



June 9, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-1785-P,
Mail Stop C4-26-05
7500 Security Boulevard,
Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems; Quality Programs and for Eligible Hospitals and Critical Access Hospitals

The American College of Radiology (ACR), representing over 40,000 diagnostic, interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists, appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services on the Fiscal Year (FY) 2024 Hospital Inpatient Prospective Payment System (IPPS) proposed rule with comment period.

The ACR is a strong advocate and proponent for patient radiation safety as demonstrated by the multiple and various ongoing efforts and activities in which the organization and the radiology community are involved (i.e., [guidelines and technical standards](#), [imaging appropriateness criteria](#), the [Image Gently](#) and [Image Wisely](#) alliances and campaigns, [radiation safety manuals](#), [accreditation](#), [dose index monitoring and management](#), [educational products](#), [publications](#), and [performance measures](#)). The ACR fully supports entities or individuals that put forward valid and feasible tools to optimize patient exposure to radiation through dose monitoring and imaging appropriateness.

The ACR provides comments on the CMS-proposed policies described below.

Proposed Policies

CMS proposes to adopt the *Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient)* eCQM into the Inpatient Quality Reporting (IQR) and the Medicare Promoting Interoperability programs beginning with the calendar year (CY) 2025 reporting period/FY 2027 payment determination. CMS also seeks comments on potential future consideration of the measure into the Hospital-Acquired Condition (HAC) Reduction program. CMS identifies this measure as a hospital harm eCQM, addressing two of CMS's high-priority areas: safety and outcomes.

The ACR has concerns on the proposed Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Excessive Radiation Dose) measure below.



Hospital Inpatient Quality Reporting (IQR) Program

The ACR supports CMS's efforts to prioritize radiology-focused patient safety eCQMs that address patient outcomes. However, we caution CMS with finalizing this measure in the IQR program for use beginning with the CY 2025 reporting period for the reasons discussed below.

Implementation challenges and burdens

This measure necessitates considerable organizational efforts to access and process the data elements required to calculate the measure score. The complexity of the measure, particularly concerning methods for calculated data elements, requires the creation of measure software and logic by hospital staff or the use of a commercial product. Currently, the only software for implementing this eCQM was created and maintained by a single commercial vendor, Alara Imaging Inc., in conjunction with the measure steward. The measure steward has affirmed that organizations may obtain access to a version of the software without charge. However, just because the vendor provides a free version does not mean that there will be no cost to radiology providers.

Regardless of in-house or commercial solutions, hospital staff who are likely already juggling multiple technological priorities, software upgrades, transitions, or installations will be tasked with implementing the proposed measure. Hospital operational staff will need to oversee installation, configuration, and ongoing management of any measure software, commercial or proprietary. Software configuration requires mapping or extracting data element components from the relevant systems necessitating connections across systems, determining the source for CPT/ICD codes used to classify an exam for the CT Category field values (extracted from an EHR, billing/practice management system, or a radiology information system (RIS), as well as radiation dose and global noise values (size-adjusted dose and image quality) to determine measure performance. Thus, total costs to organizations to implement the software will be high—regardless of the price of the software.

Additionally, LOINC codes created for the measure calculated fields exist but may not necessarily be used by every institution; capturing data for the new codes will need to be configured. The LOINC codes do not rely solely on standardized fields from a system; any system that implements the fields must embed some calculations. For instance, there is a DICOM field for patient size for calculating size-adjusted doses, however, it is frequently null. Most radiation dose monitoring tools calculate patient size from CT images. Hospital staff (or other software vendors) who implement the measure will have questions regarding the exact, step-by-step methods for calculating patient size, size-adjusted dose, or global noise calculation, none of which have been provided. Will Alara Imaging Inc. or the measure steward provide detailed information to answer such questions?

Although the proposed “Excessive Dose” measure was tested at multiple pilot sites of varying facility types specified, the ACR has much more experience extracting similar data from more than 5000 facilities utilizing the ACR Dose Index Registry or that have undergone ACR CT Accreditation. Through such experience with these facilities, we have found that the ability to



extract these data elements and transform them into the calculated fields with any degree of accuracy or consistency even with an available software solution is extremely challenging. We have serious concerns about the feasibility of this approach.

The ACR also has concerns regarding the measure implementation impact on rural hospitals and those treating underserved communities, given their already limited resources; implementing this measure in these care settings may prove insurmountable for many.

Measure methodology

ACR is concerned with the lack of demonstrated validity or reliability supporting the measure, particularly with using the calculated fields. The data elements needed for the measure are calculated using multiple structured fields within the EHR and the radiology electronic clinical data systems, including the Radiology Information System (RIS) and the Picture Archiving and Communication System (PACS).

CT Dose and Image Quality Category (CT Category)

The accuracy and specificity of CPT/ICD codes to determine the true indication for an exam at the time of order is a cause for concern. Indications for exams at the time of order do not typically have standardized language that could be used to categorize the CT exam purpose (CT Category) nor fully characterize the patient's condition. As a result, the clinical reason for performing an imaging exam is often extremely limited within the exam order, even if using an ICD 10 code. For example, an order for CT abdomen with an indication of "pain" may use a low dose kidney stone or a routine CT protocol. Most health and IT systems capture CPT and ICD-10 coding for reimbursement, but codes are typically assigned after the imaging exam's completion. Since the imaging exam is a diagnostic tool to support the final diagnosis by the treating physician, which likely includes other factors, ICD and CPT codes assigned at that point would serve only as a proxy for the understood indication at the time of the imaging exam. This is a particular problem if the exam is normal/negative for the suspected condition. Additionally, EHR systems are notoriously incomplete, lacking this type of information, and interoperability issues may exist with other software systems containing such information, like billing/coding systems.

CT Size-Adjusted Dose and CT Global Noise

The two primary components of the proposed measure, "CT size-adjusted dose" and "CT global noise" are not widely accepted image quality measurements nor have they been widely tested and validated. CT noise measurements are especially problematic, as finding a reliable measure of image noise that can be taken directly from the image has proven elusive over the decades, despite a number of the world's foremost labs pursuing this in earnest for many years. The fact that Alara Imaging Inc. has proposed a proprietary version that has not been released for public review makes it difficult to verify the validity and reliability of the global noise methodology.

Actionability/Usability

The imaging protocol selection appropriate for a clinical indication is a crucial factor in radiation dose management and optimization. It requires that each component be addressed as a separate



quality action. The most accurate way to address the appropriate and safe use of multi-phase CT studies is to measure the clinical indication of an exam and the radiation output (dose indices) per exam and assess the two separately or distinctly together. However, this measure conflates the appropriateness of the protocol for the clinical indication and radiation dose optimization, disregarding applicability, from which a facility may be unable to determine if adjusting protocols or focusing on the appropriateness of the exam ordered could improve performance. Therefore, improvement may be limited.¹ Consider the following practical examples:

- Should the protocol always be adjusted because of patient size if the dose index value is high on a specific exam?
- The exam may have been inadequate for image quality, as shown by measure results, but the physician was comfortable making a diagnosis using the images. How does that relate to the image quality benchmark? Again, in cases with broad indications such as “pain”, the protocol selection may vary i.e., low dose kidney stone or a routine CT protocol.
- What is an appropriate radiation dose index benchmark for routine abdomen CT for a patient weighing 300 lbs.?

These are just a few of the many unanswered (and potentially unanswerable) questions that have not been addressed. The ACR strongly believes that it is premature to require providers across the country to measure performance on excessive radiation dose based on clinical indication thresholds until more advanced national benchmarks are standardized and available.

Use of the term “excessive radiation dose”

The term “excessive radiation dose” is subjective, imprecise, inaccurate, and alarmist. The effort to inform patients regarding risks of ionizing radiation while reassuring them that the risks are low is a delicate balance. Terminology matters a great deal, as has been highlighted by many prominent experts, especially those leading the Image Gently campaign. The ACR has developed numerous educational and guidance materials on radiation dose safety. Of note, our communications and guidance balance providing patients with awareness of the risk associated with radiation exposure and the incredible benefits medical imaging provides to patient care. We carefully craft statements so as not to raise undue alarm or fear of potential life-saving clinical care. Terms such as “optimization” or “dose lowering” are preferable to those such as “excessive dose” and using the term “excessive dose” may be inaccurate and unnecessarily alarmist.

Healthcare community understanding

The ACR recognizes that the Excessive Radiation Dose measure has received substantial support across the medical and healthcare community, including from numerous radiology groups and leadership within the specialty. Based on input received from multiple contacts, we believe that a

¹ Mahesh M. Benchmarking CT Radiation Doses Based on Clinical Indications: Is Subjective Image Quality Enough? Radiology. 2021 Nov 9:212624.



majority or large percentage of commenters support the general concept of addressing radiation dose optimization by indication for exam, which the ACR also supports, while not understanding the details of the measure approach or methods for implementation. We strongly encourage that CMS reach out to various stakeholders supporting the measure to gauge comprehension of the measure details and implementation logistics.

The ACR fully supports valid and feasible tools to optimize patient exposure to radiation dose. However, we strongly recommend that CMS take a considered approach to implementing the Excessive Radiation Dose measure into the IQR program, allowing a period for larger-scale testing and experience with the measure before attaching stricter requirements impacting hospitals providing services under the IPSS.

Promoting Interoperability Program

In 2011, the Centers for Medicare and Medicaid Services (CMS) established the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs to encourage eligible professionals (EPs), hospitals, and critical access hospitals (CAHs) to adopt, implement, upgrade, and demonstrate meaningful use of certified electronic health record technology (CEHRT). To continue its commitment to promoting and prioritizing interoperability and exchange of health care data, CMS renamed the EHR Incentive Programs to the Medicare and Medicaid Promoting Interoperability Programs in April 2018. This change moved the programs beyond the existing meaningful use requirements to a new phase of EHR measurement with an *increased focus on interoperability and improving patient access to health information*.

The Promoting Interoperability (PI) program primarily assesses the transactional capabilities, use of EHR functionality, exchange of healthcare information across organizations and with patients, and systems interoperability employed by hospitals and clinicians. Additional requirements for successful participation in the program are to report four clinically focused eCQMs, including the Safe Use of Opioids eCQM and three additional of eight currently available eCQMs. Fulfilling the eCQM requirement for the PI program also satisfies the eCQM reporting requirement for the IQR program. **The ACR does not support including the Excessive Radiation Dose or Image Quality measure in the Promoting Interoperability program based on the concerns described above, particularly regarding measure validity/reliability and implementation challenges and burdens.**

Hospital-Acquired Condition (HAC) Reduction Program

CMS seeks feedback on potential future patient-safety related eCQMs in the HAC Reduction program. The stated goals of this program are to encourage hospitals to improve patients' safety and apply best practices to reduce their rates of infections associated with health care. CMS has stated that HAC measures should align with best practices among other payers and the needs of the measures' end users. Measures should reflect widely accepted criteria established in medical literature. Indeed, the set of six measures currently in use in the HAC include the Agency for



Healthcare Research and Quality (AHRQ) developed Patient Safety Indicators PSI 90 composite set and the National Healthcare Safety Network (NHSN) Healthcare-Associated Infections (HAI) measure set; both sets meeting the standard of “widely accepted criteria established in the medical literature.” The HAC measures are event-focused, indicating rates or volumes of infections or adverse events (Pressure Ulcer Rate, Post-operative Sepsis Rate, Post-op Acute Kidney Injury Requiring Dialysis Rate, Catheter-Associated UTI incidence).

These HAC measures have been well-vetted and undergone extensive testing and “recalibration” before implementation in the HAC program. Additionally, there are vast amounts of resources (NHSN HAI resources: <https://qualitynet.cms.gov/inpatient/measures/hai/resources>; AHRQ Patient Safety Indicators resources: <https://qualitynet.cms.gov/inpatient/measures/psi/resources>) providing experientially developed recommendations of evidence-based interventions through Centers for Disease Control (CDC) required reporting to the NHSN on HAI incidence, as well as detailed guidance, specifications, and methods for calculation for each measure.

CMS is proposing to adopt into the HAC program several safety eQMs currently included in the IQR program (i.e., Hospital Harm—Opioid-Related Adverse Events eQOM, Hospital Harm-Severe Hypoglycemia eQOM, and Hospital Harm-Severe Hyperglycemia eQOM). Within this rule, the agency is also seeking comment on the inclusion of three new eQMs (also proposed for the IQR program for CY 2025 implementation) into the HAC Reduction program – Hospital Harm-Acute Kidney Injury eQOM, Hospital Harm-Pressure Injury eQOM and the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults.

The ACR has substantial concerns with CMS including the Excessive Radiation Dose or Image Quality (Excessive Radiation Dose) measure in the HAC program, primarily that it misaligns with its stated goals and approach of the HAC program. The Excessive Radiation Dose measure is not clinically event-focused; instead, it measures aggregated performance of radiation dose or image quality across all included CT exams and is not indicative of patient specific harm. This measure is not designed to assess harm to an individual patient. It is not analogous to a hospital-acquired infection, or a radiation burn for which harm to a patient can be clearly tracked (through adverse event reporting). This measure, at best, may identify a potential for harm but does not clearly or specifically identify cases of harm and is incongruent with the current and other proposed HAC measures. Characterizing CT exams above the CT Dose or Image Quality thresholds inappropriately implies that these are reportable safety or harm events to individual patients, which could result in unintended consequences, like patients refusing needed tests based on misguided fear or misunderstanding performance information.

CMS asks for comments on measures introduced in the HAC Reduction program that address emerging high-priority patient harm events or equity gaps regarding the rate and severity of patient harm events and how the HAC Reduction Program supports CMS’ goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting. The proposed Excessive Radiation Dose or Image Quality measure addresses



none of these goals, as delineated in the comments above. **The ACR does not support the use of the Excessive Radiation Dose measure in the HAC Reduction program.**

Conclusion

The ACR appreciates the opportunity to comment on the IPPS proposed rule. As stated in our introduction, the ACR is a strong advocate and proponent for patient radiation safety, as demonstrated by our many efforts, alliances, and collaborations. As evidenced by numerous commenters during the measure review process, many in the healthcare community strongly support programs and efforts for optimization and management of radiation dose associated with medical imaging. Although the ACR has outlined various concerns with the proposed measure, we are aligned with its goal. We seek to work in partnership with this stakeholder community and CMS to identify and implement measures addressing radiation dose and safety that are methodologically and scientifically sound, provide meaningful feedback and improvement opportunities, have transparent data collection and calculation methods, and are as least burdensome as possible. We hope these comments provide valuable input for your consideration.

If you have any questions, please do not hesitate to contact Samantha Shugarman at sshugarman@acr.org or Judy Burleson at jburleson@acr.org.

Respectfully Submitted,

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