



June 7, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1785-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; CMS-1785-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 May 1, 2023 *Federal Register* notice regarding proposed changes to the Hospital Inpatient Quality Reporting (IQR) 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 — Inpatient) with the CY 2025 reporting period/FY 2027 payment determination.

Executive Summary

The AAPM is and has been a leading scientific and professional organization for continual improvements and assurance of the highest quality CT diagnostic imaging and CT dose-image optimization for the safety and benefit of patient care. While AAPM supports efforts to improve patient care, we do not believe this measure will improve patient outcomes. The proposed quality measure lacks national consensus and has other significant limitations that will impact its scientific and practical value. These limitations will decrease the measure's overall likelihood of clinical acceptance and may lead to a reduction in image quality and patient safety for those facilities implementing the measure. Therefore, **the AAPM urges CMS not to adopt the proposed quality measure.** AAPM advocates for the development of a national consensus metric, with input from scientific, manufacturing and standards stakeholders, that will be meaningful and practical for tracking the assessment 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.

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.

Additional Details

The proposed measure requires users to track the CT Category (i.e., the CT exam type), the size-adjusted radiation dose [the patient's dose length product (DLP) adjusted by patient size], and the global noise (associated with the variance of the voxel values in CT images). The two reported measures are the percentage of eligible CT cases in a particular category deemed "out-of-range" compared to defined thresholds for the size-adjusted radiation dose or the global noise in a set time period.

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 and non-standardized representation of image quality, improper estimation of radiation risk, improper stratification of CT categories, and substantial oversimplified representation of implementation in practice, including not addressing the implementation challenges. We also believe that implementation of this proposed measure has potential burden for medical physics and radiological technologist staff.

The AAPM strongly agrees that effort needs 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.

Furthermore, this measure is often redundant as most hospital CT programs are already required to regularly evaluate image quality and compare radiation doses to external benchmarks to maintain accreditation (as required by Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P.L. 110-275) amended section 1834(e) of the Social Security Act).

After a detailed review by leading AAPM experts on this topic, **we have significant concerns about the proposed eCQM and do not support adoption in the final rule.** This position stems from seven 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.
- 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 the wide range of body habitus.
- 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 current standards are even 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 and misleading errors.

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*. 2021 Nov 9:212624. Doi: 10.1148/radiol.2021212624. Online ahead of print. PMID: 34751622]. 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 may lead 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*: The proposed eCQM has emphasis on 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 and potentially missed or delayed diagnosis.
- 7) *Limited expertise and experience of the company suggested to steward this measure*: The reporting of such a measure should be curated by an independent organization with expertise in national-level data acquisition and the technical aspects of CT technology. Given CT device vendor specifications and preferences, institutions may desire device-integrated and on-site eCQM software tools that directly curate and share eCQM data with CMS without use of an external, third-party curator. Similarly, open opportunity should be afforded for any entity desiring to offer solutions for the implementation of an appropriate metric.

The AAPM recognizes that this topic is complex, including scientific, technical, and clinical components. We welcome the opportunity for greater in-depth discussion 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 brings together 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 measured and assured.

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,

A handwritten signature in black ink that reads "J. Daniel Bourland". The signature is written in a cursive style with a large, stylized initial "J".

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