EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

September 22, 2023

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

Dear Ranking Member Cassidy:

On behalf of the HIMSS Electronic Health Record (EHR) Association, we are pleased to provide feedback on the role of government in regulating the AI industry and ensuring the responsible design, development, and deployment of AI technology in healthcare. We appreciate the Senate HELP Committee's initiative in seeking input on this critical matter that impacts the health and well-being of all Americans.

As a national trade organization of EHR developers, our 31 member companies serve the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs and other health IT across the United States. The EHR Association is committed to advancing health information technology to improve healthcare delivery and patient outcomes. In response to your specific inquiry, we offer the following insights into several key areas of concern regarding the integration of AI with health IT.

Clinical Validation of AI

We recognize the significance of established guidelines, such as those provided by the Food and Drug Administration (FDA) for Software as a Medical Device (SaMD) and the Office of the National Coordinator for Health Information Technology (ONC) certifications. Given that many AI products directly interface with EHR data, it is imperative for these tools to adhere to the highest standards of clinical validity.

Clinical validation, in this context, refers to a rigorous process of evaluating and confirming the effectiveness and reliability of AI systems in a healthcare setting. It entails extensive testing and verification to ensure that the AI's outcomes align with established clinical standards, providing accurate and clinically meaningful results. The assurance of clinical validity is crucial in guaranteeing the trustworthiness and accuracy of AI technologies in healthcare.

Mitigating Bias

Mitigating bias is not just a matter of ethical responsibility; it is also critical for achieving fair and equitable healthcare outcomes. AI systems interfacing with EHR data must be rigorously designed to be free from biases that could potentially harm patient care. We strongly support the implementation of ongoing audits and fairness metrics to ensure that AI remains impartial, particularly when processing a wide array of diverse EHR datasets.

HIPAA and AI

Protecting sensitive health information is non-negotiable in the era of AI-driven healthcare. Patient privacy remains a core tenet of EHR systems. Although emerging technologies have enhanced healthcare delivery and increased patient access to health information, a significant portion of this data remains outside the protective umbrella of the HIPAA framework. Any non-HIPAA regulated AI solutions interfacing with EHRs must be held to privacy standards consistent with HIPAA requirements to guarantee the utmost privacy and security of patient data.

Determining Safe and Appropriate Applications

Ensuring that AI applications are safe and appropriate is essential to prevent adverse events and enhance healthcare quality. Any AI integration with certified health IT products should be thoroughly tested in real-world clinical settings, involving both developers and clinicians. A robust feedback mechanism should be established to monitor and improve the AI's performance continuously.

Liability for Unsafe or Inappropriate AI

Clarity in liability will encourage responsible innovation and accountability. The EHR Association strongly believes in clear ownership and accountability. In cases where AI is integrated into certified health IT products, it is vital to clearly identify and hold the original AI developer accountable for any issues or outcomes directly linked to that AI technology. This transparency simplifies the process of determining responsibility and fosters trust among end-users and patients by ensuring clear lines of accountability.

In conclusion, the EHR Association is supportive of the move towards standardizing and regulating AI products that interface with EHR data. We believe that with the right regulations and transparency measures in place, AI can greatly enhance the utility of EHR systems and, by extension, 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.
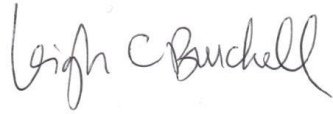
Sincerely,

David J. Bucciferro
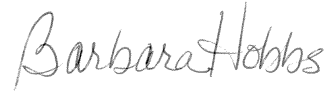Chair, EHR Association
Foothold Technology

William J. Hayes, M.D., M.B.A.
Vice Chair, EHR Association
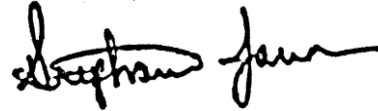CPSI

HIMSS EHR Association Executive Committee

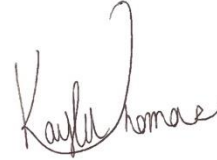Leigh Burchell
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