

# CE-IT Community

## A Clinical Engineering/IT Collaboration

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### Industry Update: [FDA Mobile Medical Applications Draft Guidance](#)

September 20, 2011

The FDA held a public workshop on their recent [Mobile Medical Applications Draft Guidance](#) which seeks guidance on the Scope, Accessories Approach & CDS Framework for their potential regulation of mobile apps.

#### Highlights:

Overall the discussion focused on the draft guidance and how the FDA should regulate mobile medical applications & devices. Generally speaking, the FDA received positive feedback on their guidance with the panels and audience with participants calling out several areas in need of additional clarification:

- 1) **Common definitions and language:** There was a call for FDA to speak a common language with regards to medical devices, not just “medical device speak”. This request includes further defining terms such as mobile platforms, intended use, etc so that all members of the mobile ecosystem may clearly understand guidance.
- 2) **Accessories - “Intended Use”:** was focused on or referenced as key criteria for establishing the need for FDA’s oversight. Intended use and functionality was highlighted more than the technology and proximity. The definition and parameters of intended use needs additional clarification, i.e. what does intended use mean and how should it be applied. It was suggested that FDA focus only on regulating use cases where clinical decision making &/or diagnostics are apparent. One suggestion called for the FDA to develop a checklist / roadmap which would lead application developers/vendors down a decision tree in order to identify whether or not their app is covered under FDA guidance. Further discussion included how TV, games, handsets and java browser games & programming would be classified, again leading to the collection of data and its intended use.
  - **Interoperability specifications** were also discussed, most especially those necessary for the transfer of data from M2M, from medical device to EHR and from the mobile app to texting or alerting systems for clinicians to act upon. Discussed the need for interoperability to include the use data from sensors used at home, ambulance, outpatient & hospital environments.
  - There was general consensus that each app should be responsible for maintaining the integrity of data transfer when passed from device to device or app to app, but when the data is being analyzed for potential clinical decision-making, the app that performs the analysis should be regulated. The question of how the FDA would regulate an app that might integrate data from multiple apps & vendors was also raised.