance for placement of radiation therapy fields.* CMS proposed to add the following radiation oncology guidance CPT codes to the list for CY 2007:

- 76370; *Computed tomography guidance for placement of radiation therapy fields*
- 76965; *Ultrasonic guidance for interstitial radioelement application.*

ASTRO supported the proposed inclusion of CPT® codes 76370 and 76965 on the bypass list and appreciate their being added to the bypass list in the final rule. We also recommended the addition of CPT code 77421; *Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy.*

For reasons that are not clear, CMS decided against our recommendation although this addition would have made the bypass list inclusive of all the guidance codes used in radiation oncology and would increase the number of "single claims" eligible for use in OPPS rate-setting, especially for image-guided radiation therapy (IGRT). We CMS to reconsider its decision and add CPT code 77421 to the bypass list when the median costs for radiation oncology APCs are calculated for the CY 2008 OPPS.

Conclusion

Thank you for this opportunity to comment on the CY 2007 OPPS final rule. We look forward to continued dialogues with CMS officials. Should you have any questions or require further discussion regarding the items addressed in this comment letter, please contact Trisha Crishock, MSW, Director of ASTRO's Health Policy Department at (703) 502-1550.

Respectfully,

Laura Thevenot

Laura Thevenot
ASTRO, Chief Executive Officer

Cc: Terrence Kay
Ken Simon, M.D.
Edith Hambrick, M.D.
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January 23, 2007

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200 Independence Avenue, SW
Washington DC 20201

Re: Medicare Program - Revisions to Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Final rule [CMS-1506-FC]

Dear. Ms. Norwalk:

The American Gastroenterological Association (AGA) appreciates the opportunity to provide comment on the Centers for Medicare and Medicaid Service's (CMS) Final Rule on Revisions to Hospital Outpatient Prospective Payment System (OPPS) for Calendar Year 2007 (CMS-1506-FC, Federal Register, Vol. 71, No. 226, November 24, 2006, p. 67960).

Ambulatory Payment Classification Assigned to CPT 43647 (comment code NI), Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum

In Addendum B of the final rule, CPT 43647 is assigned to APC 0130, Level I Laparoscopy. CPT 43647, a new code effective on January 1, 2007, describes the lead implantation procedures associated with placement of gastric electrical stimulation leads for Enterra Therapy. This neurostimulation therapy may be considered as a treatment option for patients who have chronic nausea and vomiting due to gastroparesis or delayed gastric emptying.

During the procedure, two neurostimulation leads are implanted in the wall of the stomach (antrum area) and are connected to a neurostimulator pulse generator (CPT 64590 is used for implantation of the pulse generator).

It may appear that this new CPT code solely describes a laparoscopic surgical procedure. However, it is important to recognize that this laparoscopic procedure involves placement of neurostimulation leads to stimulate the wall of the stomach. In other words, a laparoscopic technique is used for lead implantation, versus an open surgical procedure.

Since this is a neurostimulation procedure, it should be assigned to an APC that is dedicated to lead implant procedures. In doing so, the clinical and cost characteristics associated with this procedure would be accounted for while APC 0130 does not accurately recognize those. Since incisions are involved in laparoscopic procedures, it would appear that APC 0061, Laminectomy or Incision for Implantation of Neurostimulation Electrodes, would be the most appropriate alternative.

Please contact Anne Marie Bicha, AGA Director of Regulatory Affairs, at 240-482-3223 or abicha@gastro2.org if you have any questions. Thank you.

Sincerely,

David A. Peura, M.D.
Chair, American Gastroenterological Association

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January 23, 2007

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The Honorable Leslie Norwalk
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Re: **CMS-1506-FC:** Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List.

Dear Ms. Norwalk:

I am writing on behalf of BioSphere Medical, Inc., (BioSphere) to provide you with comments about the new CPT code and reimbursement rates for Uterine Fibroid Embolization (UFE), which appear in the Final Rule on Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List (Final Rule).[1] Specifically, BioSphere is concerned that CMS has assigned the newly developed CPT code for uterine fibroid embolization (UFE), 37210, to an inappropriate Ambulatory Payment Classification (APC) for purposes of Medicare hospital outpatient payment. Additionally, because some patients do not require an overnight hospital stay, UFE should be included in the list of procedures eligible for payment when performed in an Ambulatory Surgical Center (ASC) in 2007.

BioSphere specializes in the development of embolotherapy technology, including the use of microsphere embolization for the treatment of benign uterine fibroid tumors. The company also works with physicians, patients, and patient advocates to raise awareness about UFE as a safe and effective alternative to surgical options, such as myomectomy and hysterectomy.

I. CMS Reimbursement Policies Must Encourage, Not Restrict, Access to UFE.

UFE provides women with a uterine-sparing, non-surgical option for the treatment of benign uterine fibroid tumors, one of the most prevalent women's health problems in the United States today. Uterine fibroids grow on the muscle tissue of the uterus. These tumors cause pelvic pressure, abdominal bloating, heavy menstrual bleeding, anemia, urinary pressure or incontinence, and possible infertility. Twenty to forty percent of women of childbearing age

[1] 71 *Fed. Reg.* 67960 (Nov. 24, 2006).

experience fibroids; more than five million women are symptomatic. African-American women are three times as likely to be affected by the condition.

Traditionally, women suffering from fibroids have had to have invasive, painful hysterectomies (removal of the entire uterus) or myomectomies (removal of the affected portion of the uterus) that require lengthy recovery periods. UFE is a new procedure that provides women with a non-surgical alternative treatment for uterine fibroid tumors. It is minimally invasive, clinically effective, cost-efficient, and allows women to retain their uterus and fertility.

UFE is performed by inserting two small catheters to inject tiny particles into the uterine blood stream that block the blood supply to the tumor. Clinical data demonstrate that one year after UFE 90 percent of women are symptom free; five years after the procedure 73 percent of patients remain symptom free.[2] The cost associated with UFE is generally lower than surgical treatment. A recent study found that 96 percent of women who undergo UFE are satisfied with the treatment 12 months following the procedure. All of these evidence-based attributes are remarkable for a procedure that has emerged in such a short time period.

Many women prefer UFE. First, it shortens the hospitalization period. Patients undergoing UFE typically return home the same day as the procedure or have an overnight hospital stay, rather than the two-to-four day hospitalization associated with surgical treatments. Second, it provides for a quicker recovery. Patients can usually return to their activities of daily living and work in 7-10 days, as opposed to the several weeks of recovery following surgical treatment. Third, because the uterus is not removed, a patient who undergoes UFE may be able to preserve the ability to have children, which is not possible after having a hysterectomy.

In addition to its clinical benefits and patient-friendly attributes, UFE has also been shown to be more cost-effective than traditional surgical treatments for fibroid tumors. The procedure generally allows a patient to go home the same day or the next morning, rather than requiring a three-to-four day hospital stay. This difference between the surgical options and UFE significantly reduces the costs of treating fibroid tumors. Furthermore, because a patient is typically able to return to work and normal activity within 10-11 days instead of waiting the four-to-six weeks required for recovery after a hysterectomy, there is also less expense associated with recovery costs of the procedure. Given the significant population of women who experience fibroid tumors and the number of procedures undertaken each year to treat this condition, the development of UFE as a clinically effective and cost efficient treatment method holds tremendous promise for patient benefit and savings.

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[2] James B. Spies, *et al*, "Uterine Artery Embolization for Leiomyomata," *Obstetrics & Gynecology* (March 2001), 98, 29-34; James B. Spies, *et al*, .Long-Term Outcome of Uterine Artery Embolization of Leiomyomata," *Obstetrics & Gynecology* (November 2005), 106, 933-939.

II. CMS Should Appropriately Reimburse the UFE Procedure by Assigning It to APC Group 0229.

The assignment of the newly developed CPT code for UFE, 37210, to APC group 0202 does not appropriately reflect the costs associated with providing UFE treatment and, if not changed, will result in a drastic cut for providing this procedure that could result in fewer facilities that are able to offer UFE. APC group 0202 provides for a payment rate of approximately $2,600. This amount would barely cover the cost of supplies for providing the procedure.

Cost data submitted by the Society for Interventional Radiology (SIR) to the RVS Update Committee (RUC) of the American Medical Association (AMA) during the development on practice expense component of the physician fee for 37210 demonstrated that the cost of the procedure supplies (infusion catheter, guidewire, etc.) and the microspheres (drug) alone can exceed $2000 per patient. For example, in the recent Fibroid Registry study[3], researchers found that the typical patient requires (on average) five, two-milliliter syringes of microspheres, which cost approximately $1,290. This is only one component of the cost of supplies. Both the SIR and Fibroid Registry study data demonstrate that the supply cost are higher than those that would normally be associated with procedures in APC group 0202.

Instead of the current group, CMS should place UFE in APC group 0229. The procedures in this group share more clinical similarities with UFE and its costs than those procedures in APC group 0202. For example, UFE requires similar skills and time as does the transcatheter placement of a shunt. Both procedures entail placement of a small medical device in a patient using a transcatheter. Both procedures also are "combination" codes, which mean they include in their value input the costs of the additional services, such as imaging, that are critical to the performance of the procedure. Typically, for other codes, these services would be billed separately rather than being included in the main service code. As such, it is clear that the clinical requirements and coding specifications of APC 0229 and the UFE procedure are similar. Therefore, APC 0229 is a more appropriate placement than APC 0220 for the new UFE CPT code for both clinical and cost-related reasons.

Given that UFE is more efficient and cost-effective overall than surgical options, CMS should encourage its use through appropriate reimbursement policy. Furthermore, because UFE is a relatively new treatment option that is still gaining support among patients and clinicians, a flawed reimbursement policy is even more likely to have a negative impact on the availability of this procedure, thus stifling the growth of an important treatment alternative for women.

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[3] Worthington-Kirsch R, et al., "The Fibroid Registry for Outcomes Data (FIBROID) for Uterine Artery Embolization: Short Term Outcomes", *Obstetrics and Gynecology* (2005);106:52-59.

III. CMS Should Include UFE on the CY 2007 List of Procedures Eligible For Payment in the ASC Setting.

CMS should also revise the Final Rule to include UFE in the covered procedure list. Currently, most UFE procedures require an overnight hospital stay. However, as physicians adopt and refine UFE, it appears likely that many women will be able to avoid the overnight stay. CMS should encourage the further refinement of the procedure by ensuring that physicians performing it in an ASC setting receive appropriate reimbursement for it.

Clinicians specializing in UFE support providing the procedure in an ASC setting if a patient does not require intensive pain management. Today, it is true that it is less common for UFE to be performed in the ASC setting than in a hospital setting. Because UFE can be performed in some cases without requiring an overnight stay, including UFE in the list of ASC-eligible procedures would be consistent with CMS' criteria for determining what procedures should be included on the list. As physicians become more familiar and skilled in performing UFE, it seems likely that the number of patients requiring an overnight hospital stay will continue to decrease and more patients will be sent home on the same day as the procedure. Allowing UFE to be performed in the ASC setting may provide patients with a lower cost, higher quality option for undergoing the procedure, thus increasing access to an important treatment option for women suffering from uterine fibroid tumors. By including UFE on the list of covered procedures, CMS will be aligning the incentives in a manner that will encourage physicians to use the less costly ASC setting when appropriate for the patient. This approach is the correct one because it is exactly how the ASC setting is supposed to be used.

IV. Conclusion

BioSphere appreciates the opportunity to comment on this important issue for women. It is imperative that CMS ensure that its reimbursement policies do not threaten access to UFE and thwart the desire of many Members of Congress who are working to educate more women about this important and effective new alternative to surgery. To ensure access to the UFE procedure for patients, CMS must accurately account for the costs of the procedure and reimburse providers at an appropriate level. We hope the information provided above will encourage your staff to revisit the APC assignment for UFE as well as its eligibility for performance in an ASC. We look forward to working with you to provide effective and efficient services for women with fibroid tumors. Please do not hesitate to contact me at 202-457-6562 if you have questions or would like additional information.

Sincerely,

Kathleen J. Lester

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KIDNEY CARE
PARTNERS

January 23, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
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Department of Health and Human Services
Room 445-G
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200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-FC Proposed Changes to the Hospital Outpatient PPS and CY 2007 Rates; Proposed CY 2007 Update to the ASC Covered Procedures List; and Proposed Changes to the ASC Payment System and CY 2008 Payment Rates

Dear Ms. Norwalk:

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments on the changes to the Ambulatory Surgery Center payment methodology for CY 2007 Payment Rates. KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care of individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[1]

KCP is pleased that CMS recognizes the importance of expanding the types of procedures performed in the ASC setting to include those related to the repair and maintenance of AV fistula and grafts, as evidenced by the inclusion of G0392 and G0393 in the November 1, 2006 Final Rule for the Hospital Outpatient Prospective Payment System (OPPS). In reviewing the public use files of supplies, labor and equipment for the most common dialysis access procedures, there appear to be some errors. We would like to request that the technical group review the data files (equipment and supplies) for the 35475, 35476 and 36870 codes. Be advised that 35475 and 35476 are the map codes for the new G codes in 2007:

G0393-Dialysis Access Angioplasty-venous (35476 old code)

[1]A list of Kidney Care Partners coalition members is included in Attachment A.

G0392-Dialysis Access Angioplasty-arterial (35475 old code)

Specifically, we are asking for consideration of the following:

- **RVU adjustment for new G codes (G0392 and G0393)** - The corresponding CPT codes (35475 and 35476) were last reviewed in 2004. Since then, technology advances, particularly in the advent of angioplasty balloons, have improved success rates as well as decreased complications. The low profile, high pressure balloons are routine in these types of angioplasties.

- **Adjustment to equipment and supply items for common dialysis access procedures** – In reviewing the public use files, we found several missing items on the angioplasty procedure list as well as missing items pertaining to the declot code that were included in last years' public use files. In the dialysis access declot code (36870), there is nothing in the cost files to note the use of a room with angiographic equipment, table and imaging. In addition, the angioplasty procedures would need a power table in the angio room.

As always, KCP appreciates CMS' review of these comments and look forward to working with you as you finalize this regulation. Please feel free to contact Kathy Lester (202) 457-6562 if you have any questions.

Sincerely,

Edward R. Jones
Chairman
Kidney Care Partners

Attachment A

KIDNEY CARE
PARTNERS

Abbott Laboratories
American Kidney Fund
American Nephrology Nurses' Association
American Regent, Inc.
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
DaVita Patient Citizens
Fresenius Medical Care North America
Genzyme
Medical Education Institute
Nabi Biopharmaceuticals
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Renal Advantage Inc.
Renal Physician's Association
Renal Support Network
Roche
Satellite Healthcare
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U.S. Renal Care
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Re: Final Rule: Medicare Program - Revisions to Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates (CMS-1506-FC)

Dear Ms. Norwalk:

The American College of Radiation Oncology ("ACRO") is pleased to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the Final Rule: Medicare Program - Revisions to Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates (CMS-1506-FC).[1] With a current membership of approximately 1000, ACRO is a dedicated organization that represents radiation oncologists in the socioeconomic and political arenas. ACRO's mission is to promote the education and science of radiation oncology, to improve oncologic service to patients, to study the socioeconomic aspects of the practice of radiation oncology, and to encourage education in radiation oncology.

Breast Brachytherapy Facility Payments

ACRO supports the reconsideration offered by CMS and the change in APC assignment for both breast brachytherapy CPT codes (19297 and 19296). The Level IV breast surgery code (APC 0648) better reflects the resources used in these procedures. While CMS did not concur with ACRO's request for analysis with additional claims data, CMS's decision to add a procedure-to-device edit may increase the accuracy of data captured. In this manner, the cost of the specialized catheters will be more correctly reflected in the APC payment.

[1] Final Rule: Medicare Program - Revisions to Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates (CMS-1506-FC). *Federal Register*, Volume 71, No. 226, November 24, 2006, p. 67959.

We are concerned about the addition of the "T" modifier to CPT code 19297. If you subtract the cost of the brachytherapy catheter, the hospital actually receives less reimbursement by doing both the partial mastectomy (CPT 19302) and the brachytherapy catheter placement (CPT 19297) than doing the partial mastectomy alone. It does not seem to be logical or good policy to pay less for a service that involves more work and resources. This rank order anomaly should be corrected.

Stereotactic Radiosurgery (SRS) Treatment Delivery Services (APCs 0065, 0066, and 0067)

New treatment codes describing stereotactic radiosurgery were approved by the American Medical Association's (AMA) CPT Editorial Panel and RVS Update Committee (RUC), effective January 1, 2007. ACRO shares the disappointment of the American Society for Therapeutic Radiology & Oncology (ASTRO) in that only one code crosswalked the existing cost data to new CPT® code 77371; *Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cerebral lesion(s) consisting of 1 session; multi-source Cobalt 60 based.* ACRO joins ASTRO in support of the full implementation of the new AMA approved CPT codes as these codes fully describe the services' and the process of care for stereotactic radiation therapy, and therefore should replace the existing HCPCS codes.

Complex Interstitial Radiation Source Application

ACRO continues to hope that the development of more accurate codes will better reflect the services provided and lead to a more homogeneous set of claims data. We believe that there are two primary sources for the instability: (1) providers have not reliably billed for these sources; and (2) the code has been used to bill for a heterogeneous mix of patients including:

- low dose rate brachytherapy manual loading of iridium for treatment of such conditions as sarcomas or breast cancer;
- permanent low dose rate brachytherapy using radioactive iodine for prostate cancer; and
- insertion of applicators for brachytherapy for gynecological or other tumors.

We will continue to monitor the payment variability in light of coding changes being proposed.

Payment for Radioactive Sources

The payment of radioactive sources based on prospectively established compensation is an established goal of CMS. H.R. 6111[2] established an additional year to work on this effort. ACRO believes that this can be done in an accurate and reasoned manner that reflects clinically meaningful differences in sources. It is our belief that differences is "packaging" (for example: stranded versus non-stranded) can be clinically beneficial for the patient and represent legitimately different costs. Where such delivery/packaging is both clinically different and has a cost differential, ACRO supports pricing that reflects these differences. We look forward to working with CMS and others during the upcoming year on this issue.

[2] Tax Relief and Health Care Act of 2006.

Our continued goal is to promote quality radiation therapy and to see that patients have unbiased access to a diversity of radiation services. ACRO's comments on the OPPS regulations seek to ensure ongoing access to radiation oncology services. In many communities, hospital outpatient units are the key providers of radiation services. Maintaining patient access is crucial since our patients often require services 5 days a week for many weeks of life saving therapy. Patient accessibility and continuity are key components of service quality.

ACRO appreciates the opportunity to comment on the final regulations. We hope that our comments highlight our sincere interest in making radiation oncology services cost effective, properly reimbursed and readily accessible to cancer patients.

Sincerely,

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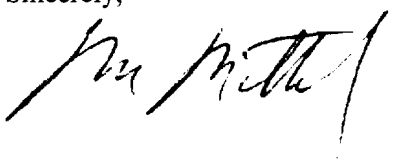
Bethesda, Maryland 20816

Sincerely,



Michael Kuettel, M.D., Ph.D.
Chair, Socioeconomics Committee
American College of Radiation Oncology
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cc: Terry Kay, Centers for Medicare and Medicaid Services
Herb B. Kuhn, Centers for Medicare and Medicaid Services

SIRTeX

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January 23, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-FC Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Final Rule with Comment Period

Dear Acting Administrator Norwalk:

Sirtex Medical Inc. ("Sirtex") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") Final Rule regarding the Hospital Outpatient Prospective Payment System ("OPPS") and CY 2007 payment rates. Sirtex manufactures SIR-Spheres® microspheres, which are biocompatible radioactive resin spheres that contain Yttrium-90 ("Y-90") and emit beta radiation to treat unresectable colorectal cancer metastasized to the liver. Y-90 is one of twelve radioactive brachytherapy devices paid for by Medicare. SIR-Spheres microspheres represent an important innovation, both from the patient's quality of life perspective and from a cost perspective. Brachytherapy has markedly fewer debilitating side effects than traditional external beam radiation therapy and chemotherapy. In addition, most brachytherapy procedures can be performed (on an outpatient basis) as a single treatment unlike traditional external beam radiation therapy and chemotherapy infusions which must be repeated monthly or weekly. Maintaining Medicare beneficiary access to these treatments is critical.

After CMS published the OPPS proposed rule in August 2006, the Congressionally-created Ambulatory Payment Classification (APC) Advisory Panel recommended that CMS maintain the current Medicare payment methodology of charges reduced to costs for brachytherapy devices. Similarly, the Congressionally-created Practicing Physicians Advisory Council (PPAC) recommended that CMS abandon their proposed prospective payment proposal.

Both of these advisory panels based these recommendations on concerns regarding the adequacy of CMS' data on brachytherapy devices. Nonetheless in the 2007 final OPPS rule, the agency finalized its decision to pay separately for brachytherapy sources effective January 1, 2007 on a prospective basis, with payment rates determined by using the 2005 claims-based median cost per source for each brachytherapy device. While Sirtex understands CMS's desire to pay for all outpatient services on a prospective basis, we feel that brachytherapy source data simply isn't accurate enough to preserve patient access.

As you know, Congress recognized the potential threat to patient access that the impending CCR payment methodology presented, and accordingly overwhelmingly passed the Tax Relief and Health Care Act of 2006 which extends for CY 2007 the current payment methodology for all brachytherapy sources of hospital charges adjusted to costs. Sirtex urges the agency in the CY 2008 OPPS proposed rule to support brachytherapy patients and the congressional action by extending the payment policy of hospital's charges adjusted to cost for all brachytherapy sources through 2008. We also urge CMS to accelerate its efforts to educate hospitals on the importance of accurate coding for devices and other technologies.

Data Accuracy Concerns

The payment methodology for radioactive sources associated with brachytherapy has been altered several times since the inception of the HOPPS in 2000. As a result, hospitals have been faced with the significant challenge of implementing new systems and re-training coders each year. As outlined below, problems with claims data accuracy and completeness persist. As a result of the drastic drop (37%) in CMS' estimate of the median unit cost in the 2007 proposed and final OPPS rules, Sirtex engaged the Moran Company to conduct an analysis of the CMS data used to calculate rates in both rules. The final rule payment rate for C2616 was based on data from 63 hospitals that billed Medicare for a total of 358 units of C2616 in 2005. The data show a significant degree of variation in per unit cost across hospitals. Moran determined that the median cost that CMS calculated as part of the final OPPS rule ($10,586.86) was lower than the median reported as part of the proposed rule ($16,848.00) because of a departmental **cost reporting error made by a single hospital**. The hospital in question accounted for the highest number of units of C2616 (31%) in the data CMS used to calculate the rates in the final rule. Moran's investigation revealed that in the proposed rule data file, the cost-to-charge ratio (CCR) applied to this particular hospital's charges for C2616 was 1.106, and in the final rule it was 0.301.[1] The change was applied to all the claims for this hospital, not just the 44 new claims included in the final rule. This had the effect of reducing the CMS cost estimate from an average of $37,608 to $10,272 per unit. The problem from a patient access standpoint is that the rate in the final rule is less than the product costs. This is unacceptable. While, we support CMS' desire to pay appropriately for medical care, it is not reasonable to set payment levels so low that physicians are forced to choose between suffering a financial loss or providing the best treatment

[1] It appears that this hospital reported a figure in the FY 2004 cost report of greater than one, but did not report any data for this same department in the FY 2005 cost report. We understand that in cases where CMS has no departmental CCR, the default is the hospital overall CCR. Looking back to previous year's cost reports, Moran found that this hospital is highly variable from year to year and may reflect an inaccurate accounting of charges and costs for this department.

for their patients. SIR-Spheres microspheres are often the only viable treatment for patients who have failed multiple chemotherapy protocols. Another serious concern we have about the accuracy of the data is that five hospitals of the 63 hospitals from the list of those submitting claims to CMS are customers of neither manufacturer of a product in the C2616 code. Finally, there are several hospital customers that do not appear on the list of hospitals submitting claims in 2005. As you know, this product is a radioactive device and has less than a two-day shelf life.

Conclusion

Sirtex was concerned that the payment rates set by CMS in the 2007 final rule would have deterred hospitals from providing Y-90 brachytherapy treatment -- a less invasive, highly-effective cancer treatment to Medicare beneficiaries. We continue to be concerned about this same issue in 2008, and therefore urge CMS to continue the CCR reimbursement methodology through the end of 2008. We appreciate the opportunity to comment on the issues raised in the final rule, and look forward to working with CMS to ensure that Medicare beneficiaries continue to have access to life-saving brachytherapy treatments such as Y-90. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions into the CY 2008 proposed rule. Please do not hesitate to contact Nat Geissel, CEO, at 847-482-9023 or Desiree Gray, VP Marketing at 617-901-6808 if you have any questions regarding these comments. Thank you for the opportunity to comment on the proposed rule and your attention to this very important matter.

Sincerely,

Nat Geissel
Chief Executive Officer

cc: Carol M. Bazell, M.D.