AMERICAN ASSOCIATION of PHYSICISTS IN MEDICINE

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Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5527-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures; CMS-5527-P

Dear Administrator Verma:

The American Association of Physicists in Medicine[1] (AAPM) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 18, 2019 *Federal Register* notice regarding the Radiation Oncology (RO) Model proposed rule. Please note that the AAPM will be submitting two comment letters regarding this proposed rule prior to the September 16, 2019 deadline. The present letter emphasizes our concerns regarding the impact of the proposed RO Model on quality and safety in radiation oncology, and includes recommendations to help ensure Medicare beneficiaries continue to receive high quality care. Our second comment letter, to be submitted at a later date, will address concerns and clarifying questions related to the design and implementation of the RO Model.

CMS proposes the creation and testing of a new payment model for radiation oncology. The intent of the proposed RO Model is to promote quality and financial accountability for episodes of care centered on radiation therapy services. The RO Model would test whether prospective episode-based payments to physician group practices (PGPs), hospital outpatient departments (HOPDs), and freestanding radiation therapy centers for radiation therapy episodes of care would reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries.

[1] The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MRI, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 7,000 medical physicists.

Complexity of Radiation Therapy and Role of a Qualified Medical Physicist:

The sophistication and complexity of radiation therapy technology has increased exponentially in the past few decades. As radiation treatments have become more targeted and precise, they have also required increasingly complex equipment and processes. Computerized beam shaping systems have augmented traditional blocking techniques to improve radiation field sculpting capabilities; multimodality imaging-based virtual simulation and inverse planning techniques have replaced hand calculations to improve dose conformity; rotational delivery techniques have replaced static treatments to improve treatment efficiency. The addition of stereotactic devices, on-board image guidance systems, and robotic positioning systems has improved the precision of field placement. As the accuracy and precision of radiation treatments has improved, so too have patient outcomes.[2]

As the complexity of radiation therapy treatments has grown, the work of ensuring treatment accuracy and patient safety throughout a prescribed course of treatment has also become more demanding in expertise and attention. The inherent danger posed by the use of therapeutic levels of radiation dose is managed and minimized by the medical physicist. Medical physicists are tasked with ensuring that each and every radiation therapy treatment is safely and accurately delivered in accordance with the radiation oncologist's prescription. Medical physicists have the core responsibility of ensuring the safe and proper functioning of all major medical equipment; developing and guiding the implementation of standard operating procedures that govern clinical use of the equipment; consulting with the radiation oncologist to address unique patient circumstances; and providing ongoing monitoring and assessment of the technical aspects of care for each patient throughout their course of treatment.

Unintended Consequences of Episode of Care Bundled Payment Methodology:

AAPM supports value-based payment alternatives and welcomes the improved professional discretion to apply the most appropriate technology to each patient. However, AAPM is concerned that the bundling of historical codes with embedded medical physics services will lead to a loss of direct financial accountability of facilities for providing adequate technical supervision that is provided by the medical physicist to each patient, and could significantly reduce medical physics resources around the country. Under the RO Model, explicit association of medical physics reimbursement to episodes of patient care would no longer be visible to the facility management. We expect that change to have the unintended consequence of granting hospital and practice administrators the authority to determine the portion of the RO Model episode payment to be allocated in support of the work of the medical physicist. In the absence of explicit direct correlation of RO model payments to medical physics effort, administrators would be motivated to reduce those services they perceive to be non-revenue generating in order to cut costs. This would inevitably drive a loss of medical physics support, and thus would pose **an immediate and direct threat to patient safety and treatment quality**. If the work of the medical physicist goes undone, serious harm to patients could result due to the irreversible nature of radiation treatment delivery. The dangers posed by radiation therapy – and the harm that can result from mistakes associated with technical errors – such as those reported in a highly publicized New York Times investigative series,[3] are well documented.

[2] Citrin DE. Recent Developments in Radiotherapy. *N Engl J Med* 2017; 377:1065-1075.
[3] Bogdanich W. When Radiation Treatment Turns Deadly. *New York Times*, January 23, 2010.

Recommendations to Maintain the Essential Role of the Medical Physicist under the RO Model:

Ideally, the work of the medical physicist would be explicitly required and fully reimbursed by CMS for each patient's course of therapy as a part of the new RO Model. However, should this not be achievable, codification of accreditation requirements is critical to ensure safe and accurate delivery of radiation therapy services.

CMS has previously recognized and codified the necessity of *accreditation* for advanced diagnostic imaging services. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) was enacted making changes to the Medicare program. Specifically, MIPPA mandated that beginning January 1, 2012, any entity performing the technical component of advanced diagnostic imaging services (including a physician's office) was required to receive accreditation from a national accrediting agency approved by the Secretary of Health and Human Services. Further, the Secretary established criteria for accreditation, including standards for equipment performance, patient safety, quality assurance and quality control, and qualification of medical personnel who are not physicians.

To ensure that medical physics support for the technical elements of care is maintained under the RO Model, **the AAPM urges CMS to require accreditation of all RO Model participants as part of model compliance.**

The American College of Radiology (ACR), the American Society for Radiation Oncology (ASTRO), and the American College of Radiation Oncology (ACRO) all have national accreditation programs that provide a thorough and impartial review and evaluation of patient care in a radiation oncology department. Facility staffing, standard operating procedures for use and quality control of equipment, radiation safety records, and patient-safety policies are assessed. Facilities that obtain practice accreditation must demonstrate that their systems, personnel, policies and procedures meet standards for high-quality patient care.

To allow for RO Model participants who do not currently hold practice accreditation to prepare and complete the RO Model review process, **the AAPM recommends that CMS allow for a 3-year transition period such that the accreditation requirement would take effect in 2024**.

Lastly, to help ensure safe and high quality care during the transition period, **for those participants that are not yet accredited, the AAPM recommends that CMS add 3 clinical data reporting requirements specific to medical physics beginning in 2020 and in subsequent years until national accreditation is obtained.** Although the proposed clinical data measures do not reflect the full and dynamic nature of the medical physicist's role in patient care and represent just a portion of the ongoing physics oversight, we feel that they represent a reasonable surrogate during the transition to an accreditation requirement that will ensure radiation oncology patients receive safe and high quality care. The clinical measures recommended below are included in the ACR, ASTRO, and ACRO accreditation program standards.

- Initial Chart Review - A Qualified Medical Physicist verifies the following elements before treatment implementation and when changes are made to the plan. The treatment plan is

compared to treatment prescription, pertinent dosimetric parameters are evaluated, and patient-specific quality assurance is performed and analyzed. Documentation of this review must be part of the patient's treatment record.

- Ongoing Chart Review - A Qualified Medical Physicist must periodically review each patient's chart to ensure accuracy of calculation, appropriateness of charting data, and fulfillment of the physician's written prescription. Any deviation from the radiotherapy prescription should be reported in a timely manner to the responsible radiation oncologist so that corrective action can be taken. The physics chart review must be conducted at least every five treatment fractions. Documentation of this review must be part of the patient's treatment record.

- End of Treatment Chart Review A Qualified Medical Physicist must review the entire chart to affirm the fulfillment of the initial and/or revised prescribed dose. This review must be performed within 1 week of end of treatment and documented in the treatment record. Any deviations from the physician treatment plan or radiotherapy prescription must be documented and promptly brought to the attention of the attending radiation oncologist.

Medical Physicists are a necessary and essential component of the radiation oncology team. The AAPM believes that practice accreditation or reporting key clinical data measures enhances Medicare beneficiaries' radiation safety and access to high quality cancer treatments.

We hope that CMS will consider these issues during the development of the Radiation Oncology Model final rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (904) 844-2487.

Sincerely,

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