

January 30, 2025

Senator Bill Cassidy, M.D., Chair
Committee on Health, Education, Labor, and Pensions
United States Senate
455 Dirksen Senate Office Building
Washington, DC 20510

Senator Bernie Sanders, Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
332 Dirksen Senate Office Building
Washington, DC 20510

Dear Chair Cassidy and Ranking Member Sanders,

On behalf of the HIMSS Electronic Health Record (EHR) Association, we are pleased to provide commentary on the role of government in regulating Artificial Intelligence (AI) generally and specifically in the use of AI in health care, with a focus on ensuring the responsible design, development, and deployment of such technology in healthcare. In 2023, the Senate HELP Committee sought input on this critical matter, which we provided in a [letter dated September 22, 2023](#). With the regulatory landscape for AI on the cusp of dramatic change and with more states considering and enacting laws impacting our members, we once again offer our feedback.

As the national trade organization of EHR developers, our 28 member companies serve the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers across the United States. The EHR Association is committed to advancing health information technology to improve healthcare delivery and patient outcomes. During the past year, we launched a new AI Task Force for representatives from our member companies to share their input regarding Senator Schumer's AI roadmap, the work of the House of Representatives AI Framework, the plethora of state laws introduced in the 2024 legislative session, the CHAI Framework, and other initiatives. The increased focus on AI amongst policymakers is highly relevant as our members prepare to deploy software capabilities that comply with new transparency requirements for Decision Support Interventions (DSI) involving artificial intelligence and machine learning capabilities, as outlined in the EHR certification program. Additionally, most are currently developing, piloting or have already deployed generative AI solutions to serve as an additional tool that can be applied to solve the many challenges we face in healthcare.

The new EHR Association AI Task Force has developed a set of key principles that our members believe are most critical to the safe and responsible development of AI in the healthcare space. These principles build on the priorities shared in our 2023 letter and reflect our position on current issues impacting AI governance. It is our strong preference that regulation take place at the federal level to ease the burden of compliance and create uniform reporting and transparency standards; however, we want to share with you the core issues that we would like to see addressed in legislation at all levels.

AdvancedMD	Elekta	Foothold Technology	MEDITECH, Inc.	PointClickCare
Altera Digital Health	EndoSoft	Greenway Health	Modernizing Medicine	Sevocity
athenahealth	Experity	Harris Healthcare	Netsmart	TruBridge
BestNotes	Epic	MatrixCare	Nextech	Varian – A Siemens
CureMD	Flatiron Health	MEDHOST	NextGen Healthcare	Healthineers Company
eClinicalWorks			Office Practicum	Veradigm

High-Risk Clinical Workflows vs. Other AI Use Cases

Regulations should focus on technologies with direct implications for high-risk clinical workflows and recognize that not all AI use cases in healthcare have a direct or consequential impact on patient care and, ultimately, patient safety.

Many standard definitions of “high-risk AI” utilize the definition of “health care services” from 42 U.S.C. § 234(d)(2) and incorporate any technology that could *relate to* the provision of health care, including administrative workflows like scheduling and staffing, supply chain and billing and coding solutions. We recommend a more granular approach that differentiates high-risk and low-risk workflows in healthcare, leveraging existing frameworks that stratify risk based on the probability of occurrence, severity, and positive impact or benefit to ease the reporting burden on all technologies incorporated into an electronic health record that may be utilized at the point of care.

In addition, for true high-risk use cases, the EHR Association recommends developers incorporate “human-in-the-loop” or “human override” safeguards during the development and implementation of these tools, along with other reasonable transparency requirements.

Liability

Regarding liability for outcomes that may involve AI technologies, we encourage the use of existing frameworks for medical malpractice. EHR developers should not be responsible for harm caused by the inappropriate use of an AI tool for a particular patient when they have otherwise responsibly developed AI and provided appropriate documentation regarding the scope of use to an end user.

The EHR Association believes clinicians and other end users should bear ultimate liability for an AI tool’s use when developers have provided the necessary transparency to ensure users fully understand the tool’s functionality. Clinicians are best positioned to evaluate the appropriateness of an AI-enabled tool for a specific patient and to obtain informed consent when required.

Deployer-Focused Principles

Regulations affecting deployers or end users of AI technology should account for the varying levels of internal IT support available to healthcare practices of different sizes. The EHR Association encourages the development of regulations that are manageable and applicable for both large health systems and small independent clinics, ensuring equitable access to AI tools regardless of practice size. The digital divide in this country is significant and can contribute to further inequities in care, it is important that there is equitable distribution of AI tools across various healthcare institutions.

To ensure that small independently owned practices can also benefit from AI tools, regulations and guidance for deployer adoption, use, and post-implementation monitoring must be reasonable and considerate of diverse care settings and capabilities. This approach will maximize the opportunity for widespread adoption and effective use of AI technologies.

Industry Specific Regulations

The EHR Association has reviewed numerous frameworks for AI development, deployment, and monitoring that are overly prescriptive in specifying how AI tools should be built and tested. Additionally, many state laws regulating AI fail to adequately account for the sensitive nature of patient

information and the privacy and security obligations necessary to safeguard it, resulting in an overly broad regulatory approach.

We believe regulations should prioritize outcomes and risk mitigation rather than prescribing technical specifications for how these tools must be built. Regulations should also be tailored to specific industries, recognizing that the healthcare sector, with its emphasis on patient safety, requires distinct considerations compared to consumer technologies in other areas.

We encourage regulators to focus on addressing their primary concerns and the most significant risks to patients, requiring developers to demonstrate thoughtful consideration of these issues. Rather than mandating specific steps and stages for development, training, and implementation, regulations should allow companies to enhance their current software development lifecycle (SDLC) to incorporate appropriate safeguards.

Ongoing Monitoring

The EHR Association agrees that ongoing post-deployment monitoring of AI models is essential. Given the nature of generative AI, it is crucial to ensure quality and mitigate the risk of model drift as these tools are used by end users. The constantly evolving healthcare information and data landscape heightens the risk of models becoming outdated over time.

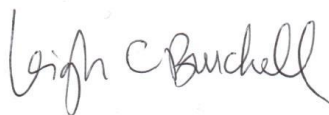
We support rules that require transparency regarding EHR developers' plans for keeping information up to date after the initial launch and visibility into when a model was last updated. This approach will help maintain the overall quality of AI models and provide end users with the necessary information to determine whether a tool operates appropriately for a particular patient. Transparency in update practices is key to maintaining trust and reliability in AI tools, ultimately improving patient care.

Conclusion

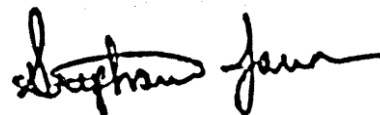
The EHR Association supports the move towards standardizing and regulating AI products that interface with EHR data. With the right regulations and transparency measures in place, AI can significantly enhance the utility of EHR systems and improve patient care.

We appreciate the Senate HELP Committee's efforts to address these critical issues and are ready to collaborate in shaping a future where AI enhances healthcare while safeguarding the rights and safety of Americans.

Sincerely,



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Chair, EHR Association
Altera Digital Health



Stephanie Jamison
Vice Chair, EHR Association
Greenway Health

HIMSS EHR Association Executive Committee



David J. Bucciferro
Foothold Technology



Danielle Friend
Epic



Michelle Knighton
NextGen Healthcare



Ida Mantashi
Modernizing Medicine



Shari Medina, MD
Harris Healthcare

Established in 2004, the Electronic Health Record (EHR) Association is comprised of 28 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.