American College of Radiology

June 6, 2024

Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-1808-P
Mail Stop C4-26-05
7500 Security Boulevard,
Baltimore, MD 21244-1850

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals

The American College of Radiology (ACR), representing over 40,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services' (CMS) fiscal year 2025 proposed rule on Hospital Inpatient Prospective Payment System and Policy Changes. The ACR would like to thank CMS for the opportunity to provide feedback.

42 CFR 412.87 - New Technology Add-on Payment (NTAP)
Per the FY 2022 IPPS/LTCH PPS final rule, CMS continues to be interested in collecting public comments on issues related to determining newness for technologies that use AI, an algorithm, or software.

- *How these technologies may be considered for the purpose of identifying a unique mechanism of action;*
- *How updates to AI, an algorithm, or software would affect an already approved technology or a competing technology;*
- *Whether software changes for an already approved technology would be considered a new mechanism of action; and*
- *Whether an improved algorithm by competing technologies would represent a unique mechanism of action if the outcomes were the same as an already approved AI new technology.*

The ACR recommends that CMS consider revisions to the New Technology Add-on Payment (NTAP) rules under 42 CFR 412.87 to establish an alternative pathway for high-value AI technologies. We recognize there may be some crossover with the existing §412.87(c) alternative pathway for "certain transformative new devices;" however, the eligibility criteria for the new AI-specific alternative pathway should focus more on clinical value and public stakeholder engagement.

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Currently, eligibility for the §412.87(c) alternative pathway is primarily determined by internal Food and Drug Administration (FDA) staff-level decisions regarding which products are included in the FDA Breakthrough Device Program. However, that program was established to prioritize internal FDA resources and assist companies with successful navigation of FDA's regulatory processes—it was not intended to inform CMS payment policy decisions, and is not limited to AI or other digital health technologies. FDA is not required to consider a product's value to the Medicare patient population as part of a Breakthrough Device designation. Moreover, due to the internal, nonpublic setting of these designations, physician experts and other stakeholders do not have prior knowledge or input into which specific products are included by FDA staff in that program.

Therefore, a new, high-value AI-specific alternative pathway under §412.87 could be created by CMS with determinations of "newness" based on whether the technology enables a clinically valuable task for the Medicare patient population not previously achievable without the technology. "Uniqueness" should be determined by whether the technology addresses a high-value clinical use case not previously addressed by other available technologies or medical procedures. CMS' understanding of "value" to the Medicare population should be guided primarily by input from physician-experts/specialists in the related fields as well as product performance data.

Additionally, for all technologies included in the AI-specific alternative pathway, CMS should require ongoing, systematic performance data collection via a clinical data registry or similar mechanism. This activity would enable evaluations into the ability of the AI technology to perform requested transactions over time and, potentially, to better understand the value of the technology to clinical end-users and Medicare patients. Lessons learned from performance data collection could inform long-term payment decisions after the technology is no longer eligible for NTAP.

CMS should also require participating manufacturers to collaborate with relevant physician specialty communities to identify other considerations that optimize the performance and clinical value of the high-value AI technology, such as end-user training/experience and applicable medical use parameters/standards. This additional information should be communicated clearly and transparently to relevant health care facilities and end-users, and should go beyond the limited scope of product data that is accessible via FDA regulatory documentation. For example, a product's "intended user" description in a 510(k) summary is often overly broad, so the qualifications of the end-user to enable optimal performance with the technology and value to Medicare patients should be communicated as part of NTAP inclusion. Optimal use information should be presented by the manufacturer and considered by CMS during initial NTAP consideration.

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Finally, CMS should consider sponsoring a public event with FDA and relevant medical/public stakeholders to inform the future requirements of any AI-specific NTAP alternative pathway.

We hope you find these comments provide valuable input for your consideration. If you have any questions, please do not hesitate to contact Kimberly Greck at kgreck@acr.org or Christina Berry at cberry@acr.org.

Respectfully Submitted,

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