



Dr. Martin A. Makary  
Commissioner of Food and Drugs  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

FDA-2024-D-4488: Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations

*Submitted via [www.regulations.gov](https://www.regulations.gov).*

Dear Commissioner Makary,

Thank you for the opportunity to share comments for the draft guidance titled "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations." This guidance represents a step forward in the work to ensure the safe and effective use of AI-enabled devices in healthcare.

The American Medical Informatics Association (AMIA) is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, and public health experts who bring meaning to data, manage information, and generate new knowledge across the health and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

The draft guidance outlines comprehensive recommendations for the lifecycle management and marketing submissions of AI-enabled devices, emphasizing transparency, bias control, and performance monitoring. These principles align with several values and positions articulated by AMIA's [Public Policy Principles](#).

AMIA's principles highlight the importance of patient empowerment, health IT safety, and the ethical use of artificial intelligence (AI) in healthcare. The draft guidance's focus on transparency and bias control is particularly commendable, as it ensures that AI-enabled devices benefit all relevant demographic groups and maintain high standards of safety and

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effectiveness. This approach is consistent with AMIA's belief that transparency around the development of health technologies is critical for trust and accountability.

Furthermore, the draft guidance's emphasis on performance monitoring and cybersecurity is essential for maintaining the integrity and reliability of AI-enabled devices. AMIA supports the development of robust data sharing infrastructures and the implementation of data standards to ensure the safe and effective use of health data. The guidance's recommendations for ongoing performance monitoring and cybersecurity measures align with these principles, promoting a secure and trustworthy healthcare environment.

### **Patient Data Privacy**

Patient data privacy is a critical aspect of healthcare that must be addressed to ensure the protection of individuals' personal health information. The draft guidance emphasizes the importance of safeguarding patient data throughout the lifecycle of AI-enabled devices. This includes implementing robust security measures to prevent unauthorized access, ensuring data integrity, and maintaining confidentiality.

AMIA's Public Policy Principles underscore the need for transparency in how patient data is used and disclosed. Patients should have complete access to their health data in both machine- and human-readable formats, and they should be informed about who has accessed their data and for what purposes. The draft guidance's focus on patient data privacy aligns with these principles, promoting trust and accountability in the use of AI-enabled devices.

### **Ethical Considerations**

Ethical considerations are paramount in the development and deployment of AI-enabled devices. The draft guidance emphasizes the importance of ethical principles such as autonomy, beneficence, non-maleficence, and justice. These principles ensure that AI-enabled devices are designed and used in a manner that respects the rights and dignity of patients, promotes their well-being, avoids harm, and ensures fairness and equity in healthcare.

AMIA's Public Policy Principles advocate for the ethical use of artificial intelligence in healthcare, highlighting the need for transparency, accountability, and fairness. The draft guidance's emphasis on ethical considerations aligns with these principles, ensuring that

AI-enabled devices are developed and deployed in a manner that prioritizes patient safety, trust, and equity.

### **Performance Monitoring and Cybersecurity**

Furthermore, the draft guidance's emphasis on performance monitoring and cybersecurity is essential for maintaining the integrity and reliability of AI-enabled devices. AMIA supports the development of robust data sharing infrastructures and the implementation of data standards to ensure the safe and effective use of health data. The guidance's recommendations for ongoing performance monitoring and cybersecurity measures align with these principles, promoting a secure and trustworthy healthcare environment.

AMIA's principles highlight the importance of transparency in the development of health technologies, including AI-enabled devices. The draft guidance's focus on transparency and bias control is particularly commendable, as it ensures that AI-enabled devices benefit all relevant demographic groups and maintain high standards of safety and effectiveness. This approach is consistent with AMIA's belief that transparency around the development of health technologies is critical for trust and accountability.

### **Importance of User Training**

User training is essential for the successful implementation and utilization of AI-enabled devices. The draft guidance emphasizes the need for comprehensive training programs to ensure that healthcare professionals, patients, and caregivers are well-equipped to use these devices effectively. Proper training helps users understand the device's functionalities, interpret its outputs accurately, and apply the information in clinical decision-making.

AMIA's Public Policy Principles highlight the importance of digital literacy and ongoing education for healthcare professionals. Training programs should be designed to address the specific needs of different user groups, including clinicians, technicians, and patients. By providing adequate training, healthcare organizations can maximize the benefits of AI-enabled devices, improve patient outcomes, and enhance overall healthcare delivery.

The draft guidance on AI-enabled device software functions is a document that looks to address aspects of lifecycle management, transparency, bias control, performance monitoring, patient data privacy, ethical considerations, and user training. It aligns with



many principles and positions of AMIA, ensuring that AI-enabled devices are safe, effective, and trustworthy.

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Thank you for your time and consideration. If you have questions or require additional information, please contact Tayler Williams, AMIA's Senior Manager of Public Policy, [twilliams@amia.org](mailto:twilliams@amia.org).