October 5, 2004

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1427-P P.O. Box 8010 Baltimore, MD 21244-8018

RE: CMS-1427-P: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates

Dear Dr. McClellan:

The American Society for Therapeutic Radiology and Oncology (ASTRO)^[1] appreciates the opportunity to provide comments on the Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2005 Payment Rates announced in the *Federal Register* on August 16, 2004. Our comments focus on (1) the proposal to move proton treatment intermediate and complex codes from their new technology APC group; (2) brachytherapy high dose rate and multiple/single claims; (3) stereotactic radiation therapy and (4) hyperthermia.

New Technology APCs - Proton Treatment [69 Fed. Reg. 50,465]

Proton treatment is a precise form of radiation treatment available for certain cancers and other diseases. The precision of the treatment is beneficial to the patient because it minimizes the harm to surrounding healthy tissues and allows the patient to resume normal activities with few to no side effects. There are only two facilities providing proton therapy at this time, with an additional facility to begin proton treatment soon, and approximately five other facilities in the start process. Upon review of the NPRM, we would like to comment on the proposal to move CPT code 77523 *Proton treatment, intermediate* and CPT code 77525 *Proton treatment, complex* from the new technology APC 1511 to APC 0419 as indicated in Table 14.—Proposed APC Reassignment of New Technology Procedures Into Clinical APCs.

The data CMS received for proton treatment was submitted from the two facilities currently providing proton treatment—Loma Linda University Medical Center (Loma

¹ The American Society for Therapeutic Radiology and Oncology is the largest radiation oncology society in the world with more than 7,500 members who specialize in treating patients with radiation therapies. As a leading organization in radiation oncology, biology and physics, the Society's mission is to advance 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 evolving socioeconomic healthcare environment. Nearly two-thirds of all cancer patients receive radiation therapy during their illness. Medicare/Medicaid is the predominant source or reimbursement for radiation oncology procedures.

Linda) and Massachusetts General Hospital (Mass General). Loma Linda's volume was much greater, so in effect the payment rates will be based upon only one center. We believe it is most appropriate for these codes to remain in their current new technology APC (1511) until such time that more proton centers are active and submitting claims. It is important to note that the charges for the 4th quarter increased for both CPT codes at Loma Linda and for CPT code 77523 at Mass General. **ASTRO recommends that the proton treatment codes 77523 and 77525 remain in the new technology group APC 1511 and continue to be reimbursed at the CY 2004 payment amount of \$950.**

Brachytherapy [69 Fed. Reg. 50,493]

We would like to thank CMS for accepting The APC Panel's recommendations regarding brachytherapy, including the addition of Cxxx1 *Brachytherapy source, high activity, Iodine-125, per source* and Cxxx2 *Brachytherapy source, high activity, Palladium-103, per source* as well as including "per source" in all of the HCPCS code descriptors for Palladium-103. ASTRO also appreciates CMS's attention to the statute (Pub. L. 108-173) that allows for a new linear source Palladium-103 HCPCS code Cxxx3 *Brachytherapy linear source Palladium-103, per 1mm.* 69 Fed. Reg. 50,540

The new HCPCS codes for brachytherapy sources are helpful in capturing the radioactive material costs of this valuable means of target-specific radiation treatment. ASTRO is concerned, however, that other (non-radioactive) supplies used in treatment delivery are either not being accounted for or considered. For example, in the category of brachytherapy, there are only two HCPCS codes for non-radioactive materials (needles C1715 and catheters C1728). Whereas the delivery of brachytherapy usually involves not only needles and catheters, but also devices or supplies called template guides, tandems, ovoids, single and multi-channel vaginal cylinders, nasopharyngeal, esophageal, and endobronchial applicators, stepper units, superflab applicators, custom mold devices, and many others.

ASTRO supports the development of new HCPCS codes for the placement of catheters and needles for the brachytherapy services. We are not sure if the added complexity will cause disruption to the hospital billing process for brachytherapy applications, however, it would appear that these new codes would help capture all of the resources related to brachytherapy. Therefore, we would support the development of new HCPCS codes for previously unrecognized, but commonly used, brachytherapy devices and supplies, and we would like to work with CMS to determine what types of codes need to be created to accurately describe the applicator insertion practice.

We would also like to bring to your attention three new codes regarding the insertion of catheters for breast brachytherapy, effective January 1, 2005. These codes include:

• 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;

- CPT code 19297 Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with parital mastectomy (List separately in addition to code for primary procedure); and
- CPT code 19298 Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance.

Hospitals will be using these codes in 2005. Previously hospitals used the unlisted code 19499 which is in APC 0028 with a proposed payment rate of \$1,081. We believe this rate is too low to appropriately capture the costs of these procedures because there have been recent advances in performing these procedures. We would be happy to work with CMS on this issue.

Over the past several years, there have been many changes in both the statutes and regulations in the reimbursement process for this radiation therapy treatment. Since brachytherapy often involves coordination of many hospital departments, including radiation oncology, surgery, cardiac catheter laboratory, the endoscopy suite, and radiology, it is not surprising that confusion might arise in the accounting of provided brachytherapy services. It is a continued challenge for hospital staff to keep current on how to bill for brachytherapy services. ASTRO recently published an educational article entitled, "Brachytherapy Coding Guidance for Outpatient Hospital Departments" to assist hospital staff with the complicated reimbursement procedures (http://www.astro.org/pdf/HealthCare/coding/brachycodguide.pdf, ASTRO 2004). We will continue our efforts to educate facilities on correct coding practices for brachytherapy.

Stereotactic Radiation Therapy [69 Fed. Reg. 50,464]

ASTRO appreciates the continued opportunity to comment on the reimbursement issues surrounding stereotactic radiation therapy (SRT). There are several technically different ways to deliver SRT. As we mentioned in our September 29, 2004 letter to you solely regarding SRT issues, we noted that, as a consequence of these differences, the current coding schema:

- a) Does not accurately represent the process of care;
- b) Does not fully account for the facility expense;
- c) Sometimes is considered restrictive and at other times permissive so as to create incongruence in the application of this nomenclature; and
- d) Describes a vendor-specific technology when a more generic designation is warranted.

Stereotactic Radiation Therapy (SRT) is the general term for stereotactic based treatment. In its initial application for cerebral lesions, this treatment modality became known as stereotactic radiosurgery (SRS). Unfortunately, the term "radiosurgery" is

misleading nomenclature because surgery is not involved, except for the placement on the patient of an externally attached coordinate reference frame. This treatment usually consists of one or may (8 or more) high dose radiation treatments delivered by either a linear accelerator (sometimes called linac based radiosurgery) or a cobalt-60 unit (sometimes referred to as the Gammaknife®).

SRT may be correctly applied to certain malignant and benign neoplasms of the brain, cranial nerves, and meninges, arteriovenous malformations of cerebral vessels, as well as other non-neoplastic conditions. In all applications of SRT, extreme accuracy of relative position of the beam to the patient is required. It may be achieved through a rigid immobilization device affixed externally or through sophisticated "frameless" image-based techniques. Three-dimensional or inverse based treatment planning is an absolute requirement of SRT irrespective of specific SRT delivery vehicle.

The NPRM notes that there has been confusion in the coding used for SRT planning using G0242 (Cobalt 60-based SRT plan) and G0243 (Cobalt 60-based SRT delivery). We wish to point out that SRT treatment planning is already well described by CPT codes 77295 or 77301 (selection depending on various technical factors) and that other simulation, physics codes are currently used by physicians for their portion of the procedure. Eliminating the "G" codes for SRT planning would help "clean up" the current coding puzzle, while more accurately describe the process and reduce duplication in codes. This change is consistent with the changes made, for example, for prostate brachytherapy where brachytherapy codes G0261 and G0256 were deleted in favor of the existing CPT codes. ASTRO therefore recommends the elimination of G0338 and G0242 codes and instead utilize existing CPT codes 77295 or 77301 as determined by the process of care.

The initial resources involved for the first SRT treatment delivery are identical whether additional treatment sessions (known as fractions) are given or not. We believe that payment for single session SRT and the first treatment of a multi-session SRT should be identical. When subsequent fractions are delivered, the resources for those treatments are less and should be coded accordingly. *Therefore, ASTRO recommends that a logical split in the delivery codes to segregate the initial or first fraction from subsequent fractions.*

New technology is often developed simultaneously by different vendors. The dates of introduction may vary somewhat, and as codes are developed there is a natural tendency toward what we call "vendor-specificity." We believe that you will agree that vendor-specific codes are undesirable. It is the process of care that is important and different equipment may involve slightly different ways to deliver that care. The coding patterns should reflect the process of care as closely as possible. ASTRO believes that in the past there have been some inconsistencies and confusion caused by the creation of vendor-specific G-codes. ASTRO strongly recommends that one uniform series of treatment codes be developed for all of the different kinds of SRT, based on the process of care, and not specific technology ("G" codes and subsequently

CPT codes). In the event that it is not possible to develop these codes in time for the 2005 Final Rule, we request that you consider including this issue on the agenda for an upcoming meeting of The APC Panel. We are concerned that all SRT technologies will soon be described as "robotic", thus shifting patient care. We caution CMS that market incentives may be created, due to CMS payment levels that are not supported by the process of care or patient outcomes.

Hyperthermia

The payment for APC 314 hyperthermia is proposed to decrease approximately 9% for 2005. ASTRO has reviewed the claims data used to set the hyperthermia rates for 2005 and has serious concerns with the hospital data. Hyperthermia is a very expensive procedure with tremendously high capital expenditures. The hospital charges do not reflect the true costs associated with these hyperthermia procedures. ASTRO recently submitted updated hyperthermia practice expense data through the PEAC process, as well as updated pricing information through the MFS process. Although we recognize that direct practice expense inputs are not part of the OPPS process, ASTRO requests that CMS consider this pricing information for the 2005 OPPS hyperthermia rates. ASTRO also notes the utilization for these procedures is questionably high, which ASTRO interprets as possible miscoding. *ASTRO requests that CMS maintain the 2004 rates for hyperthermia in the 2005 schedule. This will provide additional time for ASTRO to educate members and hospitals on the proper coding for hyperthermia and give guidance on how to incorporate all the resources used for hyperthermia in their charge setting process.*

Conclusion

ASTRO applauds the CMS staff for their efforts to use more current data and to make more information available to the public in the proposed, rather than the final rule. Our recommendations include the following:

- (1) Maintain current APC grouping for proton treatment CPT codes 77523 and 77525;
- (2) Create new HCPCS codes for brachytherapy applications;
- (3) Work with us to ensure that the new breast brachytherapy CPT codes 19296, 19297, and 19298 are placed in an appropriate APC;
- (4) Eliminate G0338 and G0242 codes and utilize existing CPT codes 77295 or 77301:
- (5) Create a logical split in SRT delivery codes to segregate the initial or first fraction from subsequent fractions:
- (6) Create a uniform series of SRT treatment codes, based on the process of care and not specific technology; and
- (7) Maintain current APC 2004 payment rate for hyperthermia services.

The American Society for Therapeutic Radiology and Oncology appreciates the opportunity to offer these comments and looks forward to working with CMS to address

these important issues. If you require further information, please contact Trisha Crishock, MSW, Director, Health Policy and Economics Department at (703) 502-1550.

Respectfully,

Laura Thevenot

ASTRO, Executive Director

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