



September 5, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1786-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Proposed Rule; CMS-1786-P

Dear Ms. Brooks-LaSure,

The American Association of Physicists in Medicine (AAPM)¹ is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 31, 2023 *Federal Register* notice regarding proposed changes to the Hospital Outpatient Quality Reporting (OQR) Program.

Specifically, CMS is proposing the adoption of a new electronic clinical quality measure (eCQM) for Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level — Outpatient), beginning with the voluntary CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period for CY 2028 payment determination.

Executive Summary

For 66 years, the AAPM is and has been a leading scientific and professional organization for continual improvements and assurance of the highest quality imaging and dose-image optimization for the safety and benefit of patient care. Based on our broad expertise and deep track record, **the AAPM urges CMS not to adopt the quality measure as proposed.** The proposed quality measure lacks national consensus of stakeholders and practitioners and further has significant scientific limitations that will impact its safety and practical value. These limitations will decrease the measure's overall likelihood of clinical impact and may even negatively impact image quality, patient safety, and patient outcomes. Further, this measure would disproportionately burden hospitals serving a low-income population (e.g., rural and inner-city hospitals) due to their older equipment and lack of in-house physicists.

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, MR, 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 9,000 medical physicists.

Given that CMS has paused implementation of the Appropriate Use Criteria for Advanced Diagnostic Imaging, we believe that a quality measure that addresses excessive CT radiation dose is important; however, the science behind this specific proposed quality measure is lacking. AAPM advocates for the development of national consensus metrics, with input from scientific, manufacturing, and standards stakeholders, towards scientific, meaningful, and practical assessment and tracking of CT dose and image quality. The Quality Measures Roundtable, noted at the end of this letter, offers an opportunity to anchor such measures on professional consensus, informed by science and practical relevance. **The AAPM would like to work with CMS and interested and affected parties to improve and revise the proposed quality measure prior to implementation.**

Additional Details

While efforts to enhance consistency of CT practice are noble and include initiatives by AAPM and others nationally and worldwide, the proposed measure has significant limitations that impact its scientific and practical value. These limitations include non-consensus, non-standardized, and gross under-representation of image quality, improper estimation of radiation risk (in terms of dose length product (DLP) adjusted by patient size, not the actual patient dose and explicitly prohibited by the AAPM standard), over-simplified stratification of CT categories, and substantial oversimplified representation of implementation in practice, including not addressing the implementation challenges. We also believe that even attempting to implement this proposed measure would cause excessive burden for medical physics and radiological technologist staff without any clear benefit.

The AAPM strongly agrees that efforts need to be continually placed on ensuring diagnostic quality CT imaging, optimizing CT dose, and achieving consistency across facilities, considering differing technologies and practices. The non-profit entities of the AAPM, the American College of Radiology (ACR), and Image Wisely and Image Gently Alliances have spent decades working towards this goal and continue to do so through many initiatives. Among them, the non-profit ACR CT Dose Index Registry (DIR; <https://www.acr.org/Practice-Management-Quality-Informatics/Registries/Dose-Index-Registry>, established in 2011) has the significant stature of implementing a dose registry that enables facilities to compare dose indices nationally, to ensure the highest quality imaging with lowest possible dose. The ACR CT DIR implementation incorporates the expert, consensus opinions of the medical imaging community.

Analysis and Concerns

AAPM's significant concerns about the proposed eCQM and its adoption in the final rule are based on detailed reviews by leading AAPM experts on this topic, and broad consensus across multiple committees of experts that we have conducted in the last few months. This position stems from six major concerns about the proposed measure:

- 1) *Unscientific characterization of CT scan risk:* The proposal is based on risk estimation approaches and their uncertainties that are not reflective of the consensus of the scientific community. At the present time, epidemiological evidence supporting increased cancer incidence or mortality from radiation doses below 100 mSv is inconclusive.² Given the lack of scientific consensus about potential risks from low doses of radiation, predictions of hypothetical cancer incidence and mortality from the use of diagnostic imaging are highly speculative. The AAPM, and other radiation protection organizations, specifically discourages these predictions of hypothetical harm.

² <https://www.aapm.org/org/policies/details.asp?id=2548>

- 2) *Inactionability of the measure to enable targeted change to improve practice:* It is not clear how the proposed measure can be practically used to improve imaging practice and how a facility can achieve compliance, given the wide variety of factors and technologies involved. For instance, estimation of patient size for CT dose estimation remains an evolving challenge due to the wide range of body habitus. In addition, the proposed measure uses size-adjusted DLP to characterize radiation exposure, but there is no established and accepted method for adjusting DLP by patient size.
- 3) *Inadequate addressing of the complexity of CT categorization:* The proposal does not address the magnitude of the complexity of CT categorization (e.g., body, adult, dynamic, etc.) nor does it suggest means to overcome it given that even current standards are lacking in the uniform characterization of protocols. The CT categorization scheme proposed in this measure inadequately addresses criteria such as the reason for the scan, CT reconstruction parameters, and patient size. Inaccurate classification of data can lead to significant errors in the resulting aggregated data, leading to erroneous conclusions negatively impacting patient care.

For example, one reference cited to support the proposed measure has an accompanying editorial highlighting the proposed approach's limitations [Mahesh M. Benchmarking CT Radiation Doses Based on Clinical Indications: Is Subjective Image Quality Enough? *Radiology*. 2022; 302:2, 390-391]. The editorial and stated limitations are not addressed in the eCQM proposal.

- 4) *Inadequate assessment of noise:* Use of "global noise" can misrepresent the quality of an exam and does not account for the diversity of influences on noise in a CT image, such as differences in CT technologies or new reconstruction methods that may dramatically alter noise. Further, noise does not have a singular value in a CT exam.
- 5) *Inadequate assessment of image quality:* Image quality is affected by a myriad of factors including resolution and contrast, as well as the intended purpose of the exam. A singular representation of image quality via global noise is a gross simplification of image quality, leading to misrepresentation of image quality that detracts from patient care. By example, a CT image protocol may be purposefully designed that yields higher noise to best address a particular diagnostic imaging task. A recent study by leading CT experts presented at last year's annual meeting of the Radiological Society of North America clearly documents that CT noise is only a tertiary consideration of image quality as judged by leading radiologists (Gress et al. Ranking the Relative Importance of Image Quality Features in CT by Consensus Survey, RSNA 2022 – the refereed paper is currently under review by *Radiology*).
- 6) *Emphasis on dose reduction instead of dose optimization:* We appreciate inclusion of both radiation dose and image quality as factors in the proposed eCQM as a balance; however, the proposed eCQM incorrectly emphasizes dose reduction, instead of dose *optimization*, for the imaging task at hand. Individualization and optimization of care and safety should be the goal, not dose minimization. Minimizing doses can lead to patients being underexposed, resulting in reduced image quality, potentially missed or delayed diagnosis, and even repeat scans thereby ultimately increasing dose to the patient.

The AAPM recognizes that this topic includes scientific, technical, and clinical components. We welcome the opportunity for greater in-depth discussions to develop consensus and meaningful measures of quality imaging practice that will benefit patient care. Towards that goal, the AAPM is conducting a Quality Measures Roundtable, to be held at AAPM's headquarter in Alexandria, Virginia, on October 20, 2023. The roundtable is formed by an invitation to all organizational leaders including all leading professional societies, federal agencies including CMS, and manufacturers who are involved and have a vested interest in the quality of medical CT imaging. Through dialogue consisting of organizational perspectives, the goal of this roundtable is to form a broad consensus about how medical

imaging quality and safety can be properly measured and assured. We strongly encourage the participation of CMS in this roundtable.

We thank you for this opportunity to submit our comments and request that CMS carefully consider these issues for the final rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (561) 631-0677.

Sincerely,



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President, American Association of Physicists in Medicine



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