**Core Background**

1. FDASIA Section 618 **(statute excerpt on page 2 of this document)**
2. ONC Website on the ONC HIT Certification Program:

<http://www.healthit.gov/policy-researchers-implementers/onc-hit-certification-program>

1. FDA Medical Devices–Overview of Device Regulation Website: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm>
2. FDA Draft Guidance on Mobile Medical Applications: <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>
3. FCC Health Website:

[www.fcc.gov/health](http://www.fcc.gov/health)

1. FDA Mobile Medical Data Systems (MDDS) Website: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/MedicalDeviceDataSystems/default.htm>

**Recommended**

1. Institute of Medicine (IOM) Report “Health IT and Patient Safety: Building Safer Systems for Better Care” *[attached via email]*
2. Bipartisan Policy Center (BPC) Report “An Oversight Framework for Assuring Patient Safety in Health Information Technology”: <http://bipartisanpolicy.org/sites/default/files/Bipartisan%20Policy%20Center%20Oversight%20Framework%20for%20Assuring%20Patient%20Safety....pdf>
3. FDA MDDS final rule: <http://www.gpo.gov/fdsys/pkg/FR-2011-02-15/pdf/2011-3321.pdf>
4. U.S. House of Representatives Energy & Commerce Committee Hearings on Health Information Technologies and Mobile Applications (Hearings and Witness Testimony):
   * Day 1 (3/19/13): <http://energycommerce.house.gov/hearing/health-information-technologies-harnessing-wireless-innovation>
   * Day 2 (3/20/13): <http://energycommerce.house.gov/hearing/health-information-technologies-how-innovation-benefits-patients>
   * Day 3 (3/21/13): <http://energycommerce.house.gov/hearing/health-information-technologies-administration-perspectives-innovation-and-regulation>
5. ISO 14971:2007 “Medical Devices – Application of Risk Management to Medical Devices (*requires payment for full standard, but summary on page 3 below*)
6. European Commission “Guidelines on the Qualification and Classification of Stand Alone Software Used in Healthcare within the Regulatory Framework of Medical Devices”:

<http://ec.europa.eu/health/medical-devices/files/meddev/2_1_6_ol_en.pdf>

**SEC. 618. HEALTH INFORMATION TECHNOLOGY.**

(a) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ‘‘Secretary’’), acting through the Commissioner of Food and Drugs, and in consultation with the National Coordinator for Health Information Technology and the Chairman of the Federal Communications Commission, shall post on the Internet Web sites of the Food and Drug Administration, the Federal Communications Commission, and the Office of the National Coordinator for Health Information Technology, a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.

(b) WORKING GROUP.—

(1) IN GENERAL.—In carrying out subsection (a), the Secretary may convene a working group of external stakeholders and experts to provide appropriate input on the strategy and recommendations required for the report under subsection (a).

(2) REPRESENTATIVES.—If the Secretary convenes the working group under paragraph (1), the Secretary, in consultation with the Commissioner of Food and Drugs, the National

Coordinator for Health Information Technology, and the Chairman of the Federal Communications Commission, shall determine the number of representatives participating in the working group, and shall, to the extent practicable, ensure that the working group is geographically diverse and includes representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise, as determined by the Secretary.

**Summary**

**ISO 14971:2007**

It is the specified standard for risk management used to demonstrate compliance with the Risk Management requirements of the Medical Devices Directive (MDD). The standard addresses risk management to patient, operator, other parties, external equipment and/or the environment. Risk Management Process ISO 14971 requires the manufacturer to establish, document and maintain a risk management process for:

• Reviewing the intended use (intended purpose) of the medical device

• Identification of hazards (known and foreseeable)

• Estimation of the probability of occurrence of harm

• Estimation of the severity of each hazard and its harm

• Evaluation of associated risks (decision making)

• Control of these risks

• Monitoring of the effectiveness of these controls throughout the whole life-cycle of a medical device.

The risk management process does not end with the design and manufacturing process but also includes applicable sterilization, packaging, labeling, storage, handling/ transport, distribution and market surveillance. The manufacturer shall apply risk management from the initial conception until the ultimate decommissioning and disposal of the product. Therefore, the gathering of post- production information is a required part of the process.