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Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg and Director Shuren:

HIMSS appreciates this opportunity to comment on the [Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications](#) published in the *Federal Register* by the Department of Health and Human Services (HHS) Food and Drug Administration on July 21, 2011.

HIMSS is a cause-based, not-for-profit organization exclusively focused on providing global leadership for the optimal use of information technology (IT) and management systems for the betterment of healthcare. Founded 50 years ago, HIMSS and its related organizations have offices in Chicago, Washington, DC, Brussels, Singapore, Leipzig, and other locations across the United States. HIMSS represents more than 40,000 individual members, of which two-thirds work in healthcare provider, governmental and not-for-profit organizations. HIMSS also includes over 500 corporate members and more than 150 not-for-profit organizations that share our mission of transforming healthcare through the effective use of information technology and management systems. HIMSS frames and leads healthcare practices and public policy through its content expertise, professional development, and research initiatives designed to promote information and management systems contributions to improving the quality, safety, access, and cost-effectiveness of patient care.

HIMSS appreciates the FDA's interest in engaging the community in a dialogue on the requirements for establishing guidance on mobile medical applications. HIMSS notes that many hospitals, health systems, and providers self-developing mobile medical applications, as well as current and future professional developers, do not have experience being regulated as a mobile medical device manufacturer by the FDA. Such entities have limited or no knowledge of the Draft Guidance and overall [FDA medical device classification and regulatory oversight program](#).

Due to this reality, HIMSS encourages the FDA to use every opportunity to educate hospitals, health systems, providers, and current and future developers on correct FDA policies and procedures for achieving success. Education by the FDA is going to be critical to achieving compliance, ensuring patient safety, and promoting innovation in mHealth. We encourage the FDA to consider communicating with these communities in a proactive manner. Such communication keeps innovation flowing in the healthcare market, while also fulfilling the FDA's mission to safeguard the public from preventable harm.

For example, FDA-offered education could be very effective in helping these hospitals, health systems, providers, and future developers understand the FDA process. In the several weeks HIMSS has been talking with members about the Mobile Medical Applications Draft Guidance, the organization has received numerous requests for FDA to clarify its guidance. These requests illuminate a lack of understanding of current FDA policies, including:

- The point where a mobile medical application becomes an accessory to an existing mobile medical device;
- The intended definition of a medical device as outlined in the Food and Drug Act;
- The regulatory triggering mechanism that transforms a mobile medical application or general purpose computer into a medical device; and,
- If a mobile application is not intended to have a medical use, what FDA approaches are best utilized for notifying potential end-users in a healthcare setting.

Clinical Decision Support

One of the many benefits of EHRs includes the ability to improve care at the point-of-delivery with a wide variety of software system support tools collectively known as Clinical Decision Support (CDS). For the purpose of responding to the FDA Draft Guidance, HIMSS suggests that using CDS in broad terms can be a challenge, and that the healthcare community's education and capabilities associated with CDS are different based on user types (doctors, nurses, physician assistants, patients, etc.), clinical setting the user frequents, and type and source of the data used in the CDS process. For the purpose of our response, HIMSS comments focus on CDS associated only with Mobile Medical Applications.

HIMSS recommends that any FDA review of general CDS applications and functionality, especially CDS operating as an extension of an existing EHR, be addressed in separate draft guidance.

The FDA has requested guidance on the assessment of stand-alone software that provides CDS functionality. HIMSS members' experience with CDS is that there are varying degrees of sophistication in both software and provider understanding. CDS data sets can be quite basic, or more sophisticated. For example, providing general clinical knowledge such as a link to, or a summary of, journal articles may not influence the provider's decision to the same extent as a real-time alert that demands attention. Prioritizing the actions of the CDS, and intrusiveness of the information introduced into the decision-making process, are indicative of the level of the CDS' sophistication, and impacts user acceptance.

Due to the extreme variability of current data sets as outlined above, it could be counterproductive for the FDA to receive live clinical data sets for the purpose of validating CDS integrity. It is for this reason that HIMSS does not believe that it is necessary that actual clinical data be submitted to support CDS integrity. In fact, similar to other testing and quality control processes, the data sets should be authenticated by a third party. These test data sets will be validated to ensure they represent the actual clinical data that would be processed by the software in production.

Finally, the FDA has requested comments regarding the specific controls that manufacturers should implement that could change the risk classification or reduce the premarket data requirements for particular types of stand-alone software that provide CDS functionality. HIMSS suggests that when the FDA develops its definition of software assurance, it consider such concepts as software life cycle processes and product conformance to requirements, standards, and procedures. Software Assurance should include the disciplines of software quality, safety, reliability, usability, verification and validation, and in many cases independent verification and validation. This definition is derived from the [NASA Software Assurance program](#) and consistent with the definition of Software Quality accepted by the IEEE.

To effectively implement a software assurance program, HIMSS is recommending that the FDA consider leveraging existing Federal programs and existing best practices to establish a program of software assurance for CDS vendors. These programs include:

- [NASA Software Assurance Program](#)
- [NIST Software Assurance Metrics and Tools Evaluation Program](#)
- [DHS/US-CERT Build Security In Program](#)
- [The Software Assurance Maturity Model](#)

Conclusion:

HIMSS appreciates the opportunity to provide comments to the FDA on the Draft Guidance on Mobile Medical Applications. We look forward to supporting increased guidance and clarity in our continued dialogue with the FDA. If you have any additional questions please contact [Thomas M. Leary](#), Senior Director, Federal Affairs, 703.562.8814.

Sincerely,



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