

## ADOPTION CERTIFICATION WORKGOUPO DRAFT WORKING DOCUMENT

March 29, 2010 Workgroup Meeting

### FDA Recommendation—Straw Proposal

9. The FDA: A number of concerns were expressed about the potential for increased FDA regulation of EHR systems. These concerns include:

a. The FDA focuses on vendors who market their products. As a result, the FDA's efforts do not cover open-source software and might not cover some self-developed EHR modules. This "uneven playing field" is a significant concern because a patient centered approach to safety should not depend on the source of the software involved.

b. The FDA focuses on problems caused by individual "devices". As a result, it does not seem to cover situations where problems occur even though the software is operating correctly.

c. The FDA reporting system focuses on serious injuries and death caused by individual devices. That reporting process might not cover many unsafe conditions and hazards, like incompatible work-processes in which no actual injuries occur.

d. The QSR process is inconsistent with the incremental nature of HIT development, and, as a result, could harm innovation and increase EHR vendor costs.

While we have concerns, we've also seen that the FDA has valuable experience that could help the ONC accomplish its goals. Two possible ways that the ONC and the FDA could collaborate are:

1. Collaborate on certification criteria that improve patient safety.
2. Focus on HIT areas that are creating safety risks for EHR implementations. For example, retail pharmacies create safety problems because they do not process electronic order cancellations, which can result in over-medication of patients. Additionally, most retail pharmacies are not providing compliance data. The FDA could be a valuable ally to address this type of patient safety issue with non-certified software systems that connect to the EHR

We recommend that the ONC work with the FDA to determine the role that the FDA should play to improve the safe use of *Certified EHR Technology*. Broad public participation is suggested for this topic.