

Safety-enhanced Design

Safety-enhanced Design Overview

- Three safety-enhanced design recommendations:

Two recommendations would require documentation of specific processes utilized during EHR development:

- **#1** The first recommendation would require documentation of user centered design principles throughout development
- **#2** The second recommendation would require use of standard quality criteria for software development captured in documentation
- **#3** The third recommendation requires that a system have the ability to generate a file for reporting EHR safety events to the PSO. This recommendation was suggested for comment in the NPRM.

Recommendations

- **#1** Workgroup favors the recommendation noting that this is a reasonable first step toward increasing usability of products. The recommendation includes appropriate principles, identification of high priority areas of risk, focus on safety aspects of HIT, increased transparency for customers and a low burden for most vendors. Note that the safety specifications are not directly defined nor is there a quality measure for the process or its documentation
- **#2** Workgroup favors this recommendation. This recommendation increases awareness of the value of QA, provides transparency for certification & customers, and sets the foundation for future software QA requirements. Note that since no measure exists to determine the quality of the process or the documentation the recommendation may not go far enough.
- **#3** Workgroup favors this recommendation. Would assist organizations in reporting patient safety events currently and encourage expansion of reporting. Potential benefit is ability to aggregate data nationwide. Could have a negative affect on usability of products if the design used simply added another button to screens that already very crowded