CALL FOR PRESENTATIONS for
Workshop on Medical Device Interoperability: Achieving Safety and Effectiveness
Co-Sponsored by FDA/CDRH, Continua Health Alliance, and CIMIT
January 25-27, 2010
FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993

The public workshop is being sponsored with the intention to focus on a specific area of medical device interoperability: achieving safety and efficacy. In order to ensure that presentations are relevant to interested groups, germane to the scope of the workshop and can be presented within the agenda times, the steering committee may suggest guidance for submitted or approved presentations.

Attendees are invited to submit short (15 minute) presentations on any of the use-case scenarios described below, any combination of these use-case scenarios, or their own. Presentations should include a high level description of the use-case, an analysis of the relevant strengths, weaknesses, opportunities, and challenges (with focus on any potential safety hazards), and a proposal for a path forward in support of potential use in the USA. Presentations will be immediately followed by a moderated discussion with an expert panel and the audience.

Presentations will be selected to cover a wide range of uses and environments. Not all topics may be covered in the workshop. Presentations focused solely or principally upon wireless specific or FCC (e.g. non-FDA) issues will not be covered in this workshop. Presentations that focus on one company or product may not be selected.

Use cases presented could include, but are not limited to:

- Packaging (meaning all associated labeling)
    - E.g. specifically when considering the intended use of an interoperable device. How to accomplish accepting an intended use statement that includes claims of data transfer with types of devices rather than a specific version / manufacturer of the device. “The Device A can interoperate with Devices B and C that comply with Standard Y.” This means that system level testing of specific devices would not be accomplished via testing against a specific set of devices. Rather the testing would be accomplished via compliance to a particular communication standard. The verification testing would be valid for all current AND future device types claimed that also show compliance to a specific communication standard.
- Data transmission
    - Any type of transmission; uni-directional, bi-directional, real-time, or asynchronous). Could also include the actors involved in the transmission and receipt of information as well as the type of information transmitted.
- Standards
    - Existing or potentially needed; ISO, AAMI, IEC, etc. Discussion could also include scope of recognition of the standard.
- Control
    - Quality assurance, in-process quality checks, risk mitigation options or controls.

- Safety and effectiveness
  - Consideration for all actors should be considered.
- Usability
  - Consideration for all actors should be considered relative to ease of use (i.e. human factors) aspects of the use-case, especially where usability aspects contribute to overall safety and effectiveness of the devices involved.
- Workflow
  - Consideration for all actors should be considered e.g. healthcare provider, caregiver, principle user (i.e. patient).
- Consumer Awareness
  - Consider general knowledge (education) of intended user groups, training possibilities, troubleshooting, use support provided by caregiver, healthcare provider, manufacturer, etc, and role FDA could / does play.
- Manufacturing
  - Consider design, development, verification, validation, monitoring (passive and active), field support, suppliers (service, component, contract manufacturing, contract sterilization, packaging, etc), lifecycle management, and product discontinuation.
- Marketing or advertising
  - Consider from aspect of a single actor and multiple (co-marketing, co-branding, co-packaging, cross labeled, etc).
- Physician or nurse practice
  - Include considerations for similar actors and healthcare delivery mechanisms (e.g. nurse practitioners, company on-site facilities, schools (primary and secondary), clinics, etc)

Solutions presented could include, but are not limited to:

- Manufacturing best practices
- Design guidelines
- Marketing guidelines
- Physician or nurse training
- Regulatory pathways
- Regulatory guidelines
- Changes in the law
- Standards
- Technology
- Contracts
- Consumer education, awareness

Nothing is limited to current practice, products, or technology. Outside of the box thinking is encouraged.

These use-case scenarios have been identified as potentially interesting presentations by the workshop. Attendees should feel free to propose presentations for consideration based on these use-case scenarios or their own.

Connected Health

1. Regulated Medical Device plug-and-play integrated with an unregulated Cell phone/consumer electronic device. This could include the use of certified compliance with standards.
2. Multiple regulated medical devices from different vendors integrated and marketed with unregulated consumer electronics devices and a disease management service.
3. Different classes of regulated medical devices marketed and packaged together.
4. Regulated wearable Medical Device moving with a user/patient from home to an ambulance to an ER.

Traditional Care

5. Regulated Medical Device to EHR (e.g. this ONC use case: http://healthit.hhs.gov/portal/server.pt?open=512&objID=1202&&PageID=15659&mode=2&in_hi_userid=10732&cached=true)

6. PHR to EHR integration, containing data originally from regulated medical devices and a legal medical record.
7. Regulated wearable Medical Device and resulting data moving with a patient/user from home to ambulance to ER to an inpatient environment and finally back to their home, with a focus on completely the care and data loop from home to hospital and back to home.
8. Inpatient multiple manufacturer real-time or "plug-and-play" integration, such as multiple infusion pumps using one port and controlled from an EHR.

Implementation

9. Integration by Hospital/Professional users of regulated medical devices and PHRs or EMRs.
10. Integration by Consumer users of regulated medical devices and consumer electronics.
11. Consumer support and customer service for systems comprising regulated and unregulated medical device, consumer electronics/Cell phones, and PHRs. Might include recall or software updates.
12. Root cause analysis of errors in "plug-and-play" or "integrated on the fly" interoperable systems. Could include reporting requirements.
13. Integrated systems where the components have mixed levels of regulatory classification.
14. Integrated systems where the components or subsystems have a different intended use different than the complete system. For example a pulse-Ox used in a controlled loop medication dispensing system.
15. Very short time-line development and deployment of Pandemic monitoring & diagnosis capabilities in non-healthcare settings.

Proposals will be evaluated on January 11, 2010. Submissions received after January 12 may not be considered for presentation. Instructions for submitting presentations are found on the registration site.