American College
of Radiology™

February 24, 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: (Docket No. FDA-2025-P-5560) *Medical Devices; Exemption from Premarket Notification: Radiology Computer-Aided Detection and/or Diagnosis Devices and Computer-Aided Triage and Notification Devices*; **Comments of the American College of Radiology**

The American College of Radiology (ACR)—professional association representing more than 40,000 physicians practicing diagnostic radiology, interventional radiology, radiation oncology, and nuclear medicine, as well as medical physicists—appreciates the opportunity to comment on the Food and Drug Administration (FDA) notice of a petition, *Medical Devices; 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), published in the Dec. 29, 2025, *Federal Register* (90 FR 60730).

I.   ACR AI Initiatives

ACR established its Data Science Institute (DSI) in 2017 to advance the safe, effective, and clinically meaningful use of AI in radiology. ACR DSI works collaboratively with radiology professionals, industry, government partners, patients, and other stakeholders to develop the programs, standards, and resources needed to support the responsible implementation of AI that improves patient care. This work includes:

- Defining clinically relevant use cases intended to guide the development of useful imaging AI (ACR Define-AI).
- Establishing and making broadly available the first national recognition program for safe and effective implementation of AI in imaging practices (ACR ARCH-AI), which is now used in many different sites across the U.S.
- Creating opportunities to monitor the effectiveness of AI models in real-world clinical practice, including the first large-scale quality registry for AI performance monitoring (ACR Assess-AI).
- Participating in the Healthcare AI Challenge, a multi-institution collaborative effort dedicated to radiologist crowdsourced evaluation of draft reports created by general purpose and increasingly, radiology specific generative AI solutions.
- Maintaining a comprehensive, curated online repository of FDA cleared radiology AI models (including model cards, training/characteristics) to help radiologists choose optimal candidate models for their practices and patients (ACR AI Central).
- Organizing thought leadership activities regarding the regulatory, legal, and ethical issues associated with radiology AI and the emerging use of generative AI in radiology.

Additionally, ACR has drafted a future practice parameter for radiology AI use, which will be presented for review and approval by the ACR Council in Spring 2026 and which is intended to

inform a [future practice accreditation program](#) akin to accreditation of radiology imaging and therapy modalities. Practice accreditation will address the need for site-level quality management programs to oversee the use and performance of clinical AI models at local institutions before, during, and after deployment. Accreditation could provide additional quality-focused guardrails beyond manufacturer- or device-level oversight.

II.   Petition Background

A radiology AI manufacturer submitted a citizen petition in Oct. 2025 under 21 CFR 10.30 requesting that the FDA grant a partial exemption from 510(k) premarket notification procedures for certain radiology AI devices with added special controls. The petition covers four radiology AI device types and six product codes under 21 CFR Part 892:

- CADx under §892.2060 (product code POK)
- CADe ("medical image analyzer") under §892.2070 (product code MYN)
- CADe/x under §892.2090 (product codes QBS and QDQ)
- CADt under §892.2080 (product codes QAS and QFM)

Eligibility would be conditional on manufacturers with at least one prior clearance for a CAD-type device, with CADt eligibility restricted to prior CADt clearances due to key special controls differences. Manufacturers would still need to comply with the Quality Management System Regulation (QMSR), which requires them to maintain an ISO-13485-based quality system to ensure devices are consistently safe and effective. Existing establishment registration and device listing requirements would continue. Exempted devices would need to meet all special controls in the existing device classification regulations under Part 892. The petition would also add new special controls, including:

- Creating/implementing a post-market plan, including performance monitoring.
- Ability to export retrievable AI results.
- Access to an electronic version of instructions for use within the user interface.
- Limiting device distribution to sites that implement device-specific training programs, including differentiation of qualified end users as those with necessary qualifications and training to independently interpret medical images without the aid of the device.

Although filed administratively as a §10.30 citizen petition, FDA is processing it under the FD&C Act Sec. 510(m)(2), which requires FDA to publish a notice and rapidly issue a final order. FDA published its required notice on Dec. 29, 2025, indicating that a decision is expected 120 days later (i.e., in or around late-April 2026). If FDA grants the petition, the final order will directly amend the classification regulations in 21 CFR Part 892 without conventional notice-and-comment rulemaking.

III.   General Considerations for the FDA

ACR is a staunch advocate for the advancement of safe, effective, clinically valuable AI that meets radiologists' needs, is interoperable with their workflow, and enhances their ability to provide appropriate, high-quality imaging care for patients. ACR also strongly supports the FDA's essential role in ensuring that radiologists, patients, and the broader public have reasonable assurance of the safety and effectiveness of AI-enabled medical devices.

As with the petitioner and the agency, ACR wants to ensure radiologists can access and use these devices with confidence in their real-world performance. ACR urges FDA to ensure that any future decision/final order maintains reasonable assurance of these devices' safety and effectiveness—a key function that underpins the confidence that patients, physicians, and health systems place in FDA oversight.

Additionally, ACR is extensively on-record supporting regulatory framework enhancements, including increased AI model transparency, continuous post-deployment AI performance monitoring, and clearly defined "qualified end user" role requirements to ensure that primary clinical users are capable to help mitigate risk for patients. The petitioner's documentation accurately references many of these positions and supporting papers. We believe these pillars are necessary considerations for manufacturers, clinical sites, end-users, regulators, and payers, regardless of the FDA's future decision on this petition.

IV.   Radiologist Perspectives Shared with ACR

ACR solicited member feedback on the petition in early Jan. 2026, shortly after publication of the FDA's *Federal Register* notice. Respondents consistently emphasized that patient safety should remain the agency's highest priority and cautioned that, while most manufacturers would comply in good faith, a partial exemption could unintentionally enable strategically flexible interpretations. Members noted that companies with less experience in FDA regulatory processes or in radiology workflows may be particularly vulnerable to making suboptimal exemption decisions.

Radiologists also emphasized that FDA clearance of a single CAD device does not necessarily demonstrate the maturity or robustness of a manufacturer's quality management system across all CAD technologies, particularly when different body areas, modalities, or specific required imaging findings introduce distinct technical and clinical considerations. Accordingly, if FDA were to grant the petition, many radiologists believe the exemption criteria should undergo refinement via modifications to better reflect relevant experience, enhance regulators' oversight capabilities, and strengthen special controls to clarify/standardize baseline expectations for AI transparency and post-market monitoring.

Respondents expressed concern that many newly exempted devices entering the U.S. market in a brief period could exceed the FDA's practical capacity for timely identification and correction of issues, including cases in which devices are marketed under inaccurately selected or attested product codes. If such a scenario were to occur, it could complicate the ability of radiologists and other physicians to identify dependable and clinically appropriate products, inadvertently hindering adoption. For these reasons, members stressed the importance of enhanced transparency and appropriate monitoring mechanisms to support AI discoverability and ensure appropriate clinical use. FDA may also consider ways to narrow or limit exemption eligibility and scope.

Radiologists were concerned that the partial exemption would effectively redirect responsibility for assuring device safety and effectiveness from the regulator and manufacturer to deployment sites and end-users without any corresponding change in payment policy or reimbursement to support the additional work required. Under current reimbursement structures, providers of radiology services receive no dedicated payment for the validation, monitoring, or ongoing quality-assurance activities necessary to confirm that AI-enabled devices perform as intended in clinical environments. Large institutions with extensive compliance, testing, and evaluation infrastructures

may be able to absorb these responsibilities, but most radiology practices, particularly small and community providers, will necessarily rely on manufacturers' assurances and may lack the resources to independently verify device performance. Any regulatory framework that reduces premarket FDA review should therefore consider the practical burdens placed on clinical sites and the uneven capacity across the delivery system to manage them.

Eliminating the FDA 510(k) clearance for exempted devices could complicate Category I CPT code additions and changes to support reimbursement. In the current AMA CPT criteria, "all devices and drugs necessary for performance of the procedure or service have received FDA clearance or approval when such is required for performance of the procedure or service." While AMA could interpret an optional partial exemption as that device not requiring clearance, the CPT Category I criteria rely on regulatory status clarity, widespread real-world adoption, and robust published clinical evidence (including data supporting 510(k) premarket notification procedures).

Finally, radiologists have expressed concern about general uncertainty regarding how the conditions associated with a 510(m)(2) exemption might influence future provider liability. Although such exemptions do not directly alter the liability framework relative to 510(k) clearance, changes in regulatory posture, expectations, or status assumptions could indirectly affect how courts or institutions interpret the applicable clinical standard of care.

V.   ACR Recommendations
If the FDA were to grant the petition with modifications, ACR recommends the following:

1.   Maintain or Strengthen Petitioner's Special Control Requiring a "Qualified End User"
ACR strongly agrees with the petitioner that manufacturers should distribute exempted devices only to facilities that implement and maintain the required device-specific training program, particularly to ensure that primary clinical end users possess the qualifications and training necessary to independently interpret medical images without reliance on the device. This represents an important risk-mitigation measure for radiology CAD devices in general, regardless of the FDA's determination on this petition. However, FDA should clarify the device-specific training program—either through revisions to the special controls or dedicated guidance—to specify the criteria of an adequate program, how its effectiveness and continuity should be verified, and which parties are responsible for implementation and ongoing monitoring.

Historically, intended use statements for radiology AI devices have sometimes contained ambiguous user descriptions which fail to distinguish primary clinical end users (e.g., appropriately trained physicians) from other personnel who may have secondary or operational interactions with the device. In certain cases, this ambiguity appears linked to enterprise-wide deployment models, but it can also lead to misinformed medical use that extends beyond what the FDA would consider part of the "practice of medicine," and that may meaningfully alter the device's risk profile when applied in real-world clinical care. The addition of this special control would help promote appropriate distribution and use by signaling that exempted devices should be operated by individuals with the requisite clinical qualifications to ensure device safety and effectiveness.

If the FDA maintains that primary clinical end users of exempted devices must be individuals with the qualifications to independently interpret medical images (for example, radiologists or other physicians in imaging specialties), the relevance of reader improvement studies as a premarket evidentiary requirement may diminish. These users already possess the expertise assumed in the

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regulatory framework. Accordingly, FDA could consider revising the applicable special controls so that requirements for "improved reader performance" or "improved assisted-read detection/diagnosis" instead defer to standalone performance criteria, reflecting the importance of accuracy and emphasizing the device's intended role in augmenting—rather than substituting for—expert clinical judgment.

2. Enhance Transparency for Exempted Devices in Lieu of 510(k) Summaries

In the current marketplace, 510(k) summaries are the primary source of device background, performance, and limitations accessible to the public-at-large. For example, ACR's AI Central repository uses 510(k) summaries as the foundational component of shared device information. If the FDA grants a partial exemption, 510(k) summaries would no longer be available for exempted devices, further restricting model information access as an unintended effect.

The petitioner includes new transparency requirements, such as access to the instructions for use in the user interface—which are also critically important—however, this would be specific to post-adoption scenarios in which the end user is accessing the device. ACR recommends that the FDA adopt a replacement public transparency mechanism as a special control to enable device visibility to potential customers and other public stakeholders. This would help ensure that physicians, patients, and institutions maintain pre-deployment access to essential safety and performance information about exempted devices. Specifically, the FDA should require the following:

- A publicly accessible AI device information summary or "model card" that is centrally posted on the FDA's website or a third-party resource (for example, ACR's AI Central);
- Public access to a post-market plan summaries via the same centralized resource(s) (i.e., FDA's website or a third-party resource like ACR's AI Central), as these summaries should be available to purchasers/prospective deployers before vendor contracts are signed; and,
- Public availability of post-market results summaries (for example, modeled in part on the 522 Postmarket Surveillance Studies Database or the ACR's Assess-AI registry).

3. Expand MAFs to Support Compliance Visibility to Regulators

If feasible under the agency's existing statutory authorities, FDA should consider expanded and enhanced use of [Device Master Files (MAFs)](link) to provide FDA with nonpublic, premarket information supporting compliance with special controls. Enhanced MAFs could include evidence packages, validation methodologies, risk-management approaches, and other technical materials that manufacturers would otherwise submit as part of a 510(k). This expansion would empower the FDA to access key device information without requiring the initiation of an inspection, while still protecting proprietary content. The partial exemption pathway itself would be optional, and therefore, enhanced MAFs would remain voluntary even if mandated for exempted devices.

If the petition were granted with modifications, regulators must rely on standardized, auditable documentation to support QMSR inspections, enforcement actions, assessment of device modifications, and ongoing oversight of post-market performance. Expanded use of MAFs would not substitute for the 510(k) process, but it would provide a middle ground of regulator-accessible information describing how exempted devices meet the applicable special controls and maintain safety and effectiveness throughout the total product lifecycle. This approach would also help ensure that the shift toward greater post-market reliance is supported by adequate regulatory visibility into how the exempted devices are designed, validated, and maintained.

4. Require Third-Party National Registry Participation

The FDA should require, via added special controls or refinements to the petitioner's proposed special controls, that manufacturers participate in a trusted, independent national registry capable of benchmarking device performance across diverse clinical environments based on collection of real-world data from front line practices, including stratified performance reporting by patient and technical subgroups. Registry participation would create a standardized and trusted mechanism for continuous monitoring, add a data source potentially powering an oversight layer beyond QMSR and manufacturer-affiliated mechanisms of monitoring, facilitate early detection of performance drift, and prevent the volumes of exempted devices from exceeding practical performance monitoring capabilities.

We recognize that many manufacturers maintain their own post-market performance-monitoring capabilities pursuant to the QMSR; however, there remains a need to ensure baseline standardization and interoperability of these processes to support regulatory visibility and enable external assessments, including evaluating whether the exemption pathway is functioning as intended. In addition, manufacturer-controlled post-market monitoring mechanisms should, where feasible, interoperate with qualified third-party registry programs or be subject to independent assessment to ensure that exempted devices are monitored by an external entity and included in appropriate benchmarking or comparative analyses.

The FDA could implement this through two complementary requirements for the special controls:

- To enable post-market monitoring, manufacturers must demonstrate that their device is interoperable with (i.e., conforms to the standardized ingestion specifications of) a qualified, national, third-party registry that compares site-level radiology AI device performance to nationwide benchmarks (for example, ACR Assess-AI); and,
- Exempted devices may be distributed only to clinical sites that have contractually committed to actively participating in the registry throughout the lifecycle of the device, ensuring that real-world performance data is consistently available and being compared across settings.

5. Align Exemption Timing and Eligibility with QMSR Maturity

FDA's QMSR took effect on Feb. 2, 2026, replacing the former Quality System Regulation (QSR) via incorporation by reference of ISO 13485:2016. If feasible under its existing authorities, the FDA should consider whether to delay the effective date of these exemptions until QMSR implementation is fully mature within the AI industry and the FDA.

FDA should also consider clarifying how AI-specific risk-management expectations under the QMSR apply to key AI software device considerations such as model drift, retraining triggers, bias evaluation, and real-world performance variation. As these issues directly affect clinical safety and reader performance, the FDA could reinforce that QMSR documentation (e.g., risk-management files, internal audits, and management reviews) must support continued transparency, traceability, and standardized communication of performance information from manufacturers to clinical users.

In addition, the FDA should consider establishing some form of QMSR-based maturity criteria as a prerequisite to eligibility. Not all manufacturers will have equally mature ISO-aligned quality

systems, and the risk-based oversight envisioned under the QMSR assumes stable, well-functioning quality processes. FDA could, for example, conduct initial readiness assessments and/or targeted audits before allowing a manufacturer its first exemption. FDA might also require evidence of validated post-market performance monitoring systems capable of detecting clinically meaningful changes in performance over time.

6. Maintain or Narrow the Product-Code-Based Scope of the Exemption

ACR agrees with the petitioner that product-code-level differentiation should serve as an important mechanism for managing the scope of any partial exemption. Product codes provide the FDA with an administratively precise and operationally practical means to distinguish among subtypes of devices within a single classification regulation and to apply differing regulatory expectations accordingly. This approach is particularly important because classification regulations group devices under a broad general intended use, and specific indications or technological variations within that scope can carry different risk considerations. Use of product-code granularity, therefore, enables the FDA to maintain premarket review requirements for devices whose characteristics, intended uses, or risk considerations differ from those the agency determines can safely be exempted.

Accordingly, any partial exemption should be strictly limited to the specific product codes identified in the petition (MYN, POK, QBS, QDQ, QAS, and QFM), or even to a narrower subset of those codes, or perhaps to dedicated product codes established by the FDA to further target the exemption to appropriate CAD-subtype devices and to manufacturers with demonstrably mature QMSR capabilities. The exemption should not automatically extend to other radiology AI devices, including newer or less mature technologies that may subsequently fall under the broader classification regulations at 21 CFR 892.2060, §892.2070, §892.2080, or §892.2090.

Moreover, because exemption eligibility depends on the accuracy of manufacturer-selected product codes rather than FDA assignment through the 510(k) process, the FDA should further require a brief justification and an administrative verification of product-code selection at the time of device listing for exempted AI devices to prevent inadvertent or strategic misclassification and increase regulatory visibility.

7. Ensure Prior Clearance Relevance to Exempted Device Technology

We recognize the petitioner's rationale for grouping device types based on similarities in their special controls. Importantly, meaningful differences can exist between these device types, including differences in intended use, clinical context, imaging modality, and underlying technical considerations. While we expect most radiology software manufacturers to comply in good faith, the proposed eligibility criteria could inadvertently incentivize "strategic" 510(k) submissions designed solely to obtain a qualifying clearance and thereby unlock downstream exemption eligibility for more complex, novel, or less-mature technologies.

To help mitigate this risk and ensure that exemption eligibility reflects genuine experience with the specific technology to be exempted, the FDA should consider narrowing eligibility in three additional ways:

- **By device type:** Require that a manufacturer hold at least one prior clearance for the same device type as the exempted product, consistent with how the petition already treats CADt

devices under 21 CFR 892.2080. Applying this logic to §892.2060, §892.2070, and §892.2090 could help ensure that manufacturers have demonstrated experience with the specific type of CAD functionality for which they intend to use the exemption.

- **By technological characteristics:** Future CAD devices developed with novel or nascent AI technologies—for example, foundation model-enabled CAD functions—may present safety, performance, and risk-management considerations that differ materially from those associated with more mature AI technologies. Accordingly, eligibility conditions should require that a manufacturer's exempted devices employ model paradigms and technological approaches that present equivalent risk profiles to those used in the prior device clearance(s). For example, a prior clearance for a narrow, task-specific device (e.g., one utilizing a traditional convolutional neural network) should not confer exemption eligibility for a new device powered by a broad, general-purpose foundation model unless performing a similar task-specific function.
- **By imaging modality, body area, and disease/context:** Require prior clearance in a clinically relevant domain to ensure manufacturers have experience with the modality-specific, anatomy-specific, or disease-specific considerations that shape dataset selection, performance characteristics, human-factors factors, and deployment risks. Because model development and data representation for 2D imaging differ fundamentally from those for 3D cross-sectional imaging, exemptions should not bridge these major modality differences. For example, a prior clearance for a 2D chest X-ray CADe device should not grant exemption eligibility for a 3D chest CT CADe device. Conversely, to promote innovation, prior experience within the same modality and CAD category—such as a manufacturer leveraging experience from a CT chest CADe to develop a new CT abdomen/pelvis CADe—demonstrates sufficient transferable risk-management experience to warrant exemption eligibility.

8. Expand Audits/Inspections and Reporting

In the petition's proposed framework, manufacturers would remain subject to inspections/audits, documentation obligations, and other requirements under the QMSR. To ensure that real-world device performance remains safe and effective, the FDA should expand its inspection strategy to include both randomized audits and targeted, risk-based audits of manufacturers' post-market monitoring activities. Such audits should be supported by timely analysis of monitoring data so the agency can rapidly identify and respond to emerging performance concerns.

Consider that relying solely on the legacy Manufacturer and User Facility Device Experience (MAUDE) database is inadequate for radiology AI devices. MAUDE is a passive, complaint-driven system and is not well suited to detecting nuanced performance degradation or context-specific failures of AI-enabled radiology tools in clinical workflows. Furthermore, discordance between an AI result and radiologist interpretation of an individual finding at the time of service rarely rises to a level of concern for the radiologist to interrupt their routine workflow to report it to MAUDE (for which workflow support is lacking). More commonly, the interpreting radiologist enshrines their binding impression in the radiology report and moves on. FDA should therefore leverage structured post-market monitoring data required under this petition and explore establishing a new, dedicated reporting pathway (i.e., separate from MAUDE criteria and processes) through which clinical sites and or third-party registries can directly submit performance issues in a streamlined manner. Such a mechanism would complement manufacturer-reported monitoring results and give the FDA earlier insight into potential safety or effectiveness issues.

9. Set Clear Expectations for Exempted Devices Via New/Revised Guidance Content

FDA should develop new and/or revised guidance for industry with subsections that set pre- and post-market expectations specifically for exempted radiology AI devices, including acceptable methodologies for satisfying added special controls. The FDA could consider delaying the availability/effectiveness date of the exemptions until guidance content revisions are available to inform manufacturers of the FDA's expectations moving forward.

10. Establish a Mechanism for Ongoing Evaluation and Reconsideration of the Exemption

FDA should commit to periodic reevaluation of the implementation, including any real-world impacts on patients and physicians, and remain prepared to rapidly reverse or rescind the exemption through the appropriate process.

More than anything else, ACR stresses the importance of getting this decision right for patients, radiologists and other physicians, and innovators despite the aggressive statutory timing restrictions of the 510(m)(2) process. We welcome continued discussion with the FDA on this and other AI safety and effectiveness topics. For questions about this submission, please contact Michael Peters, ACR Senior Director, Government Affairs, at mpeters@acr.org.

Sincerely,

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