

## Proposal for a New Regulatory Paradigm for Health Information Technology

The time is not right to pursue legislative changes to the federal regulation of HIT, including mobile health. At a minimum, Congress should wait until the federal agencies have had an opportunity to publish their proposed regulatory strategy mandated by section 618 of FDASIA. We also believe the stakeholders have not yet had enough time to critically consider the alternatives, and that rushing legislation through could produce substantial, detrimental impacts on both safety and innovation.

Whenever the time is right, any new, legislatively-created regulatory paradigm for HIT needs to balance the goals of assuring public safety and encouraging innovation. Protecting patients is of paramount importance here just as it is anywhere in health-care. Patients come first. But we frankly see potential opportunities down the road, after these issues have percolated a bit, to both increase patient protections while simultaneously decreasing the regulatory burdens on those who innovate in this space, producing public health advancements. That's because right now the present regulatory oversight is in some cases fragmented and even misdirected. Thus, in the future, we may have an opportunity to increase both public health protections and innovation.

Let's examine some of the key objectives we would need to consider in creating a new regulatory paradigm for HIT.

1. Good policy starts with good data. To put together a regulatory scheme that neither over regulates nor under regulates and is appropriately targeted at the true risks, we need good data on those risks. Unfortunately, right now, although there is anecdotal data regarding the safety of HIT, there's very little systematic, larger scale assessment of that topic. Consequently, before diving into new regulatory requirements for HIT, we join groups such as the FDASIA section 618 working group and the IOM in recommending shoring up and filling in the gaps of the adverse event reporting system as it applies specifically to HIT.
2. Systems Level Regulation. Any regulatory paradigm should approach HIT at a systems level, recognizing that the future of HIT is based on integrating technology. Medical device and other clinical software are converging, forming systems, and blurring the lines between them. Fortunately for everyone, previously siloed technology is being interconnected to improve patient care. And it is software that is stitching together that previously fragmented technology. Now, instead of lone medical devices doing their individual thing, we are seeing systems of care, where medical devices, electronic health records and a lot of software in between are being developed to improve the quality and coordination of care. To embrace that future, we need a regulatory paradigm that recognizes the growing importance of systems. In particular, we need a more comprehensive regulatory scheme that helps to manage risk at a system-level, while not interfering with the practice of medicine.
3. Nuanced categorization. When we look at the elements of those systems, we need a nuanced categorization scheme that takes into account the different risk factors that

characterize the element. The function of the software only tells part of the story. For example, clinical decision support software as a functional category ranges from highly risky software used, for example, to spot potential tumors in radiological images to low risk software that might simply add 5 numbers to calculate an APGAR score. In its September report, the FDASIA advisory committee provided a comprehensive assessment of the issues to be addressed in parsing the categories of software, and the risk factors that impact safety. We highly recommend that policymakers review the work of that federal advisory committee on this point. Rather than trying to separate all health-related software into a few simple buckets based largely on function, we need a categorization scheme that takes into account, for example, the fact that:

- a. Some software operates transparently so the user can understand and challenge the software, while other software might be designed to function as a black box, offering the user a take it or leave it conclusion.
  - b. The care settings and clinical uses can vary greatly, with some software merely transmitting information on a patient's diet to the doctor, while other software might alert an anesthesiologist to critical information during a delicate surgery.
  - c. The severity of the disease varies substantially, from the common cold to a brain tumor.
4. Utilizing private resources. Frankly we could learn a lot by studying the approach that the European Union is taking to regulating low risk medical technology. The EU has a system that allows low risk medical technology to reach the market with certification by private organizations called notified bodies. These private, nonprofit organizations are efficient and service oriented, providing independent third-party external review of the data validating the safety and effectiveness of new technology. We need a similar model in the US that provides oversight for these lower risk technologies in a way far more streamlined than any government agency could provide. Of course many technologies are in fact so low risk that they do not require any oversight at all.
5. Encouraging collaboration. Presently, a significant limitation associated with technology regulated by FDA is the limits placed on developers of technology to collaborate with their potential customers. Certain forms of that collaboration, if it involves technology already available, run the risk of violating federal law because government regulators consider the collaboration to be off label promotion. HIT by its very nature is connective and collaborative. Technology vendors, researchers and users need to be able to freely communicate back and forth regarding potential uses for the technology. In this era of social media, many of these technology experts want to collaborate through specialized social media focused on HIT. But those vendors who sell technology into these markets are reluctant to participate and collaborate for risk of criticism that they are somehow promoting existing products for unapproved, regulated uses. We need a better system.

These 5 topics are big and complex. Further, the solutions are not obvious, and likely require rigorous thinking by many different people. We believe there ought to be a period of public debate and discussion regarding the best way to go about accomplishing these and other objectives. Consequently, in our opinion, we as a nation are simply not ready to start talking about legislation.

## Attachment A

### Sketching a New Regulatory Paradigm for HIT

The following is a high level outline of the elements of a new paradigm for regulating HIT.

1. New terms to define the various elements of a system and the various roles and responsibilities of the organizations that make those elements. All of these terms would encompass technologies outside of the existing definition of a medical device.
  - a. HIT system. An HIT system is comprised of a group of the software programs and hardware, and may also include drugs and medical devices, that are intended to work together to manage or improve clinical care given to individual patients.
  - b. HIT system integrator. An HIT system integrator is the entity that designs and oversees the creation of a particular HIT system. Notice that the definition focuses on a function, and not an organization type. So it could be a vendor selling a turnkey solution, or it could be healthcare provider making its own. We would have to draw the line, similar to what FDA has tried to do with mobile medical apps, between a physician's practice of medicine and an institution's commercial operation.
  - c. Module. A module is a piece of software that has a single function.
  - d. Module developer. Modular developer is the organization that has responsibility for approving the final content of the software module and making any claims about what the module can do.
  - e. Program. A program is a collection of modules working in concert to fulfill some clinical purpose.
  - f. Program developer. Program developer is the organization that has responsibility for approving the final content of the software module and making any claims about what the module can do.
  - g. Component. A component is a piece of hardware intended for use in an HIT system.
  - h. Component manufacturer. The component manufacturer is the organization that has responsibility for controlling the specifications of the component, and any claims made with regard to the component and its capabilities.
  - i. Drugs and medical devices would be parts of the systems, but would retain their existing definitions. Software that constitutes a medical device might simultaneously be a module or a program. In other words, the categories would not be mutually exclusive.
2. Classifications. Programs and components would be classified by general function, and then sub-classified by risk. The statute would lay out the initial classifications, but then the process would allow the responsible agency to change the classification categories as technology changes. Each of the following classifications would be broken down further into four different classifications ranging from class 0 (unregulated) to class III (highly regulated). Class 0 would replace the much of the present informal enforcement discretion policy, although agencies will always have

- enforcement discretion. Those risk-based classifications would embody the risk factors identified by the FDASIA advisory committee.
- a. Programs could be broken down into the following major classifications
    - i. Medical device drivers embedded in the device, based on the classification of the device they drive. (class I-III)
    - ii. Medical device software accessories (Class I-III)
    - iii. Transfer, storage and retrieval of clinical data, whether or not from a medical device (class 0-I)
    - iv. Data analysis (non-image) (Class 0-II)
    - v. Image viewer (Class I-II)
    - vi. Image analysis (Class I-III)
    - vii. Wellness-- we would come up with a definition of wellness that allows incidental mention of disease and the use of motivational software all in class 0.
    - viii. Billing and administration (class 0)
    - ix. Etc. I'm sure there are several more subcategories we could list
  - b. Components. Under each of the following, we would build out risk-based classifications from 0 (unregulated) through III, although in some cases there would only be class 0.
    - i. Medical devices
    - ii. Medical device accessories
    - iii. Transfer, storage and retrieval of clinical data
    - iv. Image display
    - v. Data display
    - vi. Computing power
    - vii. Sensors
    - viii. Wellness accessories
    - ix. Etc., I'm sure several there are other categories
  - c. Modules would be unregulated by themselves, but the regulator would come up with standards that identify separateness between modules such that modifications to a module do not trigger at least certain regulatory obligations for the programs that incorporate them. We want to make it easier to keep modules up to date when they are unlikely to impact the rest of the program.
  - d. Drug would have the same definition it has today.
  - e. Medical device would have the same definition it has today for all practical purposes, but products that today would be described as subject to enforcement discretion would be explicitly carved out of the definition.
3. Regulatory requirements.
- a. Adverse event reporting requirements would be the obligation of the HIT system integrator, and would apply to systems containing class I or higher components or programs.
  - b. Recordkeeping: Program developers and component manufacturers would be required to build into their technology reporting systems that send back to those developers and manufacturers data on the performance of their products as required by standards that the regulator would develop. These requirements

would apply to class I and higher programs and components. These developers and manufacturers would be required to preserve the data for the expected life of their products. These data would be open for inspection by the nonprofits described below and the regulator.

- c. System integrators, program developers and component manufacturers must all register and list, unless they only make products in class 0
  - d. Quality system requirements
    - i. Apply a new and tailored version of the quality system regulation (QSR) to all class II or III program developers and component manufacturers. These new QSR requirements would make liberal use of privately developed standards for these networks to drive interoperability and more appropriately ensure quality.
    - ii. Exempt program developers and component manufacturers of class I products from most of the new QSR requirements, except those that drive interoperability, and of course class 0 are not regulated
    - iii. A new, special set of quality system requirements would apply to the work of HIT system integrators
  - e. Premarket requirements for components and programs
    - i. None for class 0 or class I
    - ii. No regulatory premarket requirement for class II, but require them to pass a certification by an authorized nonprofit auditor. These auditors would be overseen by the regulator.
      1. Specifically authorize for the use of component type claims
      2. Specify the required validation for class II claims
      3. Clarify the triggers for when a new certification is required for product changes
  - f. Class III, if any, require approval from the regulator before marketing
  - g. No premarket clearance requirement HIT system integrators so long as they:
    - i. Use component and programs as they were intended
    - ii. Follow the specialized quality system above for system integrators
  - h. A modernized approach to the regulation of advertising and promotion that allows for collaboration among various companies without the threat of an allegation of off label promotion
    - i. Allowing component manufacturers and program developers to work with system integrators more freely
    - ii. Allowing scientists in companies to collaborate at a professional level with a crowd of outside scientists, including scientists at potential customer sites
4. Regulator. Given how this all fits together, it is important to have one regulator responsible for all of it. However, the certification work for class II products would be done by nonprofits overseen by the regulator. Because this scheme would include hardware and software that constitutes medical devices, the regulator would need to be FDA.