RADIOLOGICAL SOCIETY OF NORTH AMERICA
820 JORIE BLVD., SUITE 200, OAK BROOK, IL 60523-2251
TEL 1-630-571-2670 FAX 1-630-571-7837
RSNA.ORG

RSNA® Radiological Society of North America

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Re: [Docket No. FDA-2025-P-5560], Exemption From Premarket Notification: Radiology Computer-Aided Detection and/or Diagnosis Devices and Computer-Aided Triage and Notification Devices

The Radiological Society of North America (RSNA) is a leading global organization representing over 52,000 radiologists and medical imaging professionals across 150 countries. Radiology and medical imaging are among the most data-intensive fields in medicine, and AI-driven technologies have begun to transform clinical practice. Radiology has experienced the highest rate of medical AI tool development and deployment, with more than 75% of the over 1,000 Food and Drug Administration (FDA)-cleared AI algorithms designed for radiological applications.

RSNA appreciates this opportunity to provide comments regarding FDA's Notice, Exemption From Premarket Notification: Radiology Computer-Aided Detection and/or Diagnosis Devices and Computer-Aided Triage and Notification Devices [Docket No. FDA-2025-P-5560].

Overview

RSNA recognizes the legitimate challenges identified in this petition but opposes the proposed exemption as an inadequate and potentially harmful solution. Approval would eliminate essential safeguards that the FDA relies upon to confirm the safety and effectiveness of AI-enabled medical devices, thereby increasing the risk to both patients and healthcare providers. The regulatory checkpoints currently in place serve a critical function by requiring rigorous review, validation, and oversight—processes that are pivotal to maintaining high standards of patient safety and clinical care. Removing these checkpoints could result in devices entering the market without sufficient evidence of their reliability or clinical benefit, potentially exposing patients to harm and undermining physician confidence in AI-assisted diagnostic tools.

Patient safety must remain the central pillar of any discussion surrounding AI governance and regulatory approaches in healthcare. A regulatory framework that allows new AI-enabled devices to be deployed in clinical care without premarket evaluation shifts risk from developers to patients and clinicians. Unlike traditional medical devices, failures in radiology AI may be silent, manifesting as missed findings, delayed diagnoses, or inappropriate triage rather than overt device malfunction. Without premarket assessment of performance, limitations, and intended use, such failures may go unrecognized while directly affecting patient outcomes. The petition's proposed exemption would further exacerbate these challenges by allowing new AI technologies to bypass FDA premarket review entirely, removing a critical checkpoint at which issues related to generalizability, clinical integration, and safety are often first identified. For adaptive, data-driven systems that function as cognitive decision-support tools, the absence of premarket evaluation is inconsistent with a risk-based approach to patient protection.

AI models have grown more complex. Modern foundation models can perform a broad range of tasks with minimal task-specific training. At the same time, vendors have variable access to real-world patient data to train and validate models. Prospective clinical trials in the space of AI/ML-enabled medical devices remain relatively lacking, with most models in medical imaging trained on retrospective data alone. Furthermore, the proposed exemption would not be limited to incremental modifications of existing technologies. It would permit entirely new radiology computer-aided detection, diagnosis, triage, and notification products, including those based on novel architecture, data sources, or technical approaches, to enter clinical use without FDA premarket review. Moreover, the petition suggests that a previous 510(k) clearance and under the same classification should allow the manufacturer to be exempt from subsequent clearance. However, this assumes a premise that is not supported by the evidence.

Model performance is highly context-dependent, shaped by the specific training data, patient population, imaging modality, disease prevalence, and clinical workflow in which the device is deployed. A model trained for mammography does not necessarily confer the same performance for lung nodule detection or brain cancer follow-up. The patient population and risk factors are different. Even the images look vastly different, spanning radiographs, computed tomographic images, nuclear medicine, and magnetic resonance imaging, obtained using different physics and mathematics principles, and each affected by unique artifacts. Furthermore, the literature on distribution shift has repeatedly shown that models validated in one setting may degrade significantly when applied in another, even within the same clinical domain. One successful product from a vendor does not guarantee another one. Each product still requires rigorous, application-specific evaluation; each new intended use introduces distinct failure modes that can only be identified through dedicated analytical and clinical validation. Streamlining regulatory review based on a developer's prior track record risks conflating engineering capability with clinical validity — an assumption that the existing premarket framework is specifically designed to test rather than presume. From a patient safety perspective, the absence of independent premarket oversight for new technologies that directly influence diagnostic decision-making, and clinical prioritization represents a significant and unacceptable regulatory gap.

Moreover, existing post-market surveillance infrastructure for AI/ML devices remains underdeveloped, meaning that the removal of premarket review would leave essentially no systematic checkpoint at which safety and effectiveness are independently assessed. Under the petition, physicians would be asked to integrate new devices into patient care based on trust in the developer rather than trust in the evidence — a standard not accepted for other medical technologies and one that should not be accepted here. The objective should not be the least possible regulation, but the right regulation, regulation that is smart, adaptive, and grounded in a shared responsibility to protect patients. Federal approaches to AI oversight should be risk-based and proportional, focusing the greatest regulatory attention on applications that directly influence clinical decision-making or patient outcomes. Streamlined regulatory pathways and clear guidance can, and should, coexist with robust safety guardrails. When designed appropriately, regulation serves not as a barrier to innovation, but a foundation for trustworthy progress, ensuring that AI enhances, rather than undermines, the integrity of medical practice and patient care.

For these reasons, RSNA urges the FDA to decline this petition in its current form and instead pursue regulatory modernization that strengthens, rather than removes, oversight of AI-enabled devices.

AI-Enabled Devices Require a Unique Regulatory Approach

AI innovation in medical imaging is often constrained by regulatory frameworks designed for static technologies rather than adaptive systems. The FDA's authority to regulate medical devices is rooted in the 1976 Medical Device Amendments to the 1938 Federal Food, Drug, and Cosmetic Act, which were written for human-operated, and largely unchanging, devices. As a result, AI tools are regulated under Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD) frameworks that do not fully accommodate continuous learning, recalibration, or iterative improvement.

Under current approaches, many AI models are required to remain "locked" following clearance or approval, limiting the ability to implement updates that could preserve accuracy, reliability, and safety over time. This rigidity can be misaligned with the realities of clinical practice, where patient populations, imaging protocols, and care environments evolve continuously. In such settings, the inability to make controlled updates may increase, rather than reduce, clinical risk.

Many radiology practices report that AI models do not perform as expected when applied to their specific patient populations, necessitating rigorous local testing and validation prior to clinical implementation. Radiology practices have also learned that AI models must be monitored closely to prevent "diagnostic drift," in which even minor changes to algorithms, input data, or clinical context can result in clinically meaningful differences in output. These challenges are amplified by the current lack of standardization across AI tools, as algorithms designed for similar purposes may generate outputs using different formats, thresholds, or assumptions. As a result, modifications to AI tools must be transparent and readily available for revalidation by end users to ensure continued alignment with clinical expectations and patient safety.

Existing mechanisms, such as the FDA's Predetermined Change Control Plans (PCCP) and related pilot programs, present valuable opportunities for the safe and flexible deployment of AI in clinical settings. However, these tools remain voluntary and inconsistently implemented. PCCPs could become a robust means for safeguarding patient safety and increasing physician and patient trust in AI-enabled medicine. To realize this potential, the PCCP framework should be strengthened and made mandatory, incorporating essential additional safeguards. RSNA acknowledges that the FDA must modernize its regulatory strategies for AI-enabled devices. However, we emphasize that any changes should be based on a risk-based framework that prioritizes patient safety and maintains public trust.

Recommended Framework for Safe and Effective AI Regulation in Radiology

RSNA proposes a framework to enhance the safety, transparency, and effectiveness of AI-enabled devices in clinical practice. Our recommendations focus on five key areas: (1) implementing a dual-reporting system so both vendors and end users can report performance deviations; (2) requiring detailed version histories and documentation for all AI tool modifications; (3) establishing rigorous, standardized validation criteria to ensure models perform reliably across different clinical settings; (4) formalizing mechanisms for end-user feedback to inform ongoing improvements; and (5) strengthening and mandating PCCPs to support safe, adaptive innovation.

RSNA recommends that the FDA requires AI tool developers to adopt standards governing algorithmic outputs and post-deployment modifications, including explicit mechanisms to identify, monitor, and mitigate performance variation related to data composition, population characteristics, and clinical context. Transparency around how

outputs are generated and how changes are introduced is essential for safe integration into complex clinical workflows, particularly in radiology environments where multiple AI tools from different vendors may be deployed concurrently.

RSNA further recommends that FDA require vendors to document and disclose all changes to AI tools through clear version histories and detailed modification documentation. Ready access to this information would allow radiology practices to compare software versions, validate updates, and troubleshoot unexpected performance changes. Long-term access to prior software versions is also critical to confirm diagnostic consistency, support root-cause analysis, and ensure continuity of care when discrepancies arise following updates.

Vigorous and standardized validation criteria are necessary to ensure that AI models are safe and effective across clinical settings and patient populations. Validation protocols should explicitly assess model performance across relevant patient and clinical subgroups and include clear criteria for identifying and addressing performance variability. RSNA encourages FDA to require developers to disclose training and validation data sources, dataset composition, and methodologies used to assess and manage performance differences, including subgroup analyses. Transparent reporting of these elements will help to enable healthcare providers to better understand model limitations, support responsible deployment, and maintain high standards of patient safety and clinical care.

While RSNA recognizes that current PCCP frameworks emphasize vendor self-monitoring, we have concerns that self-monitoring alone may be insufficient in complex clinical environments such as radiology. Radiology practices often deploy multiple AI tools from different vendors simultaneously, each with distinct functions, outputs, and update cycles. These tools may interact with shared workflows, data sources, and clinical decision processes in ways that individual vendors may not be positioned to fully observe or anticipate. In such settings, reliance solely on vendor-reported deviations risks leaving clinically meaningful performance issues undetected.

To strengthen oversight while preserving flexibility, RSNA recommends a dual-reporting model that allows both vendors and end users, like radiologists and healthcare organizations, to report observed deviations in AI tool performance directly to the FDA. In addition, RSNA encourages the FDA to establish a formal mechanism through which end users can request modifications or updates to PCCPs based on real-world experience. Radiologists may identify context-specific performance issues, population-related limitations, or workflow interactions that were not evident during initial development or testing but that materially affect safety or effectiveness in practice. Creating structured pathways for this feedback would promote collaboration among developers, clinicians, and regulators, support continuous improvement, and help ensure that AI tools remain aligned with evolving clinical needs while prioritizing patient safety.

Conclusion

Broad exemption from premarket notification would permit novel radiology AI products to enter clinical practice without independent assessment of safety or effectiveness, undermining patient trust and exposing patients to avoidable risk. Unlike traditional software, AI system behavior may vary across clinical contexts, patient populations, imaging protocols, and patterns of use, even in the absence of explicit software updates. Effective oversight must therefore address not only how a system is designed to operate, but also how it performs in real-world clinical settings over time. Clinicians and regulators should have appropriate visibility into the parameters,

assumptions, and trade-offs influencing AI outputs, particularly when those outputs inform clinical decision-making. Such transparency is essential to support accountability, enable meaningful monitoring, and ensure patient safety. Congress should consider updating FDA's statutory authority to explicitly support continuous performance monitoring, standardized reporting of performance degradation and drift, and clearly defined post-deployment safety requirements. Such authorities would help ensure that adaptive AI systems maintain clinical reliability over time while allowing for controlled improvement as clinical environments evolve.

RSNA supports efforts to modernize regulatory approaches to better reflect the lifecycle realities of AI. However, the most effective solution to the concerns raised by the petitioner is not to circumvent premarket review altogether. Instead, we should focus on strengthening FDA's existing approach, including requiring PCCPs that incorporate robust safeguards—specifically, a dual-reporting system and structured end-user feedback mechanisms. By implementing these measures, we can ensure both transparency and accountability, fostering safer, more trustworthy integration of AI tools into clinical practice.

RSNA values the opportunity to provide input on this FDA Notice. For additional information or questions, please contact RSNA's Director of Government Relations, Libby O'Hare (eohare@rsna.org).

Sincerely,

Carolyn C. Meltzer, MD
Chair of the Board
Radiological Society of North America