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July 30, 2020

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: FDA-2018-N-1910

Dear Dr. Hahn,

The Electronic Health Record (EHR) Association welcomes the opportunity to provide the Food and Drug Administration with input on the benefits and risks to patient health associated with software functions excluded from the device definition by the 21st Century Cures Act (Cures).

The EHR Association's 30 member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our core objectives focus on collaborative efforts to accelerate health information and technology adoption, advance information exchange between interoperable systems, and improve the quality and efficiency of care through the use of these important technologies.

Members of the EHR Association strongly support the provisions of the Cures Act codified in Section 3060(a), including adoption of a risk-based framework for applying medical device regulations to software. We appreciate FDA's request for input on benefits and risks for software that does not fit the definition of a medical device, as this provides an opportunity for stakeholders to share information directly, ensuring that legislatively-driven agency decisions continue to foster a patient safety-focused healthcare environment.

The 21st Century Cures Act clarified that certain software functions are not medical devices, including functions that are intended:

1. for administrative support of a healthcare facility;
2. for maintaining or encouraging a healthy lifestyle;

3. to serve as electronic patient records;
4. for transferring, storing, converting the format of, or displaying data; or
5. to provide limited clinical decision support.

EHRs may include some or all of these functions, and we support exclusion of these functions from the definition of a medical device for a number of reasons. While healthcare delivery inherently involves risk, EHRs can help mitigate existing patient safety risks in a number of ways, including those caused by errors in patient identification, medication ordering, and administration. EHRs also provide information that was frequently missed by providers in the days of paper charts, and help prevent delays in diagnostic testing follow-up. While the use of an EHR does introduce the potential for new risks, we believe regulatory oversight from the FDA is not the most efficient way to manage those risks and could, in fact, impede the innovation so necessary in today's rapidly evolving healthcare industry.

EHR developers have a longstanding commitment to patient safety. Instilling a patient safety approach is not solely reactive — it is embedded in the earliest stages of product conception, continues through collaboration with clinicians and other key stakeholders to learn from their experiences, and incorporates the concepts of patient safety in every stage of the development process. The goal is to ensure patients get the best possible care with a clinician experience that is also free from undue burden.

EHRA has provided comments to the FDA on previously-issued draft guidance on clinical decision support. In that response, we suggested that the FDA accept a health IT module's certification to the ONC 2015 Edition (a)(9) Clinical Decision Support criterion as an indication that sufficient information was provided to enable independent review, as certification requires health IT to display "source attributes" about clinical decision support. If the FDA does not accept health IT certification, it would be highly disruptive to the health IT industry, particularly if requirements from the FDA were to not align or add significant additional development and/or regulatory burden to the industry. Additionally, should the rigorous health IT certification process not be considered sufficient, further clarity will be necessary on what would be considered regulated CDS vs. non-regulated CDS. Our comments were shared with FDA in late 2019, and we look forward to updated CDS guidance.

We strongly believe that collaboration between developers and the patient safety community, combined with federal certification requirements, provide sufficient oversight and accountability for healthcare software developers. Further, we believe that additional research about patient safety will likely be forthcoming in ensuing years following changes to Federal regulation under the ONC Interoperability, Information Blocking and Certification rule, and this will enable the industry to continue learning and moving forward without the burden of additional regulatory interference.

EHRA believes the approach taken to codify, within the Cures Act, the FDA's refined jurisdiction when it comes to the oversight of health IT was warranted. Many EHR developers have committed to the EHR Association's EHR Developer Code of Conduct, which specifically addresses the developer community's commitment to patient safety and reflects a long history of collaborative engagement between EHR developers and the patient safety community. Specifically, the principles of the EHR Developer Code of Conduct promote patient safety with commitments to:

- Product design, development, and deployment in support of patient safety, basing our work on recognized standards and guidelines.
- Participation with our clients and recognized bodies, e.g., Patient Safety Organizations (PSOs), in reporting, reviewing, and analyzing health IT-related patient safety events.
- Share best practices with clients for safe deployment, implementation, maintenance, and use of our products and services.
- Implement processes for our clients and their patients to report patient safety concerns discovered during implementation, maintenance, and use of EHRs.
- Notify our clients and offer solutions, should we identify or become aware of a software issue that could materially affect patient safety.
- Recognize the value of our users' participation in discussions about patient safety in appropriate venues.
- Share best practices with EHRA members on topics such as creating a culture of patient safety in health IT organizations, and approaches to include human factors and user experience strategies that reduce cognitive burden.

The EHR Association supports the principles and recommendations of *An Oversight Framework for Assuring Patient Safety in Health Information Technology* from the **Bipartisan Policy Center (BPC)**, originally published in 2013. BPC stated that any oversight framework should recognize the important role of health IT in improving the quality, safety, and cost-effectiveness of care. We believe that the principles of that framework are already effectively met through existing regulation and that additional regulations, with the potential to impose an inflexible and delayed regulatory construct to an industry that must regularly adjust its products to meet customer needs, would be a detriment to patient safety and product innovation.

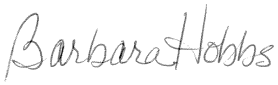
As a major stakeholder in the discussion of technology and safety in healthcare, the EHR Association appreciates the opportunity to share our long-standing commitment to patient safety. We believe that the proposed modifications based on the Cures Act, in conjunction with existing certification requirements, developer quality processes, and cross-industry collaboration, provide the appropriate level of safeguards, while mitigating the risk of an inflexible and slow regulatory construct on an industry that must regularly make rapid adjustments to products. This will ensure that software that is not intended to serve as a medical device is designed, developed, and delivered with appropriate proactive and reactive controls to ensure patient safety, while still leaving sufficient room for innovation.

Sincerely,

Hans J. Buitendijk
Chair, EHR Association
Cerner Corporation

David J. Bucciferro
Vice Chair, EHR Association
Foothold Technology

HIMSS EHR Association Executive Committee



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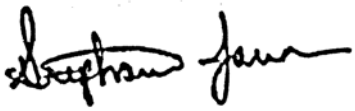

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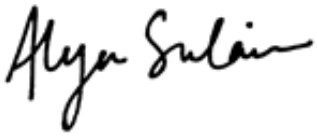

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About the HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of 30 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.