

## The Development of the US Health IT Safety Framework

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**Background:** Health Information Technology (HIT) is becoming essential to the modern practice of anesthesiology. HIT includes the use of Anesthesia Information Monitoring Systems “AIMS” as well as smartphone apps, data warehouses, and tools for advanced data analytics. HIT offers the promise of improving the safety, quality, and efficiency of current approaches to anesthetic care, while setting the stage for personalizing care based on genomic evidence and “big data” analytics. [1]

Members of the Society for Technology in Anesthesia have developed and enthusiastically led the adoption of technologies that held promise to improve patient safety, such as pulse oximetry and respiratory gas monitoring. In contrast to stand-alone technologies, HIT is inherently a pervasive system-level technology with effects (called “emergent behavior”) that are difficult to anticipate. A recent Joint Commission Sentinel Event Alert reported on emergent behaviors, and proposed approaches for the safe use of HIT. [2] The socio-technical aspects of HIT are part of a complex adaptive system that has spurred the development of new conceptual models of technology implementation to facilitate research. [3]

**Methods:** The US Congress developed legislation to address the need to balance patient safety with HIT based innovation. The FDA Safety and Innovation Act (FDASIA) of 2012 charged the FDA, HHS Office of the National Coordinator for HIT (“ONC”), and the FCC to develop a risk-based framework for HIT [4,5].

**Results:** The FDA, ONC, and FCC convened public working groups to inform the development of the FDASIA risk-based framework.[6] The FDASIA framework recognizes three categories of HIT products.

1. Administrative HIT products will remain unregulated (e.g. billing)
2. Health-management HIT, that is unlikely to lead directly to patient harm, will be managed with a yet to be finalized oversight structure anticipated to be led by ONC (e.g. medication management, and most clinical decision support apps).
3. Medical HIT software (e.g. physiologic monitor display or an alarm app) that will remain under FDA regulatory purview.

Implementation of the FDASIA framework is evolving. Products that fall under FDA purview can be reviewed and cleared by an established process. In contrast, other HIT products do not have a pathway to report and share software defects or patient injuries.

### References:

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