December 1, 2025

RE: FDA-2025-N-4203
Submitted electronically via regulations.gov

The Health Innovation Alliance (HIA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) *Measuring and Evaluating Artificial Intelligence-enabled Medical Device Performance in the Real-World* Request for Public Comment. We support the FDA's effort to unencumber innovation and progress while ensuring patient safety, consistent with the AI Action Plan's emphasis on winning the artificial intelligence (AI) race by enabling AI adoption.

HIA is a diverse coalition of patient advocates, health care providers, consumer organizations, employers, technology companies, and payers who support the commonsense use of data and technology to improve health outcomes and lower costs. We believe AI is a critical part of the future of health care along with the future of medical devices.

Recommendations

Given HIA's almost two decades of leadership on federal health IT policy and its expert membership that created guiding principles for how AI ought to be used in healthcare, we recommend the following:

1. Continue the Risk-Based Approach

FDA's existing risk-based framework for medical devices has proven effective and should remain central to AI-enabled device regulation. Oversight should be proportionate to risk, mitigated by factors such as human involvement, reliance on technology, and data transparency. This approach ensures appropriate patient protections while avoiding undue burden. Different risk levels warrant different controls – from mandatory post-market studies for high-risk devices to lighter oversight for lower-risk administrative applications. Requiring the use of a one-size-fits-all mitigation framework for all health AI applications irrespective of risk and context could fail to reach the intended outcomes while hampering innovation. In our Use Cases for AI Tools to Improve Health Care report, we discuss this issue and lay out considerations for risk according to different use cases.

2. Maximize Existing Regulatory Tools and Industry Best Practices

The FDA possesses robust post-market authorities ideally suited for AI-enabled device oversight, including post-market controls, registries, and adverse event reporting systems. As of 2025, the FDA has cleared or approved over 1,000 devices with AI/ML components dating back to 1995. We encourage the FDA to make full use of these existing authorities rather than creating new regulatory structures. Where gaps exist, address them narrowly.

The FDA can also make use of private sector best practices, such as "service cards" which enable a clinician, patient, or caregiver to understand the intended purpose of an AI model (in this case, deployed within a device). This would encourage responsible and informed use of the technology through greater transparency about limitations of a particular device.

3. Unlock the PCCP Pathway's Full Potential

The predetermined change control plan (PCCP) pathway represents an excellent model for AI-enabled devices, allowing approved iterative changes post-clearance so devices can evolve within bounds rather than undergo full approval for each modification. However, this pathway's flexibility and value are not reaching full potential. The FDA has been reticent to approve a wider variety of evolutionary pathways for AI-enabled devices, limiting PCCP utility.

While appropriate safeguards for AI/ML model evolution are essential, the FDA must allow room for innovators to innovate. The FDA has invested appreciable resources in establishing the PCCP pathway and should engage with stakeholders to maximize its effectiveness.

The critical question is: Are PCCPs, when properly approved, sufficient to address the concerns raised in this RFI? Or is the FDA seeking to either (1) augment PCCP requirements or (2) require additional post-market surveillance for all devices? Regardless, HIA encourages the FDA to maximize the PCCP pathway rather than create parallel regulatory apparatus.

4. Provide Flexibility on Human Oversight

The FDA should avoid bright-line mandates on human involvement. The appropriate role of humans and compliance requirements should be risk-based – determined by the data, context, and individual use case – and driven by what best improves patient outcomes. For example, mandating human-in-the-loop for clinicians reviewing AI-highlighted areas of concern in medical imaging may be appropriate rather than technology making final diagnostic decisions. Conversely, AI may appropriately automate lower-risk administrative tasks without burdensome reporting or monitoring requirements for every instance.

5. Align with International Standards Selectively

The FDA should adopt or align to international standards that fit the U.S. approval system and increase predictability for developers. Aligning with relevant standards like ISO 42001 (AI Management System) would provide more consistent requirements across the product lifecycle while being less prescriptive than some alternatives. This would build trust and accountability on the part of developers and deployers of AI, by having more transparent and predictable rules of the road.

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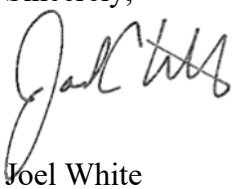
While some international standards may make sense to align with, not all should be utilized in this manner. The FDA should avoid replicating burdensome approaches, such as the UK's technology-specific regulation of AI medical scribe technology – a low-risk use case that doesn't warrant medical device classification. Centering a risk-based approach, as mentioned above, could be a useful litmus test to consider which international standards could be more readily repurposed.

Conclusion

AI-enabled medical devices present tremendous opportunities for American healthcare. From accelerating drug discovery to streamlining care delivery, AI can address entrenched health sector challenges. The FDA's regulatory framework must enable this innovation while protecting patients through proportionate, risk-based oversight using existing, proven tools.

We thank FDA for this opportunity, have provided additional perspective in the appendix, and look forward to continued collaboration.

Sincerely,



Joel White
President

APPENDIX: Supporting Details

HIA Principles for AI in Healthcare

The Health Innovation Alliance established five key principles for responsible AI development and use in the health sphere including AI-enabled medical devices:

1. **Risk-Based Approach**: Regulation of AI in health care should be proportionate to risk.
2. **Transparency**: Patients, users, and regulators should have access to information on how AI is being used, including the underlying research or validation methods informing its outputs, while maintaining the confidentiality of proprietary information.
3. **Privacy**: Any use of health information by AI should be compliant with current laws and regulations, including HIPAA.
4. **Responsibility**: Developers and users of AI programs in health care should adopt and adhere to best practices and processes, including appropriate human oversight.

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5. **Fairness**: Government investments in AI development and deployment should prioritize wide availability for all users.

Strategic Architecture

A risk-based model already exists and has proven effective within the Food and Drug Administration (FDA) regulation of medical devices, including AI-enabled devices. We encourage the FDA to continue to build upon this record of success and maintain risk as a central tenet of any revisions to approval processes and post-market surveillance in AI-enabled medical devices. A risk-based approach to AI tools would ensure the appropriate level of oversight while avoiding undue burden or bureaucracy where it is not needed. We urge governance and oversight structures to be built in proportion to the risk of the intended use of the device. Not every AI-enabled medical device needs to be held to the same standard – for either approval or post-market surveillance – to maintain appropriate patient protections, regulator awareness, and device manufacturer monitoring. Any controls for higher risk use cases could include oversight mechanisms that already exist for certain products (e.g., mandatory post-market studies for high-risk medical devices) or human involvement.

Reliability & Trust

As with any transformative technology, a core component of establishing public trust and ensuring reliable results is to have common rules of the road. AI-enabled medical devices vary greatly depending on the type of model and how the model is deployed. However, best practices and good governance models are crucial first steps to make sure that there are sufficient oversight and documentation.

HIA recommends that the FDA partner and work with other government agencies, developers, and deployers across the health care and life sciences sectors to encourage the creation and adoption of AI-enabled medical devices best practices and processes, to establish these common rules of the road. This will not only promote trust as the public learns what safeguards are in place but will also promote consistency and verifiability with a proper documentation trail.

Another core component of establishing trust is developers of these devices having documentation sufficient to inform users about the tools they are using. This documentation should include information about security, privacy, fairness, bias, intended use constraints, necessary oversight requirements, and functionality limitations. Different contexts and audiences require different explanations and levels of transparency, according to the application, the specific use case, and the resulting risk profile.

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