



October 19, 2026

Kyle A. Diamantas, JD
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

**Re: Considerations for the Regulation of Generative AI-Enabled Medical Devices:
Discussion Paper and Request for Feedback (FDA-2026-N-7874)
Submitted electronically via Regulations.gov**

Dear Acting Commissioner Diamantas:

The Workgroup for Electronic Data Interchange (WEDI) writes today in response to the “Considerations for the Regulation of Generative AI-Enabled Medical Devices: Discussion Paper and Request for Feedback” released on August 18, 2026. We are pleased to submit comments on the potential for regulation of generative artificial intelligence (GenAI)-enabled medical devices.

WEDI was formed in 1991 by then Department of Health and Human Services (HHS) Secretary Dr. Louis Sullivan to identify opportunities to improve the efficiency of health data exchange. Named in the Health Insurance Portability and Accountability Act (HIPAA) legislation as an advisor to the Secretary of HHS, WEDI is the leading multi-stakeholder authority on the use of health information technology (IT) to efficiently improve health information exchange, enhance care quality, and reduce costs. With a focus on advancing standards for electronic administrative transactions, and promoting data privacy and security, WEDI is recognized and trusted as a formal advisor to the Secretary. Our diverse membership includes health plans, providers, standards development organizations, health IT vendors, clearinghouses, federal and state government agencies, and patient advocacy organizations.

WEDI applauds the work by the Food and Drug Administration’s (FDA) Center for Devices and Radiological Health in addressing the role and implications of GenAI-enabled medical devices. These devices, alongside existing health IT software, algorithms, and AI-enabled devices have the potential to redefine the diagnosis, treatment, monitoring, and ongoing care of patients. While many see the promise of significant innovation and breakthroughs, there remain significant risks and repercussions with this novel technology that must be considered and mitigated, which the discussion paper addresses.

Introduction

AI-powered tools are being increasingly used to support clinical decision-making, identify patterns in large volumes of health data, improve diagnostic accuracy, predict patient risks, and

personalize treatment plans. Beyond clinical applications, AI automates routine administrative tasks, allowing clinicians to focus more time on patient care. As health care organizations continue to face demands related to cost, workforce shortages, interoperability, and consumer expectations, AI has emerged to assist organizations leverage data more effectively while supporting better outcomes, improved experiences, and a more efficient health care system.

Currently, common applications of AI in health care include diagnosis and treatment recommendations, patient communication, engagement and adherence, administrative activities, and others. Although there are some examples where AI may perform health care tasks as well or better than humans, there remain critical implementation issues that need to be addressed prior to wide-scale deployment of this technology. As AI and related technologies become increasingly established in the health care sector, it is important to recognize that AI in health care is not a single technology, but rather several, as outlined in the discussion paper.

GenAI raises the bar, and stakes, in its utility in clinical care. Medical devices embedded with GenAI technology have the ability to analyze data and then “think” and evolve beyond the basic programming for a specific function. This may provide flexibility to meet the changing needs of the patient, but it also introduces concerns about how to monitor the GenAI-enabled device to ensure it is performing correctly and not causing harm. Critical consideration must be given to the role of the clinician in managing, overseeing, and controlling GenAI-enabled devices.

Comments

The following are five critical issues related to the general use of AI in health care:

- I. AI and the patient perspective
- II. Opportunities that AI offers health care providers
- III. The potential for bias in the data leveraged for AI
- IV. Other challenges AI presents for health care
- V. Need for FDA action

I. AI and the patient perspective

From the patient’s perspective, the hope is that by using AI in health care, specific clinical outcomes will be improved as well as their overall health. Patients, however, are also concerned about the potential loss of personal connection with their clinician. Given the choice, patients envision AI “helping the clinician come up with better treatments for me” is far preferred to AI “getting between me and the clinician.” It is important to remember that many patients who are seeking health care are not feeling well and are at their most vulnerable. When patients are seeking care, they really value relationships and trust. Patients fear that high tech will replace high touch.

II. Opportunities that AI offers health care providers

AI has the potential to assist clinicians and improve patient care. AI-enabled systems can analyze unstructured clinical notes, prepare reports, transcribe patient interactions, and conduct conversational exchanges, along with meeting many other needs. Improvements to clinical care that can be accomplished with the use of AI include:

- Clinical decision making (Computer Decision Support)
- Early predictions of disease for patients and populations
- Retrospective analysis of disease through analysis of data sets
- Extraction of information from large patient populations
- Augmenting or even replacing human judgment in certain functional areas, such as detection of relevant findings for pathology, radiology, and other medical testing
- Reduction of medication errors and adverse events

II. The potential for bias in the data leveraged for AI

Bias in AI has the potential to cause harm and must be considered. Biases can be embedded in and related to AI, and that can, if not monitored, perpetuate disparities in health care, causing harm. Clinicians need to understand the AI being used in medical devices and how the data is driving decision-making. It is critical to have a transparent data source or sources, so clinicians know what the data was trained on. “Black box” algorithms, AI models that are not transparent with their data sources and how they get to their decision-making endpoints, have the potential of creating a lack of trust by clinicians and patients.

AI systems learn over time. Data originally used, however, can become stale or the population it serves could evolve. Recalibration of the data, algorithms, and targets on a consistent basis is necessary to ensure those changes are factored in and remain current.

III. Other challenges AI presents for health care

The following is a limited list of other challenges that health care must consider related to AI:

- AI “trust” factor (patients and clinicians)
- Integration issues enabling AI to work seamlessly with existing health IT technology
- Lack of interoperability between AI solutions
- Ethical issues related to the loss of empathy, kindness, and appropriate behavior when using AI, as it does not possess compassion
- Unreal expectations about the use of AI, or results derived from the use of AI
- Concern regarding patient data privacy and security
- Need for continuous training of data sets
- Unknown liability issues for clinicians and developers when AI is involved in an adverse outcome

IV. Need for FDA action

While progress is being made to develop AI-specific regulations to bolster existing laws and regulations, more guardrails and focus on safety are needed. AI models and their derivative products are becoming increasingly powerful and impacting health care delivery much faster than the government can react. With the incredible pace of development, it is imperative that the government regulate AI effectively.

Existing AI Regulation

The Office of the National Coordinator for Health Information Technology's (ONC's) maintains the ONC Health IT Certification Program to ensure that certified health IT meets specific functionality, security, and operational capabilities. The program is voluntary for software developers, but hospitals and clinicians must use certified systems when participating in certain Centers for Medicare & Medicaid Services (CMS) payment programs. ONC-certified health IT currently supports the care delivered by 99% of hospitals and 91% of office-based physicians nationwide¹.

ONC, through its "Health Data, Technology, and Interoperability (HTI)" regulations, has continued to advance EHR and clinical technologies. "HTI: Certification Program Updates, Algorithm Transparency, and Information Sharing" (HTI-1) established the first-of-its-kind transparency requirements for AI and other predictive algorithms included in certified health IT. Specifically, developers of predictive decision support initiatives (DSIs) included in certified health IT were mandated to provide detailed "model cards" disclosing data sources, algorithm limitations, and bias mitigation metrics to ensure AI tools were fair, appropriate, valid, effective, and safe.

The "HTI: ASTP/ONC Deregulatory Actions to Unleash Prosperity" (HTI-5) proposed rule published on December 29, 2025, proposes revising these certification requirements for AI algorithms to the point that the HTI-1 mandate would have limited affect. WEDI received feedback in our development of comments for the proposed rule that physicians found the HTI-1 requirements valuable when making informed decisions about AI purchases, implementation, and use. Specifically, physicians have identified trust, transparency, and knowledge about AI use and functionality as a centerpiece in their ability and desire to use AI in their practice. Transparency and information about limitations, data use, privacy, and bias are necessary for the use of AI in clinical decision making. While HTI-5 has not yet been finalized, we strongly encourage the FDA to continue to increase transparency of AI and AI tools to help clinicians and patients "navigate" this new technology. Having more information available about the data sets AI models are trained on will boost transparency and increase the level of trust in AI technology.

Additional need for action

Concerns have been raised over AI and its potential to make mistakes, spread misinformation, and perpetuate biases. While self-regulation may be appropriate for some less severe AI use cases, other more critical uses, including GenAI, require close monitoring. A challenge for policymakers is simply knowing what questions to ask. As this technology and how it is applied to health care is still new, the industry is continuing to grapple with how best to manage it.

The following tenets should underpin the FDA's work on the use of AI in health care:

¹ National Trends in Hospital and Physician Adoption of Electronic Health Records, June 2026, <https://healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records/>

- **Encourage innovation and research.** While government oversight over the use of AI in health care is imperative, that oversight should not stifle innovation or research or discourage the development of new and enhanced AI use cases.
- **Ensure transparency.** For patients, clinicians, and others that leverage AI, it is critical that each understand how the AI model was developed, what data was used in the creation of the tool, and what, if any, expected biases.
- **Maintain accountability.** AI vendors and those health care entities that use AI must be accountable for any problems, errors, or other issues that negatively impact patient care.
- **Protect the privacy and security of patient data.** Health care has the HIPAA privacy and security regulations as guardrails to ensure patient data is appropriately captured, used, and shared. As AI tools are developed and deployed by entities not covered under HIPAA, both vendors and end users of AI must be required to adhere to appropriate privacy and security safeguards.

WEDI calls on the FDA to consider the following in its work on GenAI and other AI-related uses:

1. **Enhancing AI oversight.** Oversight of AI policy and activity will be critical, as much of this work is establishing a baseline for the implementation and use of AI in health care. An AI oversight structure should include an FDA-specific strategy for the development, implementation, and ongoing monitoring of AI tools, products, and devices.
2. **Expanding Funding.** FDA funding, and overall government funding, should be increased for AI development, deployment, and oversight to advance the appropriate use of AI in health care.
3. **Increasing Research.** FDA research on AI in health care should be accelerated, including:
 - Sharing of clinical findings through open-source methods.
 - Reviewing data sets AI models for their clinical applicability and overall clinical value.
 - Continuous training of AI models using appropriate data sources.
4. **Developing consistent definitions.** AI and AI-related definitions must be established to ensure consistency and provide clear direction for the private sector.
5. **Establishing environment for FDA and private sector collaboration.** As AI capabilities grow, it is imperative that the FDA work in tandem with the private sector to ensure the latest AI capabilities are understood and appropriate policies are developed and implemented.
6. **Drafting a consumer AI “bill of rights.”** When AI is used to make or contribute to a decision that impacts a patient, especially in an adverse way, the patient has a right to know that AI was used and how it was used.
7. **Developing AI “nutrition labels.”** Nutrition-type labels can educate patients and clinicians on the use of AI and warn them of potential harm. Further work is needed on developing and implementing these resources.
8. **Requiring transparency.** Patients have a right to know when AI is used to make or contribute to a decision that impacts their care. Clinicians need to retain their role in

reviewing data, analyzing findings, and making decisions for their patient's care and treatment.

9. **Classifying low-risk, medium-risk, and high-risk AI.** While AI can impact health care in many ways, the potential for danger or harm will vary significantly depending on the AI and how it is being used. Categorizing AI in terms of its potential to cause harm will facilitate the development of any supporting policy.
10. **Prioritizing the development of AI privacy and security policies.** The inappropriate use of AI has the potential to improperly disclose protected health information leading to a decreased level of trust by patients and clinicians. Development of supporting privacy and security policies specific to AI is critical.
11. **Establishing standards.** Standards and guidelines for AI use, including recognizable labels, that can be applied to AI will help patients and clinicians trust that the AI will function according to the set expectations. Standards would demonstrate that the AI met defined qualifications and allow the users to identify any possible risks.
12. **Focusing on education.** National, coordinated education for both patients and clinicians focused on general AI principles, specific applications, models, and algorithms is essential.
13. **Requiring reporting of adverse events.** An adverse event reporting process should focus on capturing specific details of the event and analyzing the data to understand the issues that led to the event. Collecting these events and results of reviews can be used to improve AI and make it as safe as possible.

Conclusion

WEDI appreciates the FDA's efforts to solicit public feedback on its discussion paper on regulation of GenAI-enabled medical devices. The use of AI in health care is growing at a rapid pace, and much work is needed to ensure its appropriate use and prevent any potential harm. We appreciate the opportunity to share our perspective on this important work. We hope our comments will serve to assist you as you move forward with your work. Please contact Robert Tennant, WEDI Executive Director, at rtennant@WEDI.org with any questions on these comments and recommendations.

Sincerely,
/s/
Merri-Lee Stine
Chair, WEDI

cc: WEDI Board of Directors