October 19, 2011

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Draft Guidance for Industry and Food and Drug Administration Staff; Mobile Medical Applications; Availability Docket No. FDA -2011-D-0530].

Dear FDA Staff:

On behalf of the American Medical Informatics Association (AMIA), I am pleased to submit these comments in response to the above-referenced Draft Guidance.   AMIA is the professional home for biomedical and health informatics and is dedicated to the development and application of informatics in support of patient care, public health, teaching, research, administration, and related policy. AMIA seeks to enhance health and healthcare delivery through the transformative use of information and communications technology.

AMIA's 4,000 members advance the use of health information and communications technology in clinical care and clinical research, personal health management, public and population health, and translational science with the ultimate objective of improving health. Our members work throughout the health system in various clinical care, research, academic, government, and commercial organizations.

As health care professionals and informaticians, many of our members are involved in biomedical and health informatics research and evaluation as well as application development and implementation. AMIA is deeply interested in the Draft Guidance as it pertains to a rapidly growing area of informatics and health information technology. We welcome the opportunity to contribute to your public commenting process and to participate in discussions about a critical but complex topic.

Through its draft guidance, the FDA has proposed definitions for a small subset of mobile medical applications that the FDA believes may affect the performance or functionality of currently regulated medical devices and as such, will require FDA oversight. AMIA commends FDA for its public and proactive approach to obtain comments about its intentions regarding mobile medical apps. We would like offer the following key themes and cautionary remarks:

Need for Additional Clarification, Definitions, Terms, and Terminology
There is inconsistent use of terms and terminology such as EHRs, PHRs, mobile apps, telehealth and telemedicine, and m-health. We believe that this lack of clarity will lead to an overlap in, and fragmentation of, oversight and jurisdiction of Federal agencies. In addition the complexities of numerous rules, regulations, and legislation are likely to result in misinterpretations of the guidances, rules, and regulations.

The non-binding draft guidance states that the FDA intends to apply its regulatory requirements solely to a subset of mobile apps that it is calling *mobile medical applications* or *mobile medical apps*. A mobile app is a software application that can be run on a mobile platform (handheld computing platform such as a smart phone, though wireless connectivity is not required), or is "tailored to" a mobile platform and runs on a server. A mobile *medical* app is a mobile app that is a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and either:

1. Is used as an accessory to a regulated medical device; or
2. Transforms a mobile platform into a regulated medical device.

The draft guidance states that "Mobile apps that perform the functionality of an electronic health record system or personal health record system" are not considered to be mobile medical apps. We are concerned that this statement is both broad and vague. For example: Does this apply only to those EHRs/PHRs that store data in conjunction with a non-mobile system? AMIA notes that there could be an EHR/ PHR application that stores blood glucose values that are manually input by the users for their diabetes. Applications of this type frequently store this information and display graphs of this information. Therefore the application would no longer display, store, or transmit patient-specific medical device data in their original format. This leads us to question if the FDA would then consider this to be a mobile medical app. Also, EMRs and PHRs frequently display recommended upper and lower bounds for values and indicate which values are out of range (utilizing a very simple decision algorithm). It is not clear if this kind of functionality would be considered a mobile medical app.

There are various approaches to defining and using terms such as clinical decision support, standalone systems, devices, and mobile apps, and this variation may reflect a lack of agreement, alternate interpretations, and/or the evolution of the topics and their scope. AMIA believes that public and private sector organizations should collaborate to build consensus around working definitions of key terms before going further in discussing regulatory or safety options.

There is an ongoing need to harmonize and coordinate efforts across the federal government and between and within the research and practice communities in the public and private sectors. The FDA's goal seems to be to delineate which mobile apps should be regulated as devices, by virtue of the potential risks they pose to public health "if they fail to function as intended." Increasingly, individuals are using a growing array of mobile health devices, technology and software applications to access health information and services. In addition, health care and public health professionals are formally and informally integrating mobile technologies and applications into diverse public health practices and clinical care activities. The digitization of protected health information on and across multiple platforms, devices, and delivery mechanisms/channels is outpacing existing policies to address them. We note that advances in technology and techniques are surpassing the ability of existing policies, guidances, and regulations to address the technological functionalities and capabilities. Thus, AMIA is concerned that "in the real world" there is a blurring of lines between and convergence of (mobile and non-mobile) applications, devices, and delivery mechanisms. One might even question whether the "mobile" versus "fixed" distinction will continue to be particularly meaningful – at least as a basis for devising regulatory requirements that differ between the two environments.

We caution the FDA in focusing narrowly on certain applications or in considering mobile apps in isolation from other delivery methods or contexts. Medical and health related applications may be implemented on mobile platforms or on tethered workstations within integrated health information systems. Their safe and effective use will be dependent on the quality of the associated HIT environment, regardless of whether the application is running on a mobile device or in a mainframe setting. The functionality of applications should be central to any discussion of potential FDA guidance or oversight.

There is an ongoing and growing need for development and dissemination of best practices for HIT design and implementation, and these will have a major effect on the quality of software development and implementations as well. Efforts are needed to synthesize the results of

existing and future HIT studies to capture, compile, and disseminate best practices and guidelines for designing and implementing such systems in general; these should include usability guidelines, as well as proven technical and organizational issues.

With specific reference to mobile devices and applications, there is a need for methods to identify best practices on a national level (public-private) that can form an authoritative knowledge and evidence base for the development and adaptation of such approaches. A coordinated effort between the private and public sectors is needed. Stakeholders, building on existing models and approaches should leverage prior and ongoing research and work in informatics, quality assurance, and patient safety. There needs to be coordinated development of procedures, approaches and processes to ensure the safe and effective use of all types of health information technology, not just mobile devices or apps. Efforts should encourage system designers and implementers to focus on the use of HIT to contribute to the ultimate goal of improvement in patient care processes and outcomes

New technologies and devices along with new and evolving forms of patient care delivery and payment methods are emerging and converging rapidly (e.g., medical homes and accountable care organizations). We envision increasing achievements in personalized medicine and growing pressures for consumer engagement in healthcare decisions. Thus, we anticipate a further blurring of the lines between information delivery channels and mechanisms, devices and applications intended primarily for use by clinicians and other providers, contrasted with those intended for patients, consumers and their care givers.

Guidance and regulation established today is based upon how we understand mobile applications in existence today. However, any final regulations will need to support and enable future mobile innovations. If an EHR/PHR functions on a mobile device for viewing, clinical decision support and/or clinical data entry, then why would the EHR/PHR not be included among the mobile applications and HIE considerations that FDA is currently considering?

We acknowledge that there is great interest broadly in what kind of regulatory or oversight interventions might be warranted in order to help assure the safe implementation of applications in health care, whether delivered via mobile devices or other means, mechanisms, or HIT technology.   AMIA has been tracking these issues for many years. In 1987, the FDA summarized the agency's philosophy and approach to software regulation, with an emphasis on clinical decision-support programs (Federal Register, 52 FR:36104 and FDA Regulation of Medical Device Software (Background), distributed at the FDA/NLM Software Policy Workshop,

September 3-4, 1996, Rockville, MD, FDA, 1996.). Software was viewed as similar to a textbook or other knowledge source, as long as there was no direct computer control of a patient's care (closed-loop system). Thus the FDA stated that the presence of a "learned intermediary" (generally a physician) who interpreted the output from the computer before applying results to a patient meant that the software did not require regulatory oversight. As computing technology advanced in health care, this issue was revisited from time to time.

AMIA published a summary article with recommendations in 1997 (Miller Randolph A., Gardner Reed M., Recommendations for Responsible Monitoring and Regulation of Clinical Software Systems J Am Med Inform Assoc. 1997 Nov–Dec; 4(6): 442–457). Subsequently we have seen the increasing adoption and complexity of EHRs, PHRS, HIEs, mobile health, and other HIT systems, with roles in patient-care decision making that may have potential risks to patients and to optimal care, even when the system is not explicitly offering decision support. As a result, issues of software regulation, including the definition and enforcement of best practices, have arisen again in recent years, generally acknowledging the tension between the need to assure patient safety and the need to encourage innovation and product differentiation.

We believe that there will be increased adoption of mobile health technology such as smart phones, tablet devices, implantable and wearable sensors, home monitors, and other devices for data collection and reporting, treatment support, and information dissemination in the practice and delivery of health care and public health. As these technologies and applications evolve, the distinctions between them are likely to blur, posing additional challenges if the FDA seeks to provide possible oversight and/or regulation based on vehicle delivery rather than software content, function, and role. Further, as AMIA has previously stressed in numerous forums, ongoing research is needed to support resolution of several interrelated HIT design and implementation issues. Additionally, we believe that a comprehensive and systematic exploration of the technological considerations as well as the public policy issues is warranted.

AMIA and its members have devoted decades of attention to the technological, ethical, and organizational issues raised by the use of health information technology and software. An important challenge is to address these issues while considering regulatory and oversight options that might help to assure that devices, systems and other clinical software is suitably overseen, assessed, and monitored to assure patient safety. We are not persuaded that the simple emergence of mobile technologies, and other technologies that are rapidly evolving, should justify a major rethinking of FDA's role in such oversight and/or regulation.

Additional consideration is needed regarding privacy and security. As mobile health applications shift from consumer-directed products to products that help link patients and clinicians we believe that the FDA needs to consider issues related to data transmission between platforms, applications or devices. We are concerned about the need to protect and assure the privacy and security of protected health information that may be included, contained, stored or processed on or within any mobile application or device or platform, regardless of whether the FDA considers those as within the scope of its proposed guidance. Clinicians (and patients) are increasingly performing tasks such as reviewing electronic health records (EHR), reading test results, sharing data, accessing diagnostic tools, storing data and recording patient notes, on various mobile devices. Many clinicians and patients are communicating with each other using mobile devices. The numbers of medical and/or health applications available to run on mobile (computing, communications and storage) devices is also increasing. Thus, there is a growing concern about increased security risks to protected health information on mobile devices.

This draft guidance potentially poses challenges to mobile application developers, manufacturers, and researchers. It is likely that many of the innovative mobile application developers and manufacturers have not previously been through the FDA approval process. Many perceive that current FDA approval processes are time consuming, lengthy and complex. Thus, with FDA regulation of mobile medical applications, it is likely that requiring FDA approval will have the potential to stifle innovation, due to the level of resources required to seek and obtain FDA approval. It appears that manufacturer reporting, correcting and quality system processes are covered in the FDA guidance draft. It is not clear what the processes would be if there is a recall or alert on a mobile medical application. What are the processes and notification procedures to the users?

In addition, the proposed draft guidance is likely to pose challenges to researchers. While there is the possibility to seek exemptions for research purposes, innovators and researchers may be discouraged by the anticipation of an onerous FDA approval process, especially for projects that propose to study a new, innovative mobile medical app for which the market viability is not yet known. For example, there are potentially thousands of JavaScript, ASP, PHP, and ColdFusion-based medical calculators available on the Internet that can be accessed using a mobile phone (for example, consider the NICHD ELBW Outcomes calculator at http://www.nichd.nih.gov/about/org/cdbpm/pp/prog_epbo/epbo_case.cfm).

Some mobile phones current offer capabilities, for example, that would allow a user to enter anticipated values for the purpose of counseling a mother in preterm labor about whether to resuscitate an extremely premature newborn. If the FDA regulates "mobile apps" that are running on the local device, would these web-based "apps" thus be excluded? One could argue that JavaScript "is" running on the local device and thus qualifies to be regulated. But then, what about the equivalent "app" that could be programmed using PHP to run on the server side instead of on the mobile device? Because of these possible exceptions, focusing solely on "mobile" platforms may miss the mark.
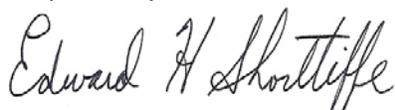
AMIA's Comments Regarding Clinical Decision Support (CDS)

The DRAFT Guidance states that" This guidance does not specifically address wireless safety considerations, classification and submission requirements related to clinical decision support software, or the application of quality systems to software. The FDA intends to address these topics through separate guidance(s)." AMIA is pleased to have had the opportunity to participate as a panelist and presenter at the FDA's public workshop on Mobile Medical Apps on September 13, 2011, focusing on the CDS topic. At that time, we provided written comments[1] and expressed our concerns about FDA's potential regulation of CDS. We request that those comments be considered as part of this response.

Summary

We appreciate the opportunity to provide these comments, and AMIA thanks the FDA for issuing this Draft Guidance and for its attention to an important public policy issue. AMIA is a source of informed, unbiased opinions on policy issues relating to the national health information infrastructure, the uses and protection of clinical and personal health information, and a variety of public health considerations. Please feel free to contact us at any time for further discussion of the issues we have raised.

 Respectfully submitted,

Edward H. Shortliffe, MD, PhD
President and CEO

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[1] See http://www.amia.org/news-and-publications/public-policy-news/amia-advises-fda-clinical-decision-support.