December 20, 2012

Ms. Marilyn Tavenner  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1590-FC  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 (1590-FC)

Dear Ms. Tavenner:

The American Society for Radiation Oncology (ASTRO)\(^1\) appreciates the opportunity to provide written comments on the “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 (CMS-1590-FC)” published in the Federal Register as a final rule on November 16, 2012.

ASTRO members are medical professionals, practicing at hospitals and cancer treatment centers in the United States and around the globe, and make up the radiation therapy treatment teams that are critical in the fight against cancer. These teams often include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers, and treat more than one million cancer patients each year. We believe this multidisciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.

In this letter, we address a number of topics that will impact our membership and the patients they serve including:

- CPT code 77418 IMRT treatment delivery
- CPT code 77373 SBRT treatment delivery

\(^1\) ASTRO is the largest radiation oncology society in the world, with 10,000 members who specialize in treating patients with radiation therapies. As the 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 evolving healthcare environment.
CPT code 77301 Radiotherapy dose plan IMRT
CPT code 77336 Physics consult
Table 8 – Codes with stand alone procedure time
Interest rate assumption
Oncology measures group for PQRS 2013 and beyond

CPT code 77418 IMRT treatment delivery
In the 2013 final rule, CMS finalized their proposed policy to reduce the assumption for the procedure for IMRT delivery (CPT code 77418) from 60 minutes to 30 minutes. The Agency’s stated rationale for this change is that they identified wide discrepancies between the procedure time assumptions used in establishing nonfacility PE RVUs for these services and the procedure times made widely available to Medicare beneficiaries and the general public. ASTRO does not support the CMS policy to revise the clinical time assumptions for CPT codes 77418.

In response to this proposal in the 2013 proposed rule, ASTRO presented thorough IMRT recommendations to the RUC at the October 2012 meeting addressing the concerns outlined by CMS in the proposed regulation. The RUC forwarded recommendations to CMS immediately following that meeting.

ASTRO submitted detailed comments to CMS in response to the proposed rule as well as to the RUC on the issue of two therapists for IMRT treatment. We presented two therapists to the RUC when the code was originally created, which the RUC approved. CMS rejected that position asserting that IMRT delivery may involve only one therapist (66 FedReg 55310). At the time, we discussed the issue with CMS, but the Agency maintained that only one therapist was needed. The use of two therapists is a safety and quality of care issue that is documented in two professional publications listed below.

“It is recommended that a minimum of two qualified individuals be present for any routine external beam patient treatment.”

This document was developed and endorsed by twelve major professional organizations in the field of radiation oncology. Additionally, the American Society of Radiologic Technologists (ASRT) position statement reads:

“It is the position of the American Society of Radiologic Technologists that two registered radiation therapists per patient per treatment unit is the minimum standard for safe and efficient delivery of radiation therapy.”

Both publications require the use of a minimum of two qualified individuals. We do believe that in many cases a full group of three therapists should be available during the delivery of IMRT to ensure and promote maximum patient safety and quality of care.

**ASTRO thanks CMS for the addition of the second therapist, which reflects the staffing of IMRT delivery in the field and is necessary for providing the service safely and appropriately.**

*Equipment Times for IMRT*

CMS also adopted their proposal to reduce the procedure times on the IMRT equipment to 30 minutes. While CMS includes seven minutes in the 2013 proposed rule and final rule to account for before treatment and post treatment activities, we do not believe this amount of time is sufficient. We oppose the CMS revisions and strongly urge CMS to update the equipment times for the accelerator, MLC, intercom, laser diode and video camera from 37 minutes to 49 minutes to appropriately account for the time the IMRT room is used during a typical IMRT treatment.

*Equipment Pricing for IMRT*

ASTRO urged CMS to update their IMRT pricing information currently used to calculate the equipment rates. The cost of the linear accelerator has increased since the code was originally valued, which was not been taken into account in CMS’ 2013 proposed drastic reductions.

**ASTRO is pleased that CMS responded to our request and updated several of the IMRT equipment items for CY 2013.**

ASTRO noted a discrepancy between the language in the regulations and the price listed in the direct practice expense input equipment file for the laser diode. The language in the rule stated the price was updated from $7,678 to $18,160; however, the equipment file still listed the price of the laser diode as $7,678.

**ASTRO requests that CMS review the details with this error and confirm that the CY 2013 payment rates are based on the correct pricing information.**

*Missing Equipment*

Subsequent to the publication of the 2012 final rule, ASTRO informed CMS that the direct PE inputs forwarded to CMS for CPT code 77418 inadvertently omitted seven pieces of equipment typically used in furnishing the service. The omitted equipment items are listed below.

- computer system, record and verify
- IMRT physics tools
- laser, diode, for patient positioning (Probe)
- video printer, color (Sony medical grade)
- intercom (incl. master, pt substation, power, wiring)
- video camera
- isocentric beam alignment device

CMS is adopting these direct PE inputs on an interim basis for CY 2013.
ASTRO is pleased CMS is incorporating the missing equipment back into CPT code 77418. They are critical for the safe and accurate delivery of IMRT. We appreciate the Agency’s consideration of comments from ASTRO and other stakeholders.

**CPT code 77373 SBRT treatment delivery**

CMS is finalizing their proposal to adjust the procedure time assumption for CPT code 77373 (SBRT treatment delivery) from 90 minutes to 60 minutes. These procedure times were first assigned to the code for CY 2007, then re-reviewed at the February 2011 meeting (CY 2012 cycle) and most recently at the September 2012 RUC meeting. Similar to CPT code 77418, the Agency’s stated rationale for this change is that they have identified wide discrepancies between the procedure time assumptions used in establishing nonfacility PE RVUs for these services and the procedure times made widely available to Medicare beneficiaries. ASTRO strongly opposed this proposal in our CY 2013 proposed rule comments, and we are disappointed that the Agency has finalized this proposal.

CMS encourages the use of valid and reliable alternative data sources when developing recommended values, including electronic medical records (with personally-identifiable information redacted) and other independent data sources. ASTRO reviewed time and motion SBRT data submitted by a high-volume center utilizing a consistent treatment delivery methodology performed by an experienced team. That data was presented to both the RUC in September 2012 and to CMS in our CY 2013 proposed rule comment letter. In that data, more than 700 SBRT cases were tracked to examine the length of treatment time for SBRT cases. The findings revealed that during the three-year period the average length of treatment time was 91 minutes. When just the lung cancer cases were examined (lung is the typical vignette for 77373 and represents the majority of the cases) the average time increased to 97 minutes. The findings from that time and motion study support the current procedure time assumption of 90 minutes for SBRT treatment delivery (actual treatment time not total room time).

In our CY 2013 proposed rule comment letter, ASTRO also cited clinical papers and technical articles supporting our recommendations. However, CMS is finalizing the change in assumption rates despite this valid and reliable evidence from the time and motion study and the consensus panel data. We are collecting data again to present to the PEAC/RUC at the upcoming RUC meeting.

**ASTRO strongly urges CMS to maintain the direct PE inputs for 2013, including clinical time of 210 minutes for CPT code 77373, the existing supplies, and the current equipment time of 114 minutes for the SBRT treatment system and the pulse oximeter. The treatment time of 90 minutes, along with the other clinical activities that take place in the room (i.e. room set up, entering treatment plan, building a correlation model, documentation and room clean up) support the 114 minutes of room time.**

**CPT code 77301 Radiotherapy dose plan IMRT**

CPT code 77301 (Radiotherapy dose plan IMRT) was identified as potentially misvalued through the High Expenditure Procedure Code screen and recently reviewed by the RUC. In the
final rule, CMS assigned interim values to this code for CY 2013. There is no change in the work value of the code. CMS accepted the RUC recommendation of 7.99 work RVUs for this code. ASTRO appreciates the Agency’s acceptance of the RUC work RVU recommendation for CPT code 77301.

CMS did make several revisions to the PE inputs for this code from the AMA RUC recommendations. ASTRO requests CMS reconsider the following revisions to the RUC approved PE inputs for CPT code 77301.

- CMS eliminated 20 minutes associated with the computer system, record and verify (ED011). The minutes assigned to ED011 are not captured elsewhere and should not be removed. ASTRO requests CMS reinstate this time.
- CMS reduced the time assigned to treatment planning system, IMRT (ED033) from 376 minutes to 330 minutes. The intra service time, along with prepare room, position patient and clean room, should be included in the calculation. In addition 46 minutes of physician time is spent on the treatment planning system (i.e. contouring). This time is independent of the clinical staff. This was discussed at great length during the practice expense review at the RUC. ASTRO requests CMS reinstate this time.
- CMS reduced the time assigned to IMRT CT-based simulator (ER005) from 58 minutes to 47 minutes. As discussed during the practice expense review of this code during the RUC meeting, the CT simulator is used for 58 minutes for this procedure. ASTRO requests CMS reinstate this time.

While ASTRO appreciates the Agency’s acceptance of the RUC work RVU recommendation for CPT code 77301, we disagree with the CMS revisions to the RUC approved PE recommendations. The code went through a rigorous practice expense review and robust discussion at the RUC, and we believe a consensus was reached based on accurate understanding of the available evidence. ASTRO requests CMS reinstate the time associated with computer system, record and verify (ED011), treatment planning system, IMRT (ED033), and IMRT CT-based simulator (ER005) for CPT code 77301.

CPT code 77336 Physics consult
In the CY 2012 final Medicare Physician Fee Schedule, CMS finalized a public nomination process for potentially misvalued codes. This newly established annual call for potentially misvalued codes consolidated the statutorily mandated Five Year Review of Work and Practice Expense. CMS believes combining the review of both physician work and practice expense for each code will better align the review of these codes and lead to a more accurate and appropriate payment. To allow for public input and to preserve the public’s ability to identify and nominate potentially misvalued codes, CMS also established a process by which, on an annual basis, the public could nominate codes. As indicated in previous comment letters, ASTRO supports this new process.

CY 2013 is the first year CMS is considering codes they received through this new process. In the 60 days following the release of the CY 2012 final MPFS rule, CMS received nominations and supporting documentation for review of 36 CPT codes. ASTRO nominated CPT code 77336
(Continuing medical physics consultation, including assessment of treatment parameters, quality assurance of dose delivery, and review of patient treatment documentation in support of the radiation oncologist, reported per week of therapy). CMS is finalizing its proposal to review this service as potentially misvalued, as well as any other services that may fall within this family of CPT codes. CMS continues to believe that changes in technology may have altered the direct practice expense inputs associated with CPT code 77336.

**ASTRO is pleased that CMS has requested review of CPT code 77336. We appreciate the Agency’s consideration of ASTRO’s and other stakeholders’ comments on this code. The specialty looks forward to working through the AMA RUC process to submit revised practice expense inputs for CPT code 77336.**

**Table 8 – Codes with stand alone procedure time**

CMS is finalizing its proposal to review and adjust CPT codes with stand-alone procedure time assumptions used in developing nonfacility (freestanding) PE RVUs (Table 8). CMS has identified several codes (mostly radiation oncology codes) that have annual Medicare allowed charges of $100,000 or more, include direct equipment inputs that amount to $100 or more, and have PE procedure times greater than 5 minutes. Although there are other CPT codes that are valued in the same manner, CMS is not proposing to review those codes at this time. The following radiation oncology services have been identified:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77280</td>
<td>Set radiation therapy field</td>
<td>77408</td>
<td>Radiation treatment delivery</td>
</tr>
<tr>
<td>77285</td>
<td>Set radiation therapy field</td>
<td>77409</td>
<td>Radiation treatment delivery</td>
</tr>
<tr>
<td>77290</td>
<td>Set radiation therapy field</td>
<td>77412</td>
<td>Radiation treatment delivery</td>
</tr>
<tr>
<td>77301</td>
<td>Radiotherapy dose plan IMRT</td>
<td>77413</td>
<td>Radiation treatment delivery</td>
</tr>
<tr>
<td>77338</td>
<td>Design mlc device for IMRT</td>
<td>77414</td>
<td>Radiation treatment delivery</td>
</tr>
<tr>
<td>77372</td>
<td>SRS linear based</td>
<td>77416</td>
<td>Radiation treatment delivery</td>
</tr>
<tr>
<td>77373</td>
<td>SBRT linear based</td>
<td>77418</td>
<td>Radiation tx delivery imrt</td>
</tr>
<tr>
<td>77402</td>
<td>Radiation treatment delivery</td>
<td>77600</td>
<td>Hyperthermia treatment</td>
</tr>
<tr>
<td>77403</td>
<td>Radiation treatment delivery</td>
<td>77785</td>
<td>Hdr brachytx 1 channel</td>
</tr>
<tr>
<td>77404</td>
<td>Radiation treatment delivery</td>
<td>77786</td>
<td>Hdr brachytx 2-12 channel</td>
</tr>
<tr>
<td>77406</td>
<td>Radiation treatment delivery</td>
<td>77787</td>
<td>Hdr brachytx over 12 chan</td>
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<tr>
<td>77407</td>
<td>Radiation treatment delivery</td>
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CMS stated that the procedure time assumptions used in developing direct PE inputs for the radiation oncology services on Table 8 have not been subject to the same rigor as other recently reviewed services since they are based on expert panels versus survey data. In response to public comments received through the proposed rule process, CMS said that they assumed that the AMA RUC deliberated on the procedure time assumptions used in developing the direct PE input recommendations for these services. Even with a RUC review, the Agency believes there is still need for a more extensive review of these services. The Agency’s position is that procedure time assumptions developed and validated by a series of expert panels have not generally been subject to the same scrutiny as the times developed through survey data or data gathered through electronic health records, for example. ASTRO disagrees with this position.
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ASTRO urges CMS to remove CPT codes 77301 and 77785-7 from the mandated re-review list. These CPT codes have been reviewed recently and repeatedly by the PEAC/RUC. CPT code 77301 was recently surveyed and was under review when the CY 2013 proposed rule was developed this spring. The direct practice expense inputs are included in Table 74 of this regulation. The RUC’s Relativity Assessment Workgroup (RAW) also reviewed action plans for 77301 and 77785-7 at the September 2012 RUC meeting after CMS included them in the Proposed Rule for re-review. After review and debate, the RAW recommended that CMS remove these four codes from Table 8.

ASTRO disagrees with CMS’ position that the review has not been subject to the same rigor as other recently reviewed services. Multiple physicians on the PEAC and within the specialty spent extensive time reviewing lengthy, detailed presentations assessing all the activities associated with each step/minute of the clinical time for these codes. Every time the codes have been presented the specialty has brought experts to present including the clinical staff that performs these procedures to answer questions.

*ASTRO requests that these codes be removed from the list of codes to be re-reviewed (Table 8). We disagree that these codes have not been subject to rigorous analysis and consideration, and note the considerable attention devoted to these codes repeatedly and recently. If these codes were presented again, we do not anticipate any changes or new issues being raised.*

**Interest rate assumption**

CMS is finalizing an update to the interest rates used in the development of PE RVUs. This update impacts the per minute cost calculated for medical equipment. Historically, the interest rate has been 11 percent. CMS will use a “sliding scale” approach based on the current Small Business Administration (SBA) maximum interest rates for different categories of loan size (price of the equipment) and maturity (useful life of the equipment). Capital-intensive specialties, such as radiation oncology, are projected to be negatively impacted by this policy.

ASTRO is very disappointed that CMS is moving forward with this policy. We understand that the Agency’s goal of the practice expense methodology is to calculate, as accurately as possible given the available data sources, the relative resources required to furnish services that are paid under the fee schedule. We agree with CMS that the 11 percent interest rate assumption in the calculation of the equipment portion of the practice expense RVUs does not reflect a market rate. As we stated in our comments on the proposed rule, we support the Agency’s efforts to ensure that the most current and accurate data are used in the development of RVUs. These efforts are consistent with the Agency’s commitment to be an active payer of high quality healthcare. While we support these efforts, ASTRO does not believe that SBA maximum interest rates appropriately capture the costs of financing medical equipment in radiation oncology, and we urge CMS to reconsider this policy.

Collecting accurate data can be a complex, time consuming, and sometimes costly process, yet it is a necessary component of maintaining the fee schedule. For example, malpractice RVUs are based on malpractice premium data. By collecting actual premium data, CMS ensures that the true costs borne by physicians for obtaining malpractice insurance are captured in malpractice
RVUs. In contrast, ASTRO does not believe this new interest rate policy will capture the true costs physicians face to borrow money to finance the purchase of radiation therapy equipment. The data we have uncovered through our research indicates none of our members get government funded SBA loans to finance the purchase of this equipment.

In other areas of the fee schedule that require data (i.e. malpractice RVUs, supplemental practice expense survey), CMS collects information directly from physicians or from relevant data sources. In this instance, CMS has failed to follow that methodology. We do not believe the SBA maximum interest rate assumptions provide a reliable benchmark for this purpose. ASTRO believes CMS should use interest rates that truly reflect the cost of financing equipment.

In the final rule, CMS is clarifying that they generally intend to update the interest rate calculation through future rulemaking only in years when they broadly update one or more of the other direct practice expense inputs. Accordingly, the Agency anticipates updating the interest rate calculation less frequently than annually. ASTRO appreciates this clarification. We were concerned annual updates would only contribute to the recent volatility of PE RVUs. We agree that updating interest rates in accordance with other components of direct practice expense inputs is a reasonable methodology.

While ASTRO supports the Agency’s efforts to ensure that the most accurate data are used to develop PE RVUs, the SBA maximum interest rates are neither an accurate nor appropriate data source. ASTRO reiterates its recommendation that CMS explore data sources, appropriate to the radiation oncology market, to use as a benchmark for interest rates.

Oncology measures group for PQRS 2013 and beyond
The Physician Quality Reporting System (PQRS) as set forth in section 1848(a), (k), and (m) of the Social Security Act, is a quality reporting program that provides incentive payments to eligible professionals who satisfactorily report data on quality measures (and payment adjustments for those who fail to do so). The regulation governing PQRS is located at 42 CFR 414.90.

Physicians and other eligible professionals have the option of participating in PQRS by either reporting individual measures or a measures group. Participating via a measures group versus individual measures significantly reduces the burden of participating in PQRS and increases the chances of success for an eligible professional. ASTRO is pleased CMS is finalizing an oncology measures group for PQRS 2013 and beyond. The following measures are included in the oncology measures group:
- 71 Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer
- 72 Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients
- 110 Preventive Care and Screening: Influenza Immunization
- 130 Documentation of Current Medications in the Medical Record
- 143 Oncology: Medical and Radiation – Pain Intensity Quantified
- 144 Oncology: Medical and Radiation – Plan of Care for Pain
• 194 Oncology: Cancer Stage Documented
• 226 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

This measures group was submitted by ASTRO and the American Society for Clinical Oncology (ASCO). It is the first measures group available for radiation oncologists or one that applies specifically to Medicare beneficiaries with a cancer diagnosis. ASTRO believes that the introduction of this measures group in 2013 and the reduced administrative burden that it provides will encourage increased participation by radiation oncologists, as well as provide CMS increased measure reporting by providers caring for patients with cancer. On a related front, ASTRO recently launched a PQRS registry for our members. We believe this PQRS measures group combined with a registry will greatly facilitate registry-based reporting among cancer care providers.

ASTRO is extremely pleased with the inclusion of an oncology measures group in the CY 2013 PQRS program. The anticipated increased participation by radiation oncologists will benefit Medicare beneficiaries, providers, and CMS.

Thank you for the opportunity to comment on this proposed rule. We look forward to continued dialogue with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Sheila Madhani, Assistant Director of Medicare Policy, ASTRO Government Relations Department at (703) 839-7372 or sheilam@astro.org.

Respectfully,

Laura I. Thevenot
Chief Executive Officer