

March 25, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
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 Radiation Therapy Alliance (RTA) appreciates the opportunity to submit comments to the Request for Information (RFI) relating to procedural episode-based payment opportunities. The RTA represents 244 freestanding cancer care facilities in 22 states caring for approximately 98,000 patients annually. The RTA was established to provide policymakers and the public with a greater understanding of the value that community-based radiation therapy facilities bring to their patients and of the importance of logical, predictable payment reform to align incentives and ensure patient access to quality cancer care. RTA members include provider companies 21st Century Oncology, UPMC Cancer Centers, and Vantage Oncology, as well as equipment manufacturers Accuray, and C&G Technologies.

Due to payment instability and unpredictability in the Medicare Physician Fee Schedule, the RTA began researching alternative payment models in 2010. After significant research, the RTA focused on episode-based case rates as a better payment model for radiation therapy reimbursement. We appreciate the RFI's description of radiation therapy as an example of a treatment where "significant opportunities exist for specialty practitioner engagement in care redesign." We agree.

Below are detailed responses to the questions raised in 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?

The RTA believes a procedural episode-based payment model could be constructed around outpatient radiation oncology treatment episodes. Patients who receive radiation therapy treatment routinely receive a distinct set of outpatient procedures that could be bundled into a single payment to encourage greater efficiency for care delivery. These episodes are predominantly defined by the presence of distinct CPT codes that are used by providers to denote the actual delivery of radiation treatment. These codes include CPTs 77402-77416, 77418,

0073T as well as stereotactic codes (77372, 77373, G0339 and G0340), which should be carefully considered to accurately capture the costs of these procedures. These treatment codes are supplemented by a separate set of codes used primarily by radiation oncologists for the planning of radiation treatment. These planning codes include CPTs 77261-77338. Many radiation therapy episodes also include imaging for more precise delivery of the radiation treatment. The imaging codes include CPTs 77014, 77417, 77421, and 70030. Although restrictions regarding the specific type of cancer may not need to be addressed in the episode-based bundle, adjustments may need to be made to account for the different level of average resources required based on different cancer modalities.

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

As stated in the previous section, we believe every common and most uncommon oncology disease states that require radiotherapeutic intervention are amenable to an episode of care based payment model. Pathways have been developed to treat these diseases in a coordinated manner (cf., ASTRO Treatment Guidelines, ACR Appropriateness Guidelines, NCCN Guidelines) using literature evidence and expert consensus panels. The billing methodology explicit in the CPT/HCPCS descriptors for radiation oncology and developed in the late 1970s to early 1980s to describe procedures, and their professional oversight incents an atomized approach to treatment rather than holistic disease management. As such, the current system **always** rewards complexity and volume rather than optimum cancer outcomes.

As cancer treatment improves and local control rates in the 70-100% range are being achieved, physicians (through prospective clinical studies and well-designed registries) are examining when shorter courses of therapy and even less intensive therapy is appropriate. While increased treatment complexity is sometimes necessary in order to avoid side effects, lower doses, and decreased numbers of treatments may be optimal. Shifting from a “high volume, high dose, low tech” approach to a “lower volume, lower dose, higher-tech” approach is a current theme in radiation oncology but the change is inhibited when the reimbursement methodology is both radiation modality specific **and** the payment is per treatment or procedure. A few examples are in order:

- **Curative Disease Treated With Radiation:** The shape of the radiation survival curve (the number of surviving cells as a function of the amount of radiation delivered) for a tumor and its surrounding normal tissue is now known to strongly influence both tumor curability and the adjacent normal tissue tolerance. For lymphomas, small fraction sizes are appropriate because the tumor does not repair radiation damage and many treatments allow for summation of the damage in the tumor compared with repair of the damage in the adjacent normal tissue. For prostate cancer, the repair capacity is much greater. Therefore, a few very large fractions of radiation to the tumor are used in newer treatment regimens to overwhelm the repair capability and allow for higher cure rates **as long as the dose is highly constrained and the adjacent normal tissue is protected**. In the mid and late 20th Century when the current treatment paradigms were being developed the significance of these biologic parameters was not well integrated into the majority of

treatment approaches: all tumors received the same daily dose (and the payment for treatment was and remains per fraction in the Physicians Fee Schedule). There are now a number of single arm trials that suggest at least equivalence of tumor outcome with possibly improved normal tissue outcome for **hypo-fractionation** for prostate, lung and breast cancer. In an era of personalized medicine radiation fraction size and number will be determined by intrinsic tumor radiosensitivity. An episode of care treatment reimbursement methodology that recognizes tumor heterogeneity is treatment number-agnostic, but requires superior tumor and normal tissue outcomes be maintained (by guideline adherence and outcomes reporting) will drive the radiation oncology specialty to a number of different treatment programs that are based upon intrinsic tumor characteristics rather than always using many small fractions of radiation.

- **Palliative Disease Treated With Radiation:** In the 1990s radiation thought leaders in the United States, Canada, and Great Britain advocated for rapid palliation of painful “uncomplicated” bone metastases (lesions in long bones not at risk for fracture) using either one large fraction of radiation or a few moderately large fractions. Most patients with bone metastases have a limited lifespan and their pain can be palliated with such a regimen (and they could be re-treated if necessary). There is also evidence in single fraction trials that the time to pain palliation is decreased compared to multi-fraction approaches. The American Society of Radiation Oncology (ASTRO) has also recently published a treatment guideline recommending single fraction radiation for uncomplicated bone metastases. Despite these developments, the single or few fraction regimens were never widely utilized in the United States. A recent review of the linked Medicare-SEER database demonstrated that the median number of fractions employed for bone metastasis pain palliation in the early years of this decade was 10 with the range between 1 and 30. A number of explanations have been advanced: a) physicians tend to do what they were taught and the teaching in the 1970s and 1980s was to employ ten fractions, b) data from the MD Anderson suggested that patients with solitary bone metastases could sometimes be cured with radiation and thus palliation was sometimes conflated with higher dose curative regimens in younger patients, and c) the Physicians Fee Schedule dis-incentivized for single fraction radiation.

We believe palliative treatment of bone metastases may be a particularly good candidate for episodic payments that offer the potential of care delivery in a more efficient manner, significantly improving quality of life for patients with advanced stage disease. The RTA is aware of a Centers for Medicare and Medicaid Innovation grant already awarded to the University of Virginia (Award C1CMS331031) that explores various aspects of care, including a specific redesign of radiation therapy to provide highly effective single-day treatment for cancer that has spread to the bone. This approach (single session Scan-Plan-QA-Treat STAT RAD Radiation Therapy Procedure) limits unnecessary travel for frequent radiation treatments, delivers more rapid radiation therapy to reduce tumor size, and is expected to decrease complications from metastatic disease. This study could provide an opportunity for stakeholders to engage with CMS on how payment for such an approach could be structured for this and other types of cancer to produce savings for CMS without setting rates so low it would undercut the costs of delivering the care or stifle innovation.

- **Radiation Modality Selection:** Brachytherapy, a radiation modality that uses radiation sources placed into needles, tubes, or specialized carriers into body cavities is highly effective in ablating small and moderate sized tumors that are amenable to implantation. Permanent implants using radionuclides that decay over time (low-dose rate brachytherapy) or temporary implants using higher source strength radionuclides (both low dose rate and high dose rate) that are removed after the desired dose is delivered, require a degree of surgical skill and training. The capital requirements for these procedures are much smaller than that of linear accelerators for external irradiation. Historically, the reimbursement for these procedures (despite ancillary payment for the use of the operating room) has been less than that for external beam methods. However, the literature demonstrates the utility of interstitial implants and intracavitary applications of radiation. In certain circumstances when implant alone or combinations of implant and external beam are compared to external beam alone for a number of head and neck, gynecological, and genitourinary cancers, the approach that uses the brachytherapy results in superior tumor control. Since median cost of either implant monotherapy or combination implant and external beam therapy tends to be less than that for the external beam monotherapy, an episode of care based reimbursement that paid for treatment of the disease, rather than differentiating payment for the modality used would again tend to improve tumor control, decrease side effects, and decrease costs.

What are the important considerations in defining the episode?

The RTA believes there are four key factors that must be considered when designing a radiation oncology episode. These factors include: episode duration; episode services; episode participants; and the intent of treatment.

- **Episode Duration:** Most patient who receive radiation therapy treatment for cancer require between 3-5 weeks of care. However, some patients may require shorter therapy, especially if the treatment intent is palliative. Likewise, some patients may require more than 5 weeks of care. The episode-based bundled payment may need to allow for both shorter and longer than average episodes.
- **Episode Services:** Patients who receive radiation therapy treatment will largely receive a limited set of services that are directly related to the actual provision of radiation therapy. However, these patients may also receive care that is unrelated to radiation therapy, and should therefore be excluded from any payment bundle.
- **Episode Participants:** Radiation therapy can be provided in either a freestanding radiation therapy center or in a hospital outpatient department, where the costs of capital equipment, vault construction and shielding, and highly qualified clinical staff are equivalent. The RTA strongly believes CMS should work with stakeholders from both hospitals and freestanding centers to develop consistent payment policies across both sites of services to reduce the risk that one site of service is so disadvantaged that it forces large shifts in care settings, forces consolidation and closures in communities, and limits patient access to innovative technologies that may only be available in a particular

community in one setting. In addition, patients may visit providers for care unrelated to the provision of radiation therapy; these providers should be excluded from the episode payment.

- **Intent of Treatment:** Patients may receive radiation therapy for curative treatment or palliative relief of symptoms. Often, the intent of the treatment determines the number of sessions a patient will receive, which in turn determines the overall resources necessary for the episode. The episode should account for this intent as an upfront adjustment.

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

The RTA believes that any drugs prescribed during this episode would be unrelated to the provision of radiation therapy treatment, and should therefore be excluded from the set of services in the bundle. While some patients may receive chemotherapy treatment in addition to radiation treatment, the amount of chemotherapy can be highly variable and therefore inappropriate to include in a radiation therapy bundle at this time. Over time, it may be feasible to expand the bundle to incorporate additional services; however, given the current delivery landscape for radiation oncology therapy, the RTA does not recommend incorporating drugs at this time.

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

For most cancer conditions, multiple therapeutic modalities – namely, surgery, radiation therapy and chemotherapy – are available for the care of the patient. In some cases, one modality may be used in order to augment effectiveness of another. An example is the use of post-operative radiation therapy following lung cancer surgery to sterilize any residual microscopic disease and therefore improve the opportunity for cure. In other cases, one modality may be used as a replacement for a more traditional treatment when the patient may be judged to be a poor candidate for the traditional therapy. An example is the use of radiation therapy in place of surgery to treat a lung cancer patient who may otherwise be too ill for an operation. One result of this variable utilization of different cancer treatments for a common disease is the challenge of accounting for all therapeutic possibilities within the structure of an episodic payment system.

To address this challenge, we have developed a 'bottoms-up' approach of seeking to complete a system of disease-specific, episodic payments for radiation therapy services first and later integrating surgical and medical oncology as alternative payments systems around those disciplines. We envision a modular method of constructing episode-based payments for specific conditions where the costs of appropriate services and supplies are determined for each discipline and then integrated and managed by a set of clinical and business rules that govern the care of the patient and ultimately the distribution of payments to the providers participating in that care. We believe such a system allows for the flexibility of different modalities to be used for common conditions as clinically appropriate while facilitating patient access to the multiple physicians who may have a component of the overall care to provide.

We believe radiation therapy offers perhaps the ideal modality to begin the effort in that detailed protocols and related clinical guidance are published and available to serve as a foundation for episodic case building. Furthermore, the appropriate selection and number of services to be utilized for most cancers within these published guidelines exist within a narrow range, and overall treatment-related costs may therefore be determined fairly easily. Consequently, we view radiation therapy as the modality with the best immediate potential for developing an opportunity in episodic payments.

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

While radiation therapy case rate methodologies are utilized by payers in selected markets, most of these are local relationships that impact small populations. Unfortunately, these arrangements are not standardized, usually require 100% manual adjudication, and are therefore not scalable for use by CMS or national payers.

One notable example of a national bundled payment arrangement for radiation oncology exists between 21st Century Oncology and Humana. Under this contract, Humana pays 21st Century Oncology a single prospective case rate at the beginning of a radiation therapy episode for 13 different cancer diagnoses. These diagnoses include breast, lung, prostate, colorectal, and other cancers that account for over 90% of the Humana members who present to 21st Century Oncology for radiation oncology services. The radiation therapy case rate covers external beam, stereotactic, and brachytherapy treatments and includes the vast majority of services required to complete a full course of therapy. Selected services as well as diagnoses falling outside of the 13 designated diseases are paid on a fee schedule.

This payer/provider relationship is unique as it has the following characteristics:

- **National scope for both organizations.** All domestic 21st Century Oncology radiation therapy locations are included in the contract. Furthermore, all Humana markets participate.
- **Broad product penetration.** With the exception of Medicare HMO, all of Humana's products pay under the bundled methodology for radiation therapy services.
- **Primarily automated contract management and adjudication.** The agreed upon methodology enables both parties to automate billing, claims submission, and adjudication for the vast majority of transactions. A limited number of exceptions (mostly related to member transitions to or from other payers) are handled manually.
- **Reduced administrative costs related to utilization management.** Aligned financial incentives have eliminated the need for onerous utilization review. Both parties benefit from elimination of these clinically and administratively intensive activities for episodes falling under the bundled payment methodology.
- **Seamless to patients.** Patients receive the benefits of upfront transparent costs and reduced authorization procedures while being otherwise insulated from the modified reimbursement methodology.

The aforementioned reimbursement methodology has been in place for over 18 months and utilized for over 525 cases to date. Both 21st Century Oncology and Humana have reviewed the results of the program from a clinical, operational, and financial perspective and have not made any substantive changes to the existing structure. As a result, it appears that this type of arrangement (or at least key components of it) may have promise for adoption on a broader scale.

What quality measures should be assessed for this type of episode to ensure safe and effective care?

Providers and payers are continuing to move from a system of quantity and cost to one of value and outcomes. A necessary component to that end is an objective, transparent patient registry that captures information regarding treatment decisions made by oncologists and their patients on the one hand and the results and outcomes of these decisions on the other. Although the Physician Quality Reporting System (PQRS) and Electronic Health Record (EHR) Incentive Program reporting has been helpful as a first step in quality reporting, neither of these programs are collecting the data necessary for meaningful, groundbreaking quality guidelines for patients receiving radiation therapy care. To that end, the RTA envisions the new episode-based model would specify that reporting to a qualified clinical data registry would consist of (1) physician adherence to existing medical guidelines and (2) the collection of meaningful outcomes and related data for the development of real-time, evidence-based guidelines that continuously evolve alongside advancements in cancer care. The RTA expects that reporting under the model would make available the data necessary for qualified clinical data registries to develop guidelines responsive to these and other key questions.

Data Reported to a Qualified Clinical Data Registry

Reporting under the new episode-based model could include patient-level data for all patients as follows¹:

- Patient characteristics (including patient risk-scores as applicable)
- Cancer-staging
- Modality of treatment, number of treatments, total radiation dose
- Physician-reported outcomes and complications, if any
- Physician adherence to evidence-based medical guidelines
- Other cancer care treatment delivery data
- Patient reported outcomes and complications, if any

¹ Data tables are provided as appendix for the following cancers: prostate, breast, lung, head/neck, rectal, anal. Patients with these cancers represent 80% of patients treated by radiation oncologists.

Data Collection

The RTA envisions data generally would be collected through EHR systems. Data would be submitted by the centers to a qualified clinical registry, determined as such pursuant to Section 1848(m)(3)(E) of the Social Security Act. In instances where a center does not have access to an EHR system or is otherwise not able to comply with the registry through their EHR system, web-based registries could be utilized such as those already tied to coverage in Local Coverage Determinations² that are compliant with the principles established in AHRQ's "Registries for Evaluating Patient Outcomes: A User's Guide". In instances where a patient objects to the submission of his/her data to a registry, such patient would have the opportunity to opt out.

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

In most cases, radiation therapy is delivered by a radiation oncologist, and this radiation oncologist is responsible for the outcomes of the patient. The patient assignment process can likely be based on the radiation oncologist who provides the planning services for the episode. Depending on the specifics of the payment model, the actual payment could be made to either the individual radiation oncologist or the center where the treatments are provided.

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

Setting appropriate bundled payment weights would be an essential aspect of the new, episode-based payment model, particularly under a system where providers move to the new system "voluntarily." CMS should engage directly with stakeholders to ensure that episodic payments reflect both current resource requirements and the latest evidence-based guidelines. If payment rates for certain cancers are set too low, providers with a particular patient mix may not wish to participate. This also could have the effect of providing inappropriately high payments for other types of cancer, assuming the new system is budget-neutral.

Of course, under a "mandatory" approach in which all providers move into the new system at a date certain, lack of participation would be a non-issue. Presumably, under such a "mandatory" system, CMS still would continue to work with stakeholders using the latest evidence-based guidelines to refine the episodic payment rates over time.

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

As is well known, private payers tend to be "fast followers" of CMS reimbursement methodologies. This has occurred with DRG, APC, RBRVS, and other key standards that dominate the provider reimbursement landscape at present. Private payers know that if CMS

² Noridian and Cahaba LCDs for Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

adopts a payment methodology that providers will have no choice but to learn about, prepare for, and develop processes to accommodate the changes. Importantly, the development of a standardized and structured radiation therapy bundling methodology by CMS would provide a foundation upon which all payers could quickly build. To the extent that CMS chose to simplify the payment algorithms (e.g., avoid complex inlier or outlier calculations, limit the number of different bundles, etc.), this might allow private payers to more quickly modify their claims systems and for providers to more readily accept the new bundled methodology.

What challenges might be encountered in implementing such a model?

The payment volatility within radiation therapy is similar to the broader volatility in the physician fee schedule. The former is a result of volatility within radiation therapy relative value units (RVUs), while the latter is a result of volatility with the sustainable growth rate (SGR) portion of the conversion factor. Because payments to physicians are the product of the conversion factor and the relevant RVUs for a procedure, radiation therapy providers have been doubly impacted by payment instability in RVUs and the SGR.

The challenge to implementing payment reform within radiation therapy is the same challenge faced by Congressional policymakers in addressing problems with the SGR and establishing “alternative payment models” (or “APMs”) for physicians as a whole. That is, in order to encourage providers to move to APMS, Congress is well aware that the SGR must be repealed and replaced with predictable conversion factor updates over the next decade. *Similarly, it is imperative that the pool of resources that will be available for a new, episode-of-care payment system be established well in advance of implementation of the new system itself.* It is for this reason that the RTA has proposed using the pool of RVUs for radiation therapy services currently in place (i.e. 2014 RVUs) as the basis to establish the pool of resources for the new episode-of-care payment system in 2018. Although we believe a bundled, episode-of-care payment system will incent salutary cost efficiencies in the program, a way to guarantee savings would be to establish the pool of resources for the new system at some lesser percentage of 2014 RVUs (or carrier priced equivalents) for radiation therapy services. For example, in the case of the bundled payment system for dialysis enacted through the Medicare Improvements for Patients and Providers Act (MIPPA), the new system was established at 98 percent of the total amount of payments that would have been made if the system had not been implemented.

Such a transitional “bridge period” is essential to establishing an episode-of-care payment model for radiation therapy services. Without such a bridge period, the payment volatility inherent in the system will preclude stakeholders and CMS from establishing appropriate payment weights for two key reasons. First, payment volatility will force stakeholders to focus on addressing payment concerns in a given year, rather than focusing on the development of the new payment system. Second, it would make it impossible for stakeholders to reach agreement on bundled payment weights as the total pool of resources for such a system would continually change from year to year. *Although we understand that CMS may not have the authority to establish a bridge period in the years before a bundled episode-of-care payment system is established, we urge CMS to be cognizant of the need for such a bridge period and work with the RTA to*

encourage Congress to direct CMS to establish this necessary bridge to a new episode-of-care payment model.

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

A fundamental consideration in the development of a procedural episode-based model and, any alternative payment model, is whether the new system should be voluntary or mandatory. A particular issue of consideration is the fact that some stakeholders may be hesitant to embark on a mandatory change to a new episode-based model. Stakeholder concerns may include wanting to ensure: (1) their own perspectives are included in the development of the new payment system, (2) the payment system will work in the “real world,” (3) new episodic payment weights are appropriately set based on the most recently available medical guidelines, (4) payment models provide mechanisms for updates in a timely fashion that account for new technology, (5) there will be adequate time to switch billing, financial and other administrative operations to the new system.

On the other hand, there are several arguments for proceeding with mandatory episode-based models. One paramount concern is that physicians may be unlikely to fundamentally redesign care for temporary payment changes or pilots with no assurance of sustainability. Compounding this problem is that results for a pilot provider would not guarantee similar results for other providers. In fact, most major Medicare payment systems have been implemented *without* formal demonstrations and evaluations in advance. These include the current Physician Fee Schedule Resource-Based Relative Value Scale (RBRVS), which was phased in over a 5 year period with no prior testing, and the Hospital Outpatient Prospective Payment System, which was implemented with no prior testing.

Ultimately, CMS would have to weigh stakeholder hesitancy to move to a new payment model against the possibility that stakeholders might never move to the new payment model voluntarily. In order to balance these concerns, the RTA has proposed a four-year transition period to a mandatory bundle to give all stakeholders adequate time to address any concerns prior to the implementation of the new episode-based system. Whether CMS chose to implement a mandatory or voluntary bundle, the aforementioned “bridge period” would be essential to the establishment of the new, episode-based model.

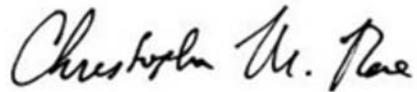
Conclusion

The uncertainty and volatility that the annual PFS process creates are a significant burden on the ability of the freestanding radiation oncology industry to provide quality care to patients. We urge CMS to pursue reforms to the Medicare payment system to incent quality outcomes instead of the current fee-for-service structure, which incentivizes volume. The RTA remains committed to the pursuit of payment reform in the form of an episode-based, bundled payment combined with appropriate quality metrics and a patient registry. Fundamental to the establishment of this new, episode-of-care system is a bridge period of payment stability to allow stakeholders to focus on long-term payment reform instead of near-term payment volatility. As we have

maintained since the establishment of the RTA in 2010, only fundamental payment reform can create the proper incentives and the predictability necessary to improve outcomes and control costs.

If you have additional questions regarding these matters and the views of the RTA, please contact RTA Executive Director Andrew Woods at (202) 442-3710.

Sincerely,

A handwritten signature in black ink that reads "Christopher M. Rose". The signature is written in a cursive, flowing style.

Christopher M. Rose, M.D., FASTRO

Chair, Radiation Therapy Alliance Policy Committee

APPENDIX

| Example: Prostate Cancer | | | | | | |
|-----------------------------|---|---------------|-----------------|----------------------------------|-------------------------|--------------------|
| TYPE OF DATA | DATA | | | | | |
| <i>Mandatory</i> | | | | | | |
| Patient Characteristics | Age & gender | Hypertension | Diabetes | Atherosclerotic Vascular Disease | Comorbidity Index Score | |
| Staging | T Stage | N Stage | M Stage | PSA Level | Gleason Score | |
| Patient Risk Scores | [F Code] | | | | | |
| Modality | [IMRT, 3DCRT, SBRT, Brachytherapy, Active Surveillance] | | | | | |
| # of Treatments | [NUMBER] | | | | | |
| Dose/Volume | D95 PTVp | D95 PTVsv | D95 PTVn | Rectal V70 (absolute) | Bladder V55 | |
| Physician-Reported Outcomes | Alive/Dead | Local Control | | Metastasis | PSA Level | |
| Adherence to Guidelines | [NCCN, ASTRO, ACRO] | | | | | |
| <i>Voluntary</i> | | | | | | |
| Other Cancer Delivery | [Chemotherapy, Surgery, Biological Therapy] | | | | | |
| Patient-Reported Outcomes | AUA Score | SHIM Score | Rectal Bleeding | Bladder Bleeding | Incontinence | Employed/ Disabled |

| Example: Breast Cancer | | | | | | | |
|-----------------------------|---|----------------------------------|---------------|--------------------------------------|----------------------------------|-------------------|-------------------------|
| TYPE OF DATA | DATA | | | | | | |
| <i>Mandatory</i> | | | | | | | |
| Patient Characteristics | Age & gender | Hypertension | Diabetes | | Atherosclerotic Vascular Disease | | Comorbidity Index Score |
| Staging | T Stage | N Stage | M Stage | ER | PR | Her2/neu | Extensive DCIS |
| Patient Risk Scores | N.A. | | | | | | |
| Modality | [IMRT, 3DCRT] | | | | | | |
| # of Treatments | [NUMBER] | | | | | | |
| Dose/Volume | D95 PTVbreast | D95 PTVboost | V100 | D0.1 cc breast (max dose) | | Lung V10/V20 | |
| Physician-Reported Outcomes | Alive/Dead | | Local Control | | | Metastasis | |
| Adherence to Guidelines | [NCCN, ASTRO, ACRO] | | | | | | |
| <i>Voluntary</i> | | | | | | | |
| Other Cancer Delivery | [Chemotherapy, Surgery, Biological Therapy] | | | | | | |
| Patient-Reported Outcomes | Breast pain (10 pain scale) | Cosmesis (Harvard 4 point scale) | | Overall satisfaction (5 point scale) | | Employed/Disabled | |

| Example: Lung Cancer | | | | | |
|-----------------------------|---|----------------------|-----------------------|----------------------------------|-------------------------|
| TYPE OF DATA | DATA | | | | |
| <i>Mandatory</i> | | | | | |
| Patient Characteristics | Age & gender | Hypertension | Diabetes | Atherosclerotic Vascular Disease | Comorbidity Index Score |
| Staging | T Stage | N Stage | M Stage | Hstology | |
| Patient Risk Scores | N.A. | | | | |
| Modality | [IMRT, 3DCRT, SBRT] | | | | |
| # of Treatments | [NUMBER] | | | | |
| Dose/Volume | Definitive/PreOp/Postop | D95 PTVprimary | D95nodes | Lung V20 | Esophagus V50 |
| Physician-Reported Outcomes | Alive/Dead | | Local Control | | Metastasis |
| Adherence to Guidelines | [NCCN, ASTRO, ACRO] | | | | |
| <i>Voluntary</i> | | | | | |
| Other Cancer Delivery | [Chemotherapy, Surgery, Biological Therapy] | | | | |
| Patient-Reported Outcomes | Global QOL (from SF-12 or SF-36) | Dyspnea (NCI CTC4.0) | Oxygen dependence Y/N | Employed/Disabled | |

| Example: Head and Neck Cancer | | | | | | |
|-------------------------------|---|--------------------|---|----------------------------------|---------------------------------|--|
| TYPE OF DATA | DATA | | | | | |
| <i>Mandatory</i> | | | | | | |
| Patient Characteristics | Age & gender | Hypertension | Diabetes | Atherosclerotic Vascular Disease | Comorbidity Index Score | |
| Staging | T Stage | N Stage | M Stage | Site of Disease | | |
| Patient Risk Scores | N.A. | | | | | |
| Modality | [IMRT, 3DCRT] | | | | | |
| # of Treatments | [NUMBER] | | | | | |
| Dose/Volume | Definitive/ Postop | D95 PTV1 | D95 PTV2 | D95 PTV3 | Mean dose contralateral parotid | Dysphagia/ Aspiration structures contoured Y/N |
| Physician-Reported Outcomes | Alive/Dead | | Local Control | | Metastasis | |
| Adherence to Guidelines | [NCCN, ASTRO, ACRO] | | | | | |
| <i>Voluntary</i> | | | | | | |
| Other Cancer Delivery | [Chemotherapy, Surgery, Biological Therapy] | | | | | |
| Patient-Reported Outcomes | Overall QOL SF12 or 36 | Taste Preservation | Ease of Swallowing from EORTC QLQ-C30 or FACT H+N | Xerostomia (U of Michigan Scale) | Employed/ Disabled | |

| Example: Rectal Cancer | | | | | |
|-----------------------------|---|------------------|---------------------------------|---|-------------------------|
| TYPE OF DATA | DATA | | | | |
| <i>Mandatory</i> | | | | | |
| Patient Characteristics | Age & gender | Hypertension | Diabetes | Atherosclerotic Vascular Disease | Comorbidity Index Score |
| Staging | T Stage | | N Stage | | M Stage |
| Patient Risk Scores | N.A. | | | | |
| Modality | [IMRT, 3DCRT] | | | | |
| # of Treatments | [NUMBER] | | | | |
| Dose/Volume | Preop vs Postop | D95 PTVpelvic LN | D95 rectum CD | Small bowel max dose, V45 (absolute cc) | Bladder V45 |
| Physician-Reported Outcomes | Alive/Dead | | Local Control | | Metastasis |
| Adherence to Guidelines | [NCCN, ASTRO, ACRO] | | | | |
| <i>Voluntary</i> | | | | | |
| Other Cancer Delivery | [Chemotherapy, Surgery, Biological Therapy] | | | | |
| Patient-Reported Outcomes | Rectal continence (from FACT-C scale) | | Overall QOL from SF-12 or SF-36 | | Employed/Disabled |

| Example: Anal Cancer | | | | | |
|-----------------------------|---|---------------------------------|------------|---|-------------------------|
| TYPE OF DATA | DATA | | | | |
| <i>Mandatory</i> | | | | | |
| Patient Characteristics | Age & gender | Hypertension | Diabetes | Atherosclerotic Vascular Disease | Comorbidity Index Score |
| Staging | T Stage | | N Stage | | M Stage |
| Patient Risk Scores | N.A. | | | | |
| Modality | [IMRT, 3DCRT] | | | | |
| # of Treatments | [NUMBER] | | | | |
| Dose/Volume | D95 PTVpelvic LN | D95 inguinal LN | D95 anus | Small bowel max dose, V45 (absolute cc) | Bladder V35 |
| Physician-Reported Outcomes | Alive/Dead | Local Control | Metastasis | Max skin reaction during treatment | Anus preservation Y/N |
| Adherence to Guidelines | [NCCN, ASTRO, ACRO] | | | | |
| <i>Voluntary</i> | | | | | |
| Other Cancer Delivery | [Chemotherapy, Surgery, Biological Therapy] | | | | |
| Patient-Reported Outcomes | Rectal continence (from FACT-C scale) | Overall QOL from SF-12 or SF-36 | | Employed/ Disabled | |