By Barry P. Chaiken, MD, FHIMSS

Regulate HIT Tools as Medical Devices? Yes and No

The Food and Drug Administration recently announced it is reconsidering its previous decision to exclude health information technology (HIT) tools from regulation as medical devices. When last evaluated in the late 1990s, this decision made common sense. At that time HIT consisted of rudimentary clinical documentation systems, electronic reference materials, and administrative applications. As even these tools were not well integrated with each other and into clinical workflow, they represented more of a digitization of paper-based activities rather than something truly transformational.

Today, HIT functionality far outstrips what was even dreamed about 10+ years ago. In addition, applications function in an integrated manner truly providing the clinician with a clinical experience much different than that offered using paper-based clinical documentation or simple clinical decision support tools.

The role of physicians, nurses, and other healthcare professionals is changing. These providers are becoming more dependent upon the clinical content within the HIT tools, often deferring to "decisions" made by these tools. Such examples include differential diagnosis, prescribed diagnostic and therapeutic treatments, choice of drug, and drug dose calculations. Although the previous rationale for not considering such HIT tools medical devices was based upon the intermediation of the provider between the recommended clinical activity and actual actions taken on behalf of the patient, the strong reliance on these very sophisticated HIT tools today puts this premise into question.

Are HIT Tools Medical Devices?

The FDA defines a medical device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in human or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes (*Wikipedia,* 2010; FDA, n.d.).

Not surprisingly, such a broad definition encompasses medical devices as dissimilar as tongue depressors and CT scanners. To address this, the FDA also categorizes medical devices into three classes:

- **Class I** devices that present minimal risk for potential harm to the user. These devices are subject to "general controls" that include manufacturer registration, good manufacturing techniques, proper branding and labeling, pre-notification of FDA before sale to the public. Examples of such devices include tongue depressors and stethoscopes.
- **Class II** devices are considered less safe than Class I devices and therefore require additional review to ensure they are safe. Such "special controls" include special labeling, requirements, mandatory performance standards, and post-market surveillance. Examples include powered wheelchairs and PACS systems.
- **Class III** devices that require scientific review to ensure their safety. Such devices require "premarket approval" as they are either life-supporting or life-sustaining, and it is very important that they are not harmful. Examples of such devices include implantable pacemakers and heart valves.

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In considering whether HIT tools require regulation as medical devices by the FDA, these definitions demand careful scrutiny to estimate their usefulness in evaluating such tools.

Striving Towards Clinical Transformation

As noted earlier, clinical roles and responsibilities are changing due to the availability of HIT tools. Clinical work that formerly required a physician is now delivered by a nurse or other clinician as HIT tools distribute the best available clinical knowledge to larger numbers of caregivers allowing them to act in place of more highly skilled professionals. Expert systems with diagnostic or therapeutic algorithms increasingly direct care as the reliance on the capability and sophistication of these applications increases.

The intermediation of the caregiver between the HIT tool and the patient is becoming less of a safety check as all types of clinicians rely upon these ever increasingly integrated and sophisticated HIT applications. Clinical decision support is no longer an electronic version of printed reference materials. These "devices" utilize patient information obtained from multiple applications, synthesize it through algorithms, and generate patient-specific clinical content that clinicians utilize in their care of patients.

These applications do not easily allow clinicians to examine all of the data points or even data sources when they present clinical content. Their ability to rapidly and accurately collect and manage multiple data sources provide clinicians with advanced views of a patient's condition, thereby offering great value to providers. When tied to evidence-based medicine, their output strongly suggests to clinicians one or more clinical activities that over time providers tend to rely upon. The HIT tools become part of the clinical workflow itself.

Of course, we could limit these systems to prevent such advanced activity, but that would lessen the value such clinical tools provide. If the goal is to improve quality and safety while reducing costs, HIT tools must not be hindered in their ability to secure the quality and productivity gains from better information management.

The FDA must study in detail the quality and safety issues inherent in integrated HIT applications before rushing to regulate HIT tools as medical devices. An uninformed effort to regulate HIT tools as medical devices may cause more harm than good. Applying the same standards used for medical devices to HIT tools makes little sense as HIT is neither a standalone application nor strictly a medical device. They are integrated applications that can impact quality and safety in ways far dissimilar to standard medical devices.

Regulation of HIT tools as medical devices is currently premature. Although HIT tools do directly impact patient care and therefore surely require some level of regulation, such regulation cannot be done without the requisite understanding of how HIT works within clinical workflow. The regulations must be constructed to advance HIT use while simultaneously protecting patients.

The FDA needs to review HIT tools and develop an evaluation process highly customized to the functionality and impact of each HIT application and the integration of the multiple tools into clinical workflow. Regulation of HIT tools based upon existing FDA processes and standards for medical devices would cripple our effort to put HIT in the mainstream of healthcare delivery. If our goal is clinical transformation, we must continue to deploy sophisticated HIT tools while implementing common sense regulations that evolve as we learn more about clinical HIT. PSQH

Barry Chaiken *is the chief medical officer of DocsNetwork, Ltd. and a member of the Editorial Advisory Board for* Patient Safety & Quality Healthcare. *With more than 20 years of experience in medical research, epidemiology, clinical information technology, and patient safety, Chaiken is board certified in general preventive medicine and public health and is a Fellow, Board member, and Chair of HIMSS. As founder of DocsNetwork, Ltd., he has worked on quality improvement studies, health IT clinical transformation projects, and clinical investigations for the National Institutes of Health, U.K. National Health Service, and Boston University Medical School. Chaiken also serves as an adjunct assistant professor in the Department of Public Health and Family Medicine at Tufts University School of Medicine. He may be contacted at bchaiken@docsnetwork.com.*

References

Medical device. (2010, April 27). In *Wikipedia, The Free Encyclopedia*. Available at http://en.wikipedia.org/w/index.php?title=Medical_device&oldid=358657422

U. S. Food and Drug Administration. (n.d.). Overview of device regulation.– Available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm