

Report of the Section 618 Regulations Subgroup - Summary

Within current regulatory frameworks there exist mechanisms that the FDA, ONC, and FCC could use to promote innovation, protect patient safety and avoid regulatory duplication (and cost). New frameworks aimed at stimulating innovation may be helpful as well.

1. FDA could use the current regulatory framework to clarify ambiguities

The FDA has several existing mechanisms that could help spur innovation. The agency should: (a) establish a policy of “Enforcement Discretion” for lowest-risk HIT, where enforcement of regulations is inappropriate; (b) most Class I devices are exempt from pre-market notification and/or good manufacturing practices (GMP) regulation; lower-risk HIT should similarly be exempt from GMP; (c) expedite guidance on HIT software, mobile medical applications (MMA) and related matters; and (d) use external facing resources to proactively educate the public about how policies and regulation impact HIT and mobile medical apps. There may exist a need for additional funding to appropriately staff and build FDA expertise in HIT and mobile medical apps. The FDA should address four main issues:

- a) Clarify the distinction between wellness and disease-related claims. Under the current approach, labeling claims for a low-risk product intended to manage general information about a disease such as obesity may likely cause it to be regulated (unnecessarily) by FDA.
- b) Define the scope of what constitutes an accessory to a medical device. The FDA has a long-standing rule which says that anything intended to be used as an accessory to a medical device is itself a medical device and regulated to the same level as the device it accessorizes. But there are many generic, low-risk accessories that should not take on the regulatory classification of the product it is intended to accessorize. More specifically, we need new accessory classifications that “down classify” these accessories (i.e., lessen the classification) in much the same manner that FDA created the MDDS classification.
- c) Define the scope of clinical decision support software that FDA regulates. FDA has long regulated certain forms of clinical decision support software, such as CAD used with medical imaging. Unfortunately, FDA has never been clear on the contours of its regulation for this broad category of general health and medical software. Much of it is low-risk, and indeed used in a manner that makes it highly unlikely that the patient could ever be hurt. FDA needs to clarify the scope of CDS regulation.
- d) Define the scope of FDA regulation of software modules. The development of software involves a high degree of incorporating existing modules into larger software programs that might have a medical purpose. But many of the individual modules are generic and not particularly intended for medical use. FDA needs to clarify how the different medical and non-medical modules used on the same platform would be regulated.

FDA also should define the quality system requirements for standalone software, and premarket and postmarket requirements for interoperable (and “interface-able”) devices.. Traditionally, medical device manufacturers seeking FDA clearance have presented a device with a well-defined intended use typically as a solo product. For interoperable medical devices, FDA should come up with a paradigm that informs developers of system interface components how to demonstrate their claim of substantial equivalence, and how to address problems residing in a network of interfaced medical devices.

The new HIT regulatory framework should not cause confusion. The FDA should withdraw the Limitation of Exemptions regulation because of the high probability that this regulation and the Health IT regulatory framework and/or guidance documents will conflict. This conflict could be especially acute with diabetes management software products.

2. The three agencies should avoid regulatory duplication

The respective jurisdictions of FDA and ONC are not clearly delineated to ensure the needed oversight, while eliminating duplicity. ONC may regulate HIT/medical device interfaces, and FDA regulates medical device/medical device interfaces; but the same medical device (e.g. infusion pump) could be installed in either configuration. It is unclear who will require interoperability when products need to be interoperable to be used safely. Furthermore, the ONC certification program is a voluntary certification program in that ONC cannot compel vendors to seek certification for their products. While certifications can be revoked if developers or products do not comply with the program requirements, the program requires interagency use and coordination to exercise the full realm of enforcement authority against fraud and wrongdoing. And finally, FCC and FDA do not coordinate their review processes on converged medical devices that are brought independently before both agencies.

3. New frameworks for consideration

Transparency in adverse events reporting. Currently, it is difficult to obtain data for system performance analysis, and the reporting pathway often does not facilitate timely resolution. When medical device-HIT “system related” adverse events occur, it is often difficult or impossible to find the root cause of the failure. Data logs may be incomplete, inaccessible, non-existent, or not in a standardized format. What is the best model for reporting and analyzing issues with systems of devices/equipment that span (multiple agency) regulated and non-regulated space? The group surveyed existing approaches: NHTSA (National Highway Traffic Safety Administration), CPSC (Consumer Product Safety Commission), ASRS (Aviation Safety Reporting System), FDA MedSun (Medical Product Safety Network) and ASTERD (Adverse Spontaneous Triggered Events Reporting – Devices), NTSB (National Transportation Safety Board), and PSOs (Patient Safety Organizations). It is essential to improve adverse events reporting, and to enable timely and broader public access to safety and performance data.

Data gathering. The subgroup recommends a period for data gathering. The IOM had recommended that certain improvements be made in the reporting and registration areas, and only if those failed to ensure safety, should FDA regulation be pursued. It will take some time to first put the regulatory mechanisms in place to collect the data and then be able to meaningfully evaluate what the data say. But a data-driven approach is essential lest we would try to solve a problem that does not exist, or worse, focus on the wrong factors because we are not guided by data.

Industry participation. The industry should enhance its own oversight of itself. The industry can develop standards to ensure the safe operating and interoperating of HIT. As the standards get developed, there is a role for private organizations to play in certifying software as meeting applicable standards. A further idea is to encourage industry to create some sort of online marketplace where software products can get more rigorously reviewed and rated.