



33 W. Monroe, Suite 1700
Chicago, IL 60603

Phone: 252-946-3546

Fax: 734-973-6996

E-mail: himssEHRA@himss.org

AllMeds, Inc.
Allscripts Healthcare Solutions
Amazing Charts
Aprima Medical Software, Inc.
Cerner Corporation
CompuGroup Medical
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October 13, 2011

Nancy K. Stade
Deputy Director for Policy
Centers for Devices and Radiological Health
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2011-D-0530

Submitted via www.regulations.gov

Dear Ms. Stade:

On behalf of the Electronic Health Record (EHR) Association, we are pleased to respond to the Food and Drug Administration's draft guidance on mobile medical applications which appeared in the July 21, 2011 *Federal Register*. These comments were developed by our Patient Safety Workgroup and our Public Policy Leadership Workgroup, with review and approval by the Association's leadership. We represent not only our member companies, but also our clients who are the vast majority of hospitals and physicians using EHRs in the US today.

General Comments

1. The EHR Association appreciates the statement in the Draft Guidance (*page 11, last bullet*) that this guidance is limited to mobile medical apps and that FDA does not consider mobile apps that perform the functionality of an EHR or personal health record (PHR) to be mobile medical apps for purposes of this guidance. We suggest that FDA reinforce the point that all functionality included as part of an EHR or PHR will be excluded under this umbrella statement to ensure that these applications are not regulated per FDA's stated position.
2. Given the above EHR and PHR carve-out, the three FDA-suggested approaches to "accessories" described in the first point in the *Federal Register* (Vol. 76, No. 140, Thursday, July 21, 2011 page 43689) draft guidance all appear reasonable, at least at the policy level. That reasonableness assumes, however, that mobile and non-mobile applications are treated similarly, i.e., that a manufacturer would not be expected to meet one set of criteria for a non-mobile application but a different set of criteria for the same application in a mobile form. We request explicit clarification on this point.

3. The definition of a mobile medical application in the draft guidance is generally clear in differentiating a “mobile medical application” from a regulated “device,” but it lacks clarity in distinguishing between the platform and the application. For example, at what point would the same or similar application run on a server, work station, laptop, tablet PC, or smart phone transition from being considered a non-mobile application to a mobile application?
4. FDA states that they expect distributors of mobile medical apps to cooperate with manufacturers in the event that corrections and removals are necessary. It is not clear, however, how FDA expects to enforce this for application distributors that are typically outside the medical device distribution chain. This issue pertains especially to recall notification. The manufacturer is obliged to have a complete list of all product users in order to provide recall information and would have to obtain this from the retailers. We suggest that FDA provide guidelines and stronger language for manufacturers to enhance interactions with such distributors.
5. With regard to potential regulation of clinical decision support (CDS) for mobile applications (second question in the *Federal Register* Vol. 76, No. 140, Thursday, July 21, 2011 page 43690), the EHR Association sees CDS as being largely independent of whether the application is non-mobile or mobile. CDS elements are present in almost all clinical information systems and, due to the integrated nature of underlying computer programming, regulation of only a CDS component is likely to have unintended impact on other components of the system. In this regard, we underscore the importance of our first point in this letter and the carve-out of EHRs and PHRs from this guidance. The EHR Association believes there needs first to be a dialogue and risk-based decision on CDS regulation overall (if any), including the CDS components of EHRs. Only after the industry has a clear understanding of the FDA’s approach to CDS regulation in general can there be any informed discussion of mobile and non-mobile guidance differentiation. Therefore, we request that CDS also be carved out of this guidance process.

We hope these comments are useful and would like to be included in ongoing dialog concerning this last point, as well as general discussions on this topic.

Sincerely,



Carl Dvorak
Chair, EHR Association
Epic



Charles Jarvis
Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee



Leigh C. Burchell
Allscripts Healthcare Solutions



Rick W. Reeves
CPSI



Pamela Chapman
e-MDs



Jason Colquitt
Greenway Medical Technologies



Michele McGlynn
Siemens



Mark Segal
GE Healthcare IT

cc: Steve Lieber, HIMSS
Gail Arnett, HIMSS
EHR Association Executive Committee

About HIMSS EHR Association

HIMSS EHR Association is a trade association of Electronic Health Record (EHR) companies that join together to lead the health information technology industry in the accelerated adoption of EHRs in hospital and ambulatory care settings in the US. Representing a substantial portion of the installed EHR systems in the US, the association provides a forum for the EHR community to speak with a unified voice relative to standards development, the EHR certification process, interoperability, performance and quality measures, and other EHR issues as they become subject to increasing government, insurance and provider driven initiatives and requests. Membership is open to HIMSS corporate members with legally formed companies designing, developing and marketing their own commercially available EHRs with installations in the US. The association, comprised of more than 40 member companies, is a partner of the Healthcare Information and Management Systems Society (HIMSS) and operates as an organizational unit within HIMSS. For more information, visit <http://www.himssehra.org>.