

Promoting Innovation

Introduction

The charter of the FDASIA Workgroup includes the mandate to “promote innovation” when advising on “an appropriate, risk-based regulatory framework for Health IT, including medical mobile applications” that “protects patient safety, and avoids regulatory duplication”. This puts innovation on equal footing with the other considerations. Innovation in healthcare is needed as issues of safety, quality, and cost remain unsolved.

Regulatory Impact on Innovation

The IOM Report “The IOM report Health IT and Patient Safety” included a study on the impact of regulation upon innovation (Appendix D) across multiple industries. It suggested innovation dimensions of regulation, which may be helpful in developing a new framework for HIT regulation. These factors include (1) flexibility and (2) information. “Flexibility”, the number of paths to regulatory compliance, enhances innovation. More prescriptive regulatory solutions reduce innovation. In the extreme, the product is designed by regulation. “Information” is defined as the effect of increasing or decreasing the amount of information in the system. More information in the system increases the likelihood for innovation within the system.

Analysis of Current HIT Regulation – Innovation Dimension

There are two main approaches to HIT regulation; (1) the FDA medical device regulation and (2) the ONC’s certification regulation. There are lessons learned from and specific recommendations for each.

FDA Advantages. The FDA approach has the advantage, in regards to promoting innovation, of

- **Defining a process** of product creation rather than defining the product itself, while giving reviewers discretion to assess the risk/benefit ration of each product individually. When it works best, this enables FDA to meet the flexibility requirement necessary for innovation.
- **Providing confidence in products** that go through the process. The end user HIT environment is a unique conglomeration of multiple products. The confidence in individual products is critical.
- **Post-marketing reporting system** that recognizes that all issues will not be resolved in the pre-marketing testing and there needs to be a means for feedback on these products.

FDA Disadvantages and Recommendations. The FDA approach can be improved.

- **Physical device versus software.** The FDA Medical Device regulation does not directly fit with HIT software, however, as its assumed initial target was physical devices. Software has significant differences with physical device (some enumerated in Appendix A) that make direct application of the Medical Device regulation less rational for software. Specific recommendations are listed in the Regulation subgroup report.
- **Physical devices with software.** Increasingly, many physical devices are driven by, monitored through, or operated in conjunction with software. Current regulation ties any modification of the software that accompanies such devices with the approval/regulation of the physical device itself. Over time, this has created a growing gap between the functionality of prescription medical devices with software elements, versus the creativity and functionality of consumer wellness devices with software elements. It is frustrating for patients who use both prescription and wellness devices to manage their chronic diseases and maintain their health. This issue needs to be addressed by any attempt to revise the regulatory framework for HIT.
- **Entry into FDA process.** The FDA approach, defining a product creation process, works when the product is started under the regulation. There is not a defined, easy compliance method for products that have already been developed, start small in scope and audience, and then grow to the point of FDA regulation.

ONC Certification Process. The ONC Certification regulation defines specific functional requirements both in regulation and in test cases; i.e., it defines the end product rather than the process to create it. This has positive

effects in regards to interoperability and standards adoption where specific requirements and limiting innovation is justified for the greater good, but has a negative innovation effect on innovation when multiple solutions exist and there is no incremental public health benefit to the specified solution. There is also little flexibility in the compliance assessment as the test cases are highly specific and are pass/fail. Less real innovation is done, in exchange for compliance innovation – working the software to pass the specific Test Cases. Because vendors have been so focused on meeting certification, they have had little time to support other needs of organizations.

ONC Certification Recommendations. Legislation does mandate a certification process. The issue then is the nature of the certification program. The recommendations are as follows:

- **Judicious use of specific functional requirements.** The ONC is encouraged to limit specific functional requirements unless there is a specific public health or patient safety issue. The regulatory description of other features should be in higher level descriptive, not functional design, terms.
- **Flexible compliance measures.** The ONC is encouraged to show flexibility in the certifying session itself to allow for multiple approaches to the desired feature. The ONC Certification process exhibits some of this approach; e.g., the certification standards for user centered design leave open the specific implementation.
- **Avoid requirements that empower a single, external certification body.** When there is a single body, the usual issues that occur when a monopoly is present become an issue.

New Regulatory Framework for HIT – Innovation-driven Recommendations

Beyond a critique of the current regulatory frameworks and short-term recommendations listed above, any new regulatory framework for HIT should promote innovation. The primary recommendations are:

- **Create a learning environment.** This recommendation is an endorsement of the IOM Report recommendations for a “shared learning environment”. A shared learning environment should be an inviting environment because of perceived individual benefit to participation rather than an environment to avoid because it is perceived as adding non-valued cost. The learning environment increases information and knowledge in the marketplace to increase innovation. The specific recommendation is for a more robust, but non-punitive reporting system. “More robust” in inviting entry by vendors and individual consumers of the software products, universal access to the data or transparency, and structuring the data to facilitate analysis. “Non-punitive reporting” in that every report does not require a specific government response and that there is tolerance for noise or false reports. The point of the reporting recommendation is to increase, not decrease, accountability through transparency, while speeding the process of rectifying any issues related to safety, functionality, implementation, or operation of the software.
- **Interoperability standards.** Interoperability standards benefit innovation by supporting a method to make components that links into a larger system and, therefore, lowers the entry impedance to the market.
- **Quality compliance.** The HIT market, especially for the end users, is a unique set of dependent components. Having some assurance of the quality of each of the components (e.g., adherence to the quality manufacturing process) increases the trust level for the component.
- **Identify appropriate levels of accountability.** This recommendation is noted in the IOM report. The vendor is not the only source of innovation and accountability. There is also a critical contribution from local configuration and use. For example, the vendor may create a decision support tool that can be applied to multiple local issues with the accountability to supply a well-designed, functional, and safe tool. The local use of the tool to do specific logic and process modification is the responsibility of the local entity to develop and test the specific logic.
 - **National level accountabilities.** National level accountabilities are largely directed to developers and vendors of software. These accountabilities are largely the subject of current regulatory frameworks.
 - **Local level accountabilities.** The HIT software, at a minimum, requires local configuration to meet local workflows and policies and local training of users. Many of the HIT software offerings support extension of the software by generation of new screens, reports, and decision logic. The recommendation is that the local level of accountabilities not be managed directly with national regulation. Rather, the accountability for local activities and content should be clearly defined as a local

accountability with a demonstrable local process to manage their accountabilities. This is not unlike the use of a medical device that is certified by the FDA for use in hospitals, but the local training and operating procedures and patient safety using the device are locally defined and managed processes with local medical accountability for the outcomes of use.

Appendix A: Medical Devices and HIT Software

HIT software does not share all the attributes of traditional medical devices for which the FDA regulations were initially targeted. The following are some of the differences for consideration in modifying current FDA regulation of HIT software, as well as consideration in any new regulatory framework.

- **Constant change.** Software is able and expected to be constantly updated.
- **Configurable by design.** The level of configuration does vary by the scope of the task that is the subject of the software, but software usually supports configuration to make it more consistent with the user's need or preferences or the environment in which it is operated. This configuration is, in fact, critical to the use of the software, making it better able to conform to use in a medical process.
- **Anticipated extensions.** Many of the larger packages of software (vended EHR systems, for example) have methods to extend the software through content. This may include (1) adding new data elements to collect, (2) creating new data collection forms and reports, and (3) creating new decision support modules or rules. Current regulation has discouraged this type of extensions and customization based on patient/user needs, which has created barriers for those managing complex chronic illness.
- **Scope of use.** Medical devices are usually designed for a single task. Software may be designed for a single task (e.g., calculation of the patient's next insulin dose) or cover one or multiple medical processes (e.g., med management process). The coverage of a medical process requires more configuration or customization to support processes in the clinical or home setting.
- **Environment.** The environment is more complex and varied for software versus physical medical devices. Many times the combination of hardware and software is unique to the implementation. For home use devices, patients have different abilities and needs, so the core functionality of the software may be appropriate for everybody but the interface may work best if it can be customized for specific needs of distinct users (i.e. diabetes patients who are blind or have poor vision, versus a young, mobile technology savvy user.)
- **Contributing suppliers.** The contributing suppliers to the end software configuration may include suppliers that have not been specifically designed for medical use. The contributing suppliers are also not under the full control of the software vendor given the local combination of software and hardware.
- **Labeling.** The physical medical device lends itself more easily to the labeling for use requirements of the regulation. Software, especially when supplied as a tool, does not have the same exactness of labeling. For example, software that includes decision support authoring tools can be applied to multiple issues within medicine that may not be anticipated in its initial labeling. It would be unhelpful to discourage the creation of platforms that could be customized by clinicians or patients by making software developers responsible for anticipating these "hacks" while negotiating a label. Further, the desired process of rapid cycle iterations and improvements would make any agreed label quickly obsolete.