April 8, 2013

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3276-NC
7500 Security Boulevard
Baltimore, MD 21244-1850

{Submitted Electronically}

Medicare Program; Request for Information on the Use of Clinical Quality Measures (CQMs) Reported Under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program, and Other Reporting Programs [CMS-3276-NC]

Dear Ms. Tavenner:

The American Society for Radiation Oncology (ASTRO)\(^1\) appreciates the opportunity to provide written comments on the “Medicare Program; Request for Information on the Use of Clinical Quality Measures (CQMs) Reported Under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program, and Other Reporting Programs (CMS-3276-NC)” published in the Federal Register on February 7, 2013.

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,

\(^1\) ASTRO is the premier radiation oncology society in the world, with more than 10,000 members who are physicians, nurses, biologist, physicists, radiation therapists, dosimetrists and other health care professionals that specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, the Society is dedicated to improving patient care through professional education and training, support for clinical practice and health policy standards, advancement of science and research, and advocacy. ASTRO publishes two medical journals, International Journal of Radiation Oncology•Biology•Physics (www.redjournal.org) and Practical Radiation Oncology (www.practicalradonc.org); developed and maintains an extensive patient website, www.rtanswers.org; and created the Radiation Oncology Institute (www.roinstitute.com), a non-profit foundation to support research and education efforts around the world that enhance and confirm the critical role of radiation therapy in improving cancer treatment. To learn more about ASTRO, visit www.astro.org.
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.

ASTRO was very pleased to see the agency exploring alternative participation options for eligible providers to the Physician Quality Reporting System (PQRS). In recent years, ASTRO has grown concerned about the growing burden of initiatives implemented by Medicare and other payors that are often redundant and time consuming. ASTRO applauds CMS for trying to better align these efforts and strongly supports the use of alternatives to PQRS.

We support the movement toward registries, and have budgeted over $1.2 million to create our National Radiation Oncology Registry (NROR) thus far. We are aware that some other larger specialty societies have budgets an order of magnitude larger than ours to maintain their registries. The cost associated with registry development and maintenance continue to be borne by the providers. We strongly urge CMS to rationalize the current reporting incentives and penalties to support specialty society developed registries as a mechanism for demonstrating quality reporting and electronic health record use. By leveraging these efforts, we hope to develop a continuous rapid learning system for Medicare beneficiaries and all patients.

**Criteria for a Registry**

Section 601(b) of the recently enacted American Taxpayer Relief Act of 2012 amended section 1848(m)(3) of the Act allows eligible professionals to be treated as satisfactorily submitting data on quality measures for covered professional services if the eligible professional satisfactorily participates in a qualified clinical data registry. For 2014 and subsequent years, the Secretary is required to treat an eligible professional as satisfactorily submitting data on quality measures under the PQRS program if, in lieu of reporting PQRS quality measures the eligible professional is satisfactorily participating, as determined by the Secretary, in a qualified clinical data registry for the year.

As a general recommendation, ASTRO urges CMS to be flexible in its approach. There are a wide range of specialties, and any one-size-fits-all approach will likely create barriers to participation for a particular specialty. For example, CMS has asked if physicians should need to report on all of the six national quality strategy domains. We think that because different measures fall within the various domains, it is unlikely that an individual physician would have measures applicable to their given specialty across all domains. Thus, we suggest all physicians report on one or two national quality strategy domains each year. We believe that clear requirements with flexible paths for physicians to meet those requirements are the only way this program will be successful.

While flexibility is important, we understand that CMS must consider some general criteria and that the agency has been tasked to establish requirements for an entity to be considered a qualified clinical data registry. ASTRO carefully considered this issue and recommends the following criteria:
• The registry should be large enough to be geographically representative of the specialty;
• The data should have adequate practice site representation—rural, suburban and urban; hospital-based and community-based practices; academic and non-academic practices;
• The data should have current data and serve to contribute to a rapid learning system. Additionally, the registry should maintain data, preferably from the last three to five years so outcomes that are realized over a longer time frame can be captured;

The measures that registries use and the feedback provided to the clinicians are equally important. Again, flexibility is very important. ASTRO recommends:

• The list of measures tracked in the registry is transparent;
• Feedback reports should be provided to clinicians at least annually;
• NQF measures should be included when they exist and are appropriate for the patient population. Additionally, measures that have been developed with multi-disciplinary input, are subject to a public comment period, and address known gaps in care of a particular population are appropriate;
• If registries and third party entities are provided the ability for PQRS and/or the EHR Incentive Program reporting, they should also be provided clear guidance for what specification standard is required for CMS to receive the quality data information. For example, in NROR (described in more detail below) we are currently using an XML feed from the three EMRs to the registry gateway application that we are building;

In recommending the above listed criteria, ASTRO considered what was necessary in order to ensure the integrity of the data while maintaining a sufficient level of flexibility.

ASTRO's Quality Improvement Programs

In this letter we also provide some details about ASTRO initiatives that we support as alternative reporting mechanisms and submit them for the agency’s consideration. Depending on how CMS defines ‘registries,’ ASTRO has several practice improvement programs in which data is being collected that might lend themselves to ‘registry’ reporting. We have highlighted these programs so that CMS can be mindful about these various types of activities as it drafts the definition for ‘registries.’

PAAROT

In 2007, ASTRO developed the Performance Assessment for the Advancement of Radiation Oncology Therapy (PAAROT) as a practice improvement model for radiation oncology. Radiation oncologists who obtained the American Board of Radiology (ABR) certification after 1995 must participate in the ABR’s Maintenance of Certification (MOC) program to maintain their certification. In the Practice Quality Improvement (PQI) domain of MOC PAAROT is qualified by the ABR as meeting all the required criteria for a PQI project. Each ABR diplomate must complete one PQI project every three years. The quality indicators included in PAAROT were developed through an evidence-based review and formal consensus process where the indicators were vetted by radiation oncology experts. When they were available, NQF endorsed measures were used. These selected indicators were developed for cancers with a high prevalence in radiation oncology practice. The indicators are primarily process measures that are intended to assess the technical aspects of care and delivery of radiation therapy. The current
PAAROT program, v.2.5, includes 18 measures that are used for performance scoring. Of the 18 performance indicators, 7 are NQF endorsed measures\(^2\); 12 are cross-cutting, 5 indicators are prostate cancer specific and 1 is specific to colon cancer care.

We have analyzed the results and physician participation in PAAROT and recently published the results.\(^3\) Our findings show that participants range across all practice settings - community hospitals, academic practices and free-standing clinics. The measures with a high-adoption rate (more than 80% performance) include: documentation of history and physical, review of physics and dosimetry plan by radiation oncologist, patient informed risks of therapy, evaluation of acute symptoms during therapy, pathology in consultation note, communication of treatment summary within 30 days of treatment completion, documentation of intent of treatment, use of clinical guidelines/published data and documentation of AJCC staging. However, lower rates of adoption were noted when these measures were converted to a composite measure. Additionally, there was low adherence to screening of pain using a standard scale (mean 57%; range: 0-100 %). This is an area that has been documented by others as a significant gap in care.\(^4\)

**NROR**

ASTRO, in partnership with our foundation -- the Radiation Oncology Institute (ROI) -- is developing the National Radiation Oncology Registry (NROR), the first of its kind for radiation oncology.

The intent of the registry is to improve the care of cancer patients by capturing real-time, real-world reliable information on radiation treatment delivery and health outcomes through a prospective electronic registry infrastructure. The pilot project for this nascent registry is beginning this spring and will be focused on radiation oncology treatments for patients with localized prostate cancer. The objectives for NROR are to:

- Collect patient-specific radiotherapy data electronically;
- Determine national patterns of care and care quality;
- Provide benchmark data and tools to practitioners and facilities for quality improvement; and
- Generate hypotheses linking processes of care and outcomes and identifying subpopulations for which particular therapies are most effective.

The NROR Prostate Cancer Data Dictionary is a collection of carefully defined data elements designed to characterize critical aspects of the treatment of patients with intact prostate cancer with various forms of radiotherapy. The Data Dictionary was developed with guidance from

\(^2\) NQF measures 28, 41, 326, 383, 384, 386, and 419 are used in the PAAROT program.


prostate cancer and technical experts, health services researchers, and medical informaticists to provide standardized data elements in seven major domains:

- Facility characteristics;
- Physician demographics;
- Patient demographics;
- Prostate cancer disease characteristics;
- Medical history and comorbidities;
- Technical radiotherapy and dosimetric data; and
- Clinician-reported outcomes.

The NROR Prostate Cancer Data Dictionary is comprised of data elements derived from authoritative sources in radiation oncology, including the Radiation Therapy Oncology Group (RTOG) radiotherapy trials, the CaPSURE (Cancer of the Prostate Strategic Urologic Research Endeavor) database, the National Cancer Institute (NCI) Common Toxicity Criteria, AHRQ processes of care elements, SEER (Surveillance, Epidemiology and End Results) Program, the North American Association of Central Cancer Registries (NAACR), National Quality Forum and the NCI Thesaurus. The data dictionary for the prostate pilot has been posted to the web.\(^5\)

Fostering feedback for quality improvement through the provision of benchmarking data to individual practitioners and facilities is one of the global objectives of the National Radiation Oncology Registry (NROR). To that end, we have developed the first set of ten radiation oncology specific quality measures. Many sources, including the NQF endorsed prostate cancer measures on bone scans and androgen deprivation therapy, were used in the development of these measures.\(^6\) Benchmarking reports based on these measures will be provided to participating institutions. Over time, the NROR registry will attempt to validate the relationship of these measures to patient-centered health outcomes, promoting the foundation of a rapid learning health care system.

We have been working on the launch of this registry for about a year and have experienced significant delays and roadblocks in our attempts to negotiate business associate and data sharing agreements with the institutions involved in our pilot registry. Our recommendations for regulatory reforms that could cultivate a productive and efficient registry environment are described later in this letter.

**Practice Accreditation**

Practice accreditation is an essential indicator of a high quality, safe radiation oncology clinic. ASTRO is developing a radiation oncology practice accreditation program that will be integrated with ASTRO’s other quality initiatives, including maintenance of certification, clinical guidelines and quality measure development, reporting medical errors to a radiation oncology patient safety organization (PSO) and medical education on safety and performance.

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\(^6\) NQF measures 398, “Prostate Cancer: Avoidance of Overuse Measure – Bone Scan for Staging Low-Risk Patients” and 390, “Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Patients” are included in the NROR.
improvement. We have posted the standards for our practice accreditation program for public comment and will invite comments from the radiation oncology community, patient advocacy groups, and payors. The new accreditation program will launch in early 2014 and be comprehensive, objective, and transparent.

ASTRO is confident that radiation oncology clinics accredited under the program will have an underlying culture committed to quality and safety, as well as the policies, procedures and quality improvement infrastructure to ensure that patients receive the very best care. Given the robust nature of both practice-level and individual physician-level quality metrics clinics will have to meet to gain accreditation under the program, ASTRO believes that the data collected through this practice accreditation program may meet the requirement for a registry.

**Regulatory Challenges**
Recent legislative packages have emphasized improving quality and lowering the costs of care, particularly in recent legislative packages such as Patient Protection and Affordable Care Act (ACA) and the American Taxpayer Relief Act (ATRA). ASTRO, as well as other stakeholders in the healthcare system, has shifted its focus to ways in which we can support this effort. Unfortunately, the interpretation of current federal regulations – particularly the Privacy and Common Rules – by various institutional review boards (IRBs) has created significant impediments to accomplishing these goals.

There is a need for regulatory agencies to establish appropriate standards for QI activities that will both adequately protect patients and not unnecessarily burden QI efforts. The difficulties posed by a designation of “human subjects research” to quality efforts cannot be overstated. In particular, the requirement for informed consent creates almost insurmountable barriers to the practical implementation of quality efforts. Since clinical registries rely on continuous, prospective collection of data to produce longitudinal evaluations of patient outcomes, the application of informed consent and other patient authorizations could significantly compromise the validity of data assessments and create significant impediments to generating data of adequate quality to drive practice improvement as well as introducing significant patient selection bias. For example, the NROR has been advised by its IRB of the need to use a patient informed consent ‘opt-out’ process to allow for the gathering of a limited dataset of PHI in order to produce longitudinal evaluation of patient outcomes. The need to introduce patient consent into what is essentially a quality improvement registry may lead to bias; it also slows and complicates the ability to gather high quality data in a timely manner.

We request that Office of Human Research Protections (OHRP) issue guidance that the Common Rule does not apply to the collection and analysis of identifiable patient information for quality improvement purposes where the entities collecting and analyzing the data (such as clinicians and a corresponding clinical data registry) are engaged in standard patient care and are in compliance with all applicable HIPAA requirements. Additionally, we seek explicit language in federal guidance to allow for clear differentiation between “human subjects research” and the

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7 Please visit our website at [https://www.astro.org/Practice-Management/Practice-Accreditation/Index.aspx](https://www.astro.org/Practice-Management/Practice-Accreditation/Index.aspx) to review the draft standards and submit comments. The comment period is April 8 – May 17, 2013.
processes related to the essential prospective analyses that will be required to advance the Nation’s quality care objectives.

For example, the National Radiation Oncology Registry is currently attempting to aggregate data on the management of prostate cancer from seven alpha testing institutions and 23 additional beta testing institutions. To date, we have expended over 100 person-hours just in correspondence with compliance officers and attorneys at our seven alpha testing institutions to obtain Business Associate and Data Sharing Agreements. As a result of the fear of Privacy Audits, some of the pilot institutions are requiring that the NROR bear impossible burdens of indemnifying the institutions in the case of data breaches. We have developed and are testing a comprehensive process for data security, but our efforts are not routinely accepted by the large research universities that comprise some of our alpha testing sites. Guidance from CMS and its federal partners would be of benefit to us in our efforts to aggregate data in a HIPAA compliant manner.

To meet their full potential value as QI tools that support evidence development, provider performance assessment and comparative effectiveness studies, registries must have the ability to have transparency to compare data across other registries and also within the same registry over time. For this to be achieved, some method of identifying a patient that is HIPAA compliant needs to be developed to track patients. If potential HIPPAcompliant solutions such as probabilistic matching are found to be unfeasible or add error to the analysis, we strongly urge CMS to work with the Office of Civil Rights (OCR) and the OHRP to modify the current HIPAA requirements to allow data with a limited PHI dataset identification to be gathered, or that a common patient identifying number within a consistent deidentification scheme be employed.

Until the health care community receives this guidance, it is inevitable that many efforts will be stalled and stymied over variability in the interpretation of guidelines relevant to clinical quality initiatives. ASTRO urges Acting Administrator Tavenner to coordinate closely with the Office of Civil Rights (OCR) to push for guidance that will protection of the rights of Medicare beneficiaries and create a regulatory environment in which registries can thrive.

Thank you for the opportunity to respond to this request for information. We look forward to continued dialogue with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Emily Wilson, Vice President, Advocacy and Clinical Affairs, ASTRO at (703) 839-7364 or emilyw@astro.org.

Respectfully,

Laura I. Thevenot
Chief Executive Officer