



April 10, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244-1850

**RE: Request for Information on Specialty Practitioner Payment Model Opportunities;
Procedural Episode-Based Payment Opportunities**

Dear Administrator Tavenner:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the “Request for Information on Specialty and Practitioner Payment Model Opportunities” posted on the website of the Center for Medicare and Medicaid Innovation (CMMI) on February 10, 2014.

ASTRO members are medical professionals, who practice 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 multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.

Through this RFI CMS is requesting input on policy considerations for the development of innovative payment and service delivery models for specialty practitioner services furnished mainly as outpatient care for patients with specific medical conditions and/or specific patient populations. ASTRO is very pleased that CMS has turned its attention to outpatient specialty care. ASTRO believes that there is significant potential to enhance patient care for Medicare beneficiaries, promote the more efficient use of resources, and protect the Medicare Trust Fund in the outpatient environment. We support Medicare payment reforms for radiation oncology and cancer treatment that improve the quality of care, reduce variations in care and decrease overall cost.

Under the traditional Medicare program, incentives are based on volume—not quality or value. ASTRO believes payment reform is critical to stabilizing and enhancing the Medicare program. In radiation oncology, advanced technology and improved treatment techniques allow cancer centers to continually improve how to target radiation to kill the tumor while protecting healthy tissue. Continued advancements in radiation therapy that improve patient care must be enhanced, not stymied, by efforts to reform the way Medicare pays physicians. In addition, we

believe it is important that changes to the program or its payment methodologies should not inadvertently limit cancer patients' access to lifesaving treatments, including radiation therapy, or compromise quality of care. We believe this RFI is an important step in the right direction of effective payment reform. We are pleased that CMS has provided an opportunity for the physician community and other stakeholders to provide input.

ASTRO represents both hospital-based and community-based radiation therapy centers. With an estimated two-thirds of all cancer patients receiving radiation therapy during the course of their illness, the specialty is a critical partner in the continuum of care available to cancer patients. In recent years radiation therapy reimbursement has been very volatile. With annual costs of cancer care projected to rise in coming years, this volatility is likely to continue. In response to this uncertainty, ASTRO released an action plan for a comprehensive payment reform initiative in 2013. ASTRO identified the following goals for payment reform:

- Revise current radiation oncology codes to more accurately reflect clinical practice and package together services typically billed at the same time;
- Ensure fair, predictable and stable payment for radiation oncologists in both hospital and free standing cancer centers;
- Reward radiation oncologists for improving quality while lowering costs; and
- Incent appropriate use of treatments that result in the best patient care and outcomes.

Redesign of key radiation therapy codes: Concerns about radiation therapy use, cost and other factors have contributed to fluctuations in Medicare reimbursement, including severe cuts to reimbursement for commonly used treatments. ASTRO worked through the American Medical Association (AMA) CPT Editorial Panel and RVS Update Committee (RUC) process to revise our conventional radiation therapy, IMRT, and image guidance CPT codes. New codes that reflect the current process of care, technology, and complexity of services will be released in 2014 and effective in 2015. ASTRO anticipates that these necessary coding changes are likely to result in short-term payment reductions but will provide more accurate and stable payments moving forward.

Implementing quality based incentives: ASTRO is launching a new practice accreditation program for radiation oncology clinics. Integrated with ASTRO's other safety and quality improvement initiatives, the robust program will accredit practices that represent the highest standard of radiation oncology care. Accreditation is the culmination and integration of multiple ASTRO quality efforts including: maintenance of certification, clinical guidelines, quality measure development, reporting medical errors to a radiation oncology patient safety organization (PSO), and medical education on safety and performance improvement. As we discussed in meetings with senior CMS officials in 2013, we urge the agency to look to ASTRO's accreditation program as a first step to link Medicare payment to quality in radiation oncology. Additionally, ASTRO is launching a data registry, beginning with a prostate cancer pilot. We believe the combination of these two programs will enhance the quality of radiation therapy care in the US and provide relevant information for patients to make informed decisions about their care and the providers they choose.

Incentivize cost effective care. ASTRO believes incentivizing cost effective care requires a comprehensive payment reform effort to identify alternatives to the traditional fee-for-service model. ASTRO hopes to identify areas where better coordinated care would improve quality and eliminate unnecessary Medicare spending on hospitalizations. To identify targeted areas, ASTRO recently contracted with the Dana Farber Cancer Institute (DFCI) to conduct an analysis of the Surveillance, Epidemiology, and End Results (SEER)-Medicare dataset to determine the average total costs of cancer care for Medicare patients treated for selected common malignancies, with a breakdown of the total costs according to the modalities (radiation therapy vs surgery vs chemotherapy agents) employed in the patient's management.

We anticipate the analysis will accomplish several goals:

- Determine the average total costs of cancer care for Medicare patients treated for selected common malignancies, with a breakdown of these total costs according to the modalities (radiation therapy vs. surgery vs. chemotherapy agents) employed in the patient's management;
- Identify the costs of cancer-related hospitalizations, and the costs of non-cancer-related medical care;
- Identify opportunities where a re-alignment of provider incentives might lead to cost savings derived from enhanced coordination and efficiency of care among specialists involved in cancer treatment;
- Identify processes that will avoid unnecessary expenditures related to preventable hospitalizations or complications of treatment; and,
- Identify ways of managing patients using less costly pathways of care, or other strategies to improve productivity while maintaining the highest quality of care.

ASTRO believes it will be most instructive to understand the magnitude and distribution of these costs within the first year after diagnosis, in the next year of management, and in the final six months of life. For example, research from the UNC Lineberger Comprehensive Cancer Center found that 19 percent of patients receiving radiation therapy had unanticipated admissions within 90 days of their first treatment.¹ By analyzing all Medicare related costs for cancer patients and their global treatment experiences, this work may help us reduce admissions for these patients in the future. Such data will also help inform the construction of episode payment models that are appropriately constructed and accurately priced as well as other innovative payment and service delivery models for future payment reform initiatives.

While ASTRO is very pleased that the agency has released this RFI, we are concerned by the statement that: "This RFI seeks information in relation to the development of models for care managed by specialist practitioners other than medical oncologists, as a potential oncology model is on a separate development track." While ASTRO understands that the issues may vary for radiation, medical and surgical oncologists, we caution the agency not to be too narrow in its focus when it comes to cancer care. An individual cancer patient typically will see multiple oncologists, as well as other complementary providers. Any comprehensive payment reform

¹ Butcher, Lola. (2013, February 13). Oncology's Stepped-Up Efforts to Cut Hospital Use. Oncology Times. Retrieved April 7, 2014, from <http://journals.lww.com/oncology-times/blog/onlinefirst/pages/post.aspx?PostID=684>.

initiative related to the treatment of cancer must consider the full range of providers treating cancer patients. We look forward to learning more about this initiative and would welcome opportunities to work with CMS and other cancer providers on the best path forward in the development of alternative payment models for cancer care.

On a related issue, ASTRO is aware of a proposal submitted to the agency and members of Congress to separate out reimbursement for hospital-based and community-based radiation oncology providers. We believe this is a flawed approach that does not get at the true question of how to appropriately reimburse for the resources used to treat cancer patients, nor how to create an environment where providing high-quality evidence-based care is not only the right thing to do, but the easy and most logical action for the provider. Specifically, we caution Medicare to ensure that such proposals do not exacerbate the already troubling gap in reimbursement levels between certain radiation therapy services provided in hospital and freestanding settings. Further, the agency should look to support proposals that meaningfully reform the way Medicare pays for radiation oncology services, rather than simply commoditizing these services at lower prices. Finally, we ask that the agency consult with ASTRO to ensure that radiation oncology payment reform proposals do not create incentives to provide radiation therapy fractionation approaches that are inconsistent with long-term outcomes data or where sufficient data has not yet emerged.

In this next section of the letter we respond to a number of questions posed in Section I (Procedural Episode-Based Payment Opportunities) of the RFI.

For which outpatient procedure(s) (surgical or non-surgical) or medical condition(s) should CMS consider testing a procedural episode-based payment model?

In payment reform literature, an episode of care is typically defined as a collection of care provided to treat a particular condition for a given length of time. In many ways, the process of care for radiation therapy makes it ideally suited for the episode payment model. The radiation oncology process of care is a series of complex steps that can be divided into five phases of care:

- Consultation,
- Preparing for treatment (clinical treatment planning, therapeutic simulation and development of dose distribution, and pre-treatment quality assurance),
- Radiation treatment delivery,
- Radiation treatment management, and
- Follow-up care management.

Each phase of care involves medical evaluation, interpretation, management and decision making by the radiation oncologist.

In terms of the specific cancer diagnosis to begin with, we urge CMS to work closely with ASTRO and other radiation oncology providers to identify the most appropriate conditions. We are confident that the SEER-Medicare analysis referenced above will prove highly useful in identifying clinical and cost areas most ripe for attention. Cancers that have both sufficient evidence, as well as volume, would be ideally suited for defining the initial episodes of care. As a scientific organization, ASTRO develops evidence based clinical practice guidelines from the

body of established literature, relying primarily on evidence, when available, from randomized clinical trials. These guidelines provide physicians with guidance to help ensure that patients receive the best possible care. Choosing a condition with sufficient volume will help with risk adjustment and protect providers from outliers that may negatively impact their data.

What are the opportunities to improve the quality of care and reduce expenditures associated with such a model in each specific case?

Payment reform is the intersection between the efficient use of resources and the delivery of high quality safe care. Estimating the resources used in delivering an episode of care is a meaningless exercise without the ability to measure the quality of care provided. The foundation of ASTRO's previously described payment reform plan is quality. When ASTRO's *Target Safely*² Initiative was released in 2010, then ASTRO chairman and a radiation oncologist at Massachusetts General Hospital in Boston, Anthony L. Zietman, MD, FASTRO stated, "Dealing with a cancer diagnosis is hard enough for patients without having the additional burden of worrying about the accuracy and safety of their treatments. With every cancer patient, the goal is to treat and/or cure his or her disease in the safest and most effective way possible, that's why ASTRO is focused completely on ensuring patient safety."³

ASTRO has invested significant resources in the development of clinical guidelines, best practices, quality measures, and comparative effectiveness research. We are supporting a robust practice accreditation program, national patient safety database and clinical data registry. The Society is committed to the development of new payment methodologies in oncology with the goal of incentivizing better quality, efficiency, coordination of care and optimal patient outcomes.

ASTRO's Measures Subcommittee is responsible for working collaboratively with other stakeholders to develop radiation oncology-specific measures that address gaps and disparities in radiation therapy care. It has commenced work on developing cancer site-specific measures, palliative measures, and broadly-applicable measures. New measures are being guided by the six National Quality Strategy (NQS) domains, including patient safety and care coordination. ASTRO believes that these measures should be assessed for inclusion in this type of episode to ensure safe and effective care.

In September 2013, as part of the national *Choosing Wisely* program ASTRO released five radiation oncology-specific treatments that are commonly ordered, but may not always be appropriate. The list identifies five targeted treatment options that ASTRO recommends for detailed patient-physician discussion before being prescribed.

² For every cancer patient, the goal is to treat the disease in the safest and most effective way possible. To meet this objective, ASTRO launched *Target Safely* in 2010. The plan focuses ASTRO's resources on improving patient safety and reducing the chances of medical errors during radiation therapy treatments.

³ American Society for Radiation Oncology. (2011). ASTRO Reaffirms Commitment to Quality, Issues Progress Report on Patient Safety Plan [Press Release] Retrieved from <https://www.astro.org/News-and-Media/News-Releases/2011/Target-Safely,-a-six-point-patient-protection-plan-developed-in-January-2010,-to-improve-the-safety-and-quality-of-radiation.aspx>.

We urge the agency to collaborate with ASTRO and other physician specialty societies to develop meaningful measures proven to improve the quality of care. We also urge CMS to support the use of registry data. We believe that a collaborative approach would result in valuable and innovative quality measures that can also be incorporated. It is only through physician input that CMS will be able to identify the truly meaningful measures that are consistent with the specialty's process of care and align with current coding conventions.

What are the important considerations in defining the episode?

While some characteristics of a treatment course of radiation therapy make it well-suited to be defined within the construct of an episode of care, there are other variables to consider that increase the complexity of defining an episode of care for radiation therapy. Radiation therapy uses high-energy radiation to shrink tumors and kill cancer cells. The delivery mechanism of the radiation treatment can vary significantly. Some common techniques utilized today include: conventional radiation therapy, intensity modulated radiation therapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiation therapy (SBRT), proton therapy, brachytherapy, intraoperative radiation therapy (IORT), and hyperthermia. All of these techniques utilize different equipment and the length of the process of care can vary significantly.

The type of radiation therapy prescribed by a radiation oncologist depends on many factors including: type of cancer, size of cancer, cancer's location in the body, how close the cancer is to normal tissue that are sensitive to radiation, how far into the body the radiation needs to travel, the patient's general health and medical history, whether the patient will have other types of cancer treatment, and other factors such as the patient's age and other medical conditions.⁴ Finally, a cancer patient may have any or all of the primary types of cancer treatment (radiation, surgery, and chemotherapy).

ASTRO believes developing separate episodes of care for the three types of cancer treatment methods is a good starting point, but that eventually an ideal episode of care system would capture the *total* costs of cancer care under a single episode. We believe that a mature and effective payment reform system for cancer treatment could capture the total costs of treating an individual, and the total costs would likely include multiple cancer providers as well as other healthcare providers.

How could accountability for drugs prescribed be factored into the payment model?

In state-of-the-art multidisciplinary management for many solid tumors, radiotherapy is given concurrently with chemotherapy to maximize the chance of cure. While there are some situations where different chemotherapy agents of different cost might achieve similar clinical outcomes, in most cases the selection of chemotherapy agents to be given alongside the radiotherapy is driven by high level clinical evidence. Patients treated in this manner do, however, often need intensive supportive care in the months following treatment. As noted above, one of the goals of the ongoing SEER-Medicare analysis is to identify subgroups of patients for whom hospitalizations or other high-resource services are commonly required in this phase of care. There might then be

⁴ National Cancer Institute (NCI). "Radiation Therapy Fact Sheet." 30 June 2010. 5 April 2014. <<http://www.cancer.gov/cancertopics/factsheet/Therapy/radiation>>.

an opportunity to explore strategies whereby well-structured, intensive outpatient management would be incentivized for the purpose of reducing the risk of needing more costly interventions in this phase of care.

Drugs may also be used during an episode of care of radiation for managing side effects and pain. While not every person treated for cancer experiences pain, it is estimated that approximately one out of three cancer patients experience pain. Once pain is identified, the physician must assess and treat it. Pain is not the same for everyone. People who have similar therapy can react differently, with some feeling more pain than others.

All of these factors make it difficult to estimate typical drug use during radiation therapy. ASTRO believes significantly more tracking and analysis must be conducted on the use of drugs within radiation therapy before it can be captured within an episode of care.

Could such a model be developed for a single medical condition where several alternative approaches exist as treatment possibilities?

As described previously, radiation therapy can be delivered through a variety of techniques to treat a single medical condition. The appropriateness of the technique depends on a variety of patient factors, and there can be significant differences in costs of the episode of care depending on the technique used. ASTRO believes that the ideal payment model would reduce inappropriate incentives for a single medical condition regardless of the radiation treatment technique used. For instance, one area that could be explored is treatment of low-risk prostate cancer, which is a high-volume diagnosis with multiple treatment techniques of various costs with similar efficacy. The decision on what management approach to use is based on numerous patient-related factors (age, quality of life, comorbidities, etc.), but a mature episode of care model may develop a single payment that is agnostic on treatment technique. However, there are significant challenges to developing a fair and appropriate reimbursement rate due to the differences in costs for the various treatment techniques and the length of the episode depending on the treatment selected. Opportunities and challenges exist in prostate cancer and other clinical conditions, and we would appreciate the opportunity to work with CMS to develop such a model.

What examples of this model have been tested in the private sector that furthers the evidence base?

Bundling in the radiation oncology environment up until this point has been fairly limited. The most well-known and largest example of bundling within the radiation oncology environment is an arrangement between 21st Century Oncology and Humana. Under this contract, Humana pays 21st Century a single prospective case rate at the beginning of a radiation therapy episode for 13 different cancer diagnosis.

This example is a case rate scenario, and while it has some advantages, such as reduced administrative burden on the provider and does not impact the patient, it falls short of a true episode of care payment model. In particular, we need to better understand the quality components tied to the model. Therefore, ASTRO believes that this example provides a potential starting point for developing an episode of care within radiation oncology, but it also

reflects that significant work needs to be done in this area. ASTRO looks forward to working with the CMS in developing more sophisticated and mature models.

How would the method for assigning responsibility for the episode to specific practitioners or practitioner groups be designed?

In an episode of care model that covers radiation therapy services, identifying the physician responsible for the services is fairly straightforward. Typically, there is one radiation oncologist who is responsible for providing the majority of services for an episode of care. With most episodes of care, the radiation oncologist would be reporting a weekly treatment management code, typically CPT code 77427. The physician who reports the majority of these codes related to a single episode of care would be the responsible physician.

In a more sophisticated episode of care for all cancer treatment beyond radiation therapy, this would become more complicated and include multiple providers and potentially different sites reporting under multiple Tax ID Numbers (TINs). Under that scenario, CMS could base responsibility on upfront patient designation or allow self-identified teams of physicians to participate.

What factors would influence a practitioner's decision about whether or not to apply to participate?

In today's environment, physicians are drowning in new and emerging clinical data; varying and inconsistent payment and coverage rules from multiple payers; and, numerous initiatives like ICD-10, Meaningful Use, and the Physician Quality Reporting System (PQRS) with complex rules and deadlines always evolving. The most consistent feedback we receive from our membership is concern about the growing administrative burden of these programs and the uncertainty of their benefit for either patient care or administrative functioning.

In designing any program and considering how to encourage provider participation, ASTRO recommends that the agency consider the following:

- Articulate the clear benefit of the program on clinical care, provider reimbursement, or administrative functionality. Provide evidence of this benefit.
- Provide clear information in advance on payments and any potential payment adjustments.
- Set rules in advance that do not change after the program starts.
- Find ways to integrate existing initiatives with new initiatives. This will address criticisms related to program redundancy and the silos of the Medicare programs.
- Allow for timely feedback to providers and opportunities for providers to give feedback on the program to the agency.
- Address the issue of how risk adjustment must vary for those specialties dealing with conditions that impact large populations (i.e. diabetes) versus those specialties dealing with conditions that impact much smaller populations (i.e. more rare cancers or other rare diseases).

How could CMS encourage the adoption of such a model among other payers?

Most providers are paid by multiple public and commercial payers; and, self-pay patients. Each of these entities may pay for services in different ways and under different rules. This lack of consistency among payers creates significant barriers for the spread of participation in payment reform. Participation by numerous providers is important because, as it has been noted, “The goal of payment reform is not just to *change payment*, but to enable and encourage *changes in the way care is delivered* in order to improve quality and lower costs. However, when physicians and hospitals change the way they care for patients, they do it for *all* of their patients, not just those covered by a particular health insurance plan. If only a subset of payers move away from fee-for-service payment, providers will either be penalized financially for those patients still being paid for under fee-for-service (if the providers change care in a way that will be supported under improved payment systems) or they will fail financially for patients covered by the newer payment systems (if the providers continue to deliver care consistent with traditional fee-for-service incentives).”⁵

In order to encourage other payers to participate, CMS should allow flexibility to adapt requirements to existing payment models or to specific features needed/wanted by other payers. CMS should work toward making sure that there is a balance between the alignment of reforms and allowing for flexibility. Other payers should also be brought into the program development process from the beginning to get their buy-in and input.

The challenge of encouraging participation by other payers may be great, but ASTRO believes it is critical in creating a true momentum for payment reform to take place.

What challenges might be encountered in implementing such a model?

The challenges of implementing payment reform within the Medicare system are significant. Expanding that model to include private payers’ increases the complexity of that challenge, but it also has the potential for great benefits.

Collaboration is always difficult for a variety of practical reasons, such as the difficulty of different systems speaking together, asking competing payers to work together, competing goals, a reluctance to share data or methodologies, and just general personality or corporate cultural differences. In a market with multiple private payers versus one in which there is one dominant private payer, the challenges may vary in the two markets.

Despite all of these challenges, the size and scope of Medicare can carry great weight and influence in a local market. ASTRO believes that strategically the most effective approach would be leadership from CMS, but with organizing efforts on a local or regional level. Like other areas of payment reform, ASTRO believes that the input of local physicians would be essential in moving these efforts forward.

⁵ Miller, Harold, “Barriers to Healthcare Payment Reform and How to Overcome Them,” Center for Healthcare Quality and Payment Reform; Dec 2012, page 20.

What other factors should CMS consider in the development of a procedural episode-based payment model?

The questions posed by CMS in this RFI raised some very important issues. We would also like to take this opportunity to raise a few other issues that we believe are important.

- *Challenges to smaller practices* – The episode of care model requires significant coordination among providers. This level of coordination might be more difficult and may require greater start-up time for smaller practices.
- *Hospital-based physicians may have unique challenges* – Physicians practicing in a hospital based environment may not have the freedom that those in a private clinical practice have. The Meaningful Use program illustrated the difficulties that hospital-based physicians may sometimes face in participating in such initiatives.
- *All specialties are not the same* – Specialists like radiation oncologists have a smaller patient pool than other specialties, the level of evidence may be less robust than other specialties, and certain data, such as outcomes data, may not be as readily available. Understanding and assessing this type of variability across various specialties is important as CMS tries to build various episodes of care models.

ASTRO has a great deal of optimism that radiation oncologists, who treat more than two-thirds of all cancer patients, can play a significant role in ensuring that cancer patients receive high quality, coordinated care. We recognize it will take time to identify the most promising areas for these new payment methodologies and to engage in significant testing of new approaches before these reforms can be rolled out further. ASTRO looks forward to working with CMS to implement innovative models of payment for specialty care – and improve upon it as knowledge grows – for the benefit of cancer patients, cancer care providers, and the Medicare program.

Thank you again for the opportunity to submit comments. If you have any questions regarding our letter, please contact Sheila Madhani, Assistant Director of Medicare Policy at 703-839-7372 or sheilam@astro.org.

Sincerely,



Laura I. Thevenot
Chief Executive Officer