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Scott Gottlieb, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Dr. Gottlieb,

The Electronic Health Record Association (EHRA) welcomes the opportunity to provide the FDA 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).

EHRA strongly supports the provisions of Cures codified in Section 3060(a) and provided our input to legislators during the legislative drafting process. EHRA has also provided comments to the FDA on previously issued draft guidance on clinical decision support, and we strongly support the adoption of a risk-based framework for applying medical device regulations to software. FDA's request for input on benefits and risks for software that does not fit the definition of a medical device provides an additional opportunity for stakeholders to share information directly to ensure legislatively-driven agency decisions continue to foster a patient safety-focused healthcare environment.

EHRA members serve the vast majority of healthcare organizations that use electronic health records (EHRs) and other health information and technology (IT) to deliver high quality, efficient care to their patients. EHRA operates on the premise that the rapid, widespread adoption of health IT has and will continue to help improve the quality of patient care as well as the productivity and sustainability of the healthcare system. 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 EHRA supports the exclusion of these functions from the definition of a medical device. While healthcare is inherently risky, EHRA believes that EHRs can help mitigate existing patient safety risks, including those caused by errors in patient identification, errors in medication ordering and administration, and delays in diagnostic testing follow-up. While EHRA acknowledges that the introduction of an EHR into the healthcare environment does have the potential for new risks, we believe additional regulatory oversight is not necessary to manage those risks.

Given the current administration's philosophy of decreasing overly burdensome regulation and the stated priorities of government agencies tasked with overseeing the nation's healthcare delivery system, EHRA strongly supports the medical device definition provisions of Cures. These provisions will allow EHR developers to focus their efforts on reducing clinician burden by improving data visualization and streamlining the referral process; increasing portability of patient data and patient engagement; developing tools to assist clinicians and patients with addressing the opioid crisis; and furthering standards adoption to promote interoperability.

EHRA believes the FDA approach within Cures is warranted, as many EHR developers have committed to EHRA'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.

The principles of the 2016 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.

EHRA is actively engaged with the nascent National Health IT Safety Collaborative, established as a direct result of Cures legislation, whose stated goals are to analyze reported patient safety events related to health technology, derive safety recommendations, and prioritize where to achieve the greatest impact. EHRA has a proven track record producing best practices through this type of collaboration. For example, EHRA participated in the review and refinement of the *SAFER Guides* with the Office of the National Coordinator for Health Information Technology (ONC) and its contractors in 2014.

The ONC Health IT Certification Program includes requirements for Safety Enhanced Design, Accessibility Centered Design and a Quality Management Systems, which complements existing industry-driven quality activities focused on developing the safest possible software.

One example of an industry-driven initiative is Design Patterns for Safety, published by EHRA in 2017. Created to provide recommendations and bring awareness to the value of design consistencies in high-risk clinical workflows, Design Patterns for Patient Safety is a simple reference guide for EHR system designers and developers that provides best practices from within and outside the health IT industry to reduce both clinical risk and cognitive load for clinician end-users.

While each of the five software functions excluded from regulatory oversight by the 21st Century Cures Act may represent some degree of clinical risk as a result of their vital importance to the healthcare system, EHRA strongly believes that collaboration between developers and the patient safety community, combined with existing self-regulating activities and federal certification requirements, provide sufficient oversight and accountability for healthcare software developers.

As a major stakeholder in the discussion of technology and safety in healthcare, EHRA appreciates the opportunity to share our long-standing commitment to patient safety. We believe that the proposed modifications based on Cures, in conjunction with existing certification requirements, developer quality processes and cross-industry collaboration, provide the appropriate level of safeguards. This will ensure that software not defined as a medical device is designed, developed, and delivered with appropriate proactive and reactive controls to ensure patient safety, while fostering innovation.

Sincerely,

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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of 34 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.