Work in Progress: FDA’s Regulation of Health Information Technology

By Michael W. Ryan

Health information technology (health IT) refers to a group of tools that promise to improve health outcomes and reduce healthcare costs by enabling the measurement, collection, storage, aggregation and transmission of patient-specific and publicly-available health information, analyzing data using publicly-available and proprietary algorithms, and making recommendations for patient diagnoses and patient management. These benefits will only be realized, however, if health IT is designed, manufactured, used and maintained in a manner that minimizes risk to patient health.

To this end, the U.S. Food and Drug Administration (FDA) has long expressed an interest in—and, for products with certain functionality, actually regulated—health IT. The Federal Food, Drug and Cosmetic Act (FDCA) gives FDA the authority to regulate medical devices—i.e., any “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article” that is “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease…”1 As such, FDA could potentially assert jurisdiction over many types of health IT.

The extent to which FDA should actually assert jurisdiction over health IT, however, has been the subject of considerable debate. For its part, FDA, in conjunction with the Office of the National Coordinator for Health Information Technology (ONC) and the Federal Communications Commission (FCC), issued a draft report in April 2014 that sets forth FDA’s intent to take a risk-based approach to the regulation of health IT.2 Certain members

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of Congress, however, remain concerned about the potential breadth of FDA’s regulatory oversight of health IT, and have proposed legislation (e.g., the PROTECT Act, the SOFTWARE Act) that would prohibit the agency from regulating certain low-risk devices. It is not clear whether Congress will consider or approve such legislation at this time.

Given the uncertain nature and scope of FDA’s oversight of health IT, it is critical that developers of and investors in health IT products:

- Understand the extent to which FDA has established requirements for health IT products (e.g., mobile applications, medical device data systems (MDDSs), and telemedicine systems); and
- Be cognizant of areas in which FDA is expected to impose requirements in the future (e.g., clinical decision support (CDS) software, electronic health records (EHR) systems).

This article provides an overview of these current requirements and anticipated regulatory developments, respectively, and offers recommendations and strategies for entities seeking to develop health IT products.

**Established regulatory pathways for health IT**

1. Mobile applications

A “mobile application” is a software application that can be run on a handheld, commercial off-the-shelf computing platform with or without wireless connectivity, or a web-based software application that is tailored to a mobile platform but executed on a server. In September 2013, FDA issued final guidance that states the agency intends to focus its regulatory oversight on two types of mobile applications, which the agency calls “mobile medical applications”:

- Mobile applications that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s), or displaying, storing, analyzing or transmitting patient-specific medical device data; and
- Mobile applications that transform a mobile platform into a regulated medical device by using attachments, display screens, or sensors, or by including functionalities similar to those of currently-regulated medical devices

Mobile medical applications that have the above-described characteristics and fall within an existing device classification are subject to the requirements established for such classification, including premarket approval/notification, registration and listing, and/or Quality Systems Regulations (QSR), as applicable.

FDA also intends to focus its regulatory oversight on mobile applications that perform patient-specific analysis and provide patient-specific diagnosis or treatment recommendations. The final guidance explicitly defers discussion of the regulatory requirements applicable to applications with this functionality; however; FDA is expected to address these issues in future guidance regarding CDS software (see below).

Mobile applications with functionality not described above may meet the FDCA’s definition of a device. Nevertheless, FDA intends to exercise enforcement discretion with respect to such applications, including applications with the following functionality:

- Facilitates supplemental clinical care by coaching or prompting patients to manage their health in their daily environment;
- Gives patients simple tools to organize and track their health information;
- Provides easy access to information related to patients’ health conditions or treatments (beyond providing an electronic “copy” of a medical reference);
- Helps patients document, show, or communicate potential medical conditions to providers, where specifically marketed for such purpose;
- Performs simple calculations routinely used in clinical practice; and
- Enables individuals to interact with EHR systems

Finally, although certain mobile applications may be used in a medical environment, FDA does not consider such products to be medical devices. Such products include those intended to:

- Provide access to electronic copies of medical reference materials (e.g., medical textbooks, articles, encyclopedias);
- Supplement medical training or reinforce training previously received (e.g., flash cards, training videos, interactive diagrams);
- Facilitate patient access to commonly used-reference information for purposes of general patient education (e.g., enable distribution of educational information, locate nearby medical facilities);
- Automate general office operations in a health care setting
(e.g., determine billing codes, analyze claims for fraud and abuse, generate appointment reminders); and

- General purpose products not intended for medical use (e.g., e-mail, audio/video recording, light, magnifying glass).

2. MDDSs
In February 2011, FDA promulgated a final rule that down-classified MDDSs from Class III to Class I, 510(k)-exempt medical devices. An MDDS is a medical device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical device(s):

- The electronic transfer of medical device data (i.e., any electronic data that is available directly from a medical device or that was obtained originally from a medical device);
- The electronic storage of medical device data;
- The electronic conversion of medical device data from one format to another in accordance with a preset specification; or
- The electronic display of medical device data. An MDDS is a device through which medical device data are “passively transferred or communicated”. A system that performs any other function or any additional function is not an MDDS.

An MDDS is a device through which medical device data are "passively transferred or communicated". As such, an MDDS does not:

- Modify, interpret, or add value to medical device data (or the display of the data);
- Create or generate any of its own data (except for information regarding the MDDS's functioning);
- Process, characterize, categorize or analyze medical device data;
- Flag, prioritize, plot, or graph medical device data (if such uses would add value to the existing data); or
- Facilitate active patient monitoring.

3. Telemedicine systems
Telemedicine systems encompass a range of products intended to facilitate the evaluation, management and/or assessment of a patient by a remote practitioner. Such systems may fall within any of several existing device classifications, including (among others):

- Radiofrequency physiological signal transmitter and receiver – a Class II device that conditions a physiological signal so that it can be transmitted via radiofrequency from one location to another, and then reconditioned into its original format for display.
- Medical image communications device – a Class I, 510(k)-exempt device that provides electronic transfer of medical image data between medical devices, and may include a physical communications medium, modem, interface, and a communications protocol.
- Picture archiving and communications systems – a Class II device that accepts, transfers, displays, stores, and/or digitally processes medical images, and may include hardware (e.g., digitizers, communications devices, computers, video monitors, data storage) and software (e.g., image manipulation, enhancement, compression, quantification) components.
- Laboratory information system – a Class I, 510(k)-exempt electronic medical device intended to “store, retrieve, and process laboratory data”.

In sub-regulatory guidance, FDA describes an LIS as "the information system that is responsible for management of data regarding patient specimen identification, tests requested, results reported, quality control testing, and other aspects of sample analysis...".

Anticipated regulatory pathways for health IT

1. CDS software
CDS software is technology that "provides health care providers and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care".

Although CDS software is intended to enhance, inform, and influence health care decisions, it is not intended to replace clinicians' judgment. Examples of CDS software include products that provide access to:

- Computerized alerts/reminders for providers and patients;
- Contextually-relevant reference information (e.g., clinical guidelines);
- Condition-specific order sets;
- Focused patient data reports and summaries;
- Documentation templates;
- Diagnostic support; and
- Recommendations for patient management.

The extent to which FDA ultimately intends to regulate CDS software...
is unclear. Currently, most types of CDS software are understood to be under enforcement discretion. After consulting with federal and private stakeholders, however, FDA intends to define the extent to which it will regulate CDS systems in future guidance. At that time, FDA is expected to impose a risk-based regulatory system that imposes additional requirements for software that provides decision support for serious or life-threatening conditions (e.g., cancer), that provides more prescriptive or directive support, and/or that operates pursuant to a proprietary, non-transparent algorithm. Notwithstanding the absence of explicit guidance, FDA has indicated that CDS software with “health management” functionality—e.g., evidence-based clinician order sets (tailored for a particular condition, disease, or clinician preference); drug-drug interaction alerts; provision of access to contextually-relevant treatment guidelines and other reference material; calculation of prediction rules and severity of illness assessments; and suggestions for possible diagnoses based on patient-specific information—is unlikely to be the focus of the agency’s regulatory oversight. Rather, FDA has indicated that CDS software with “medical device” functionality—e.g., computer-aided detection/diagnostic software; software that enables the remote display or notification of real-time alarms from bedside monitors; radiation treatment planning, and electrocardiography analytical software—will be the subject of FDA’s oversight. The line between health management functionality and medical device functionality may be difficult to discern and likely will require substantial guidance and practical experience before either the agency or the regulated community can comfortably conclude whether and when FDA will assert jurisdiction over CDS systems. In addition, FDA has not addressed how it might regulate CDS software that combines elements of “health management” and “medical device” functionality. 2. EHR systems An EHR system is: “… [A] real-time patient-centered record that allows access to evidence-based tools that can aid providers in decision-making. The EHR can automate and streamline clinician’s workflow, ensuring that all clinical information is communicated. It can also prevent delays in response that result in gaps in care. The EHR can also support the collection of data for uses other than clinical care, such as billing, quality management, outcome reporting, and public health disease surveillance and reporting.”

Like CDS software, EHRs are currently understood to be under enforcement discretion, and are expected to be the subject of FDA guidance in the future. FDA is not expected to focus its regulatory oversight on EHRs insofar as such systems automate administrative functions (e.g., admissions, claims processing, patient scheduling) or provide health management functionality (e.g., data capture and encounter documentation, provide access to clinical results). To the extent that EHRs incorporate higher-risk CDS software functionality, however, FDA may be more likely to impose significant regulatory requirements on such systems. 3. Systems that combine multiple types of functionality Health IT products may (and often do) combine the characteristics of two or more of the products described above. It is unclear, however, how FDA intends to regulate such products.

In the MDDS final rule, FDA indicated that it may, in certain circumstances, be amenable to manufacturers taking a modular regulatory approach—i.e., an approach that would exempt lower-risk components of a health IT system from requirements applicable to higher-risk components, provided such components are adequately partitioned from one another. Due to the number of potential functionality combinations, however, FDA indicated that it will only make such determinations on a case-by-case basis.

Recommendations Those involved with developing health IT should assess the extent to which the functionality of a product triggers existing—or may be the subject of future—regulatory requirements. In light of existing regulatory uncertainty, if one determines that a particular system appears to fall under a category that would be outside of medical device regulation or is under enforcement discretion, it may be appropriate to document the analysis that led to such conclusion (e.g., as a Memo to File) to respond to potential inquiries from investors or regulators. To the extent that the requirements for a product may be unclear and more certainty is desirable than one can obtain from an internal analysis alone, one may consider submitting a section 513(g) petition, pursuant to which FDA will respond with guidance regarding the regulatory requirements.
that may apply to an individual device (e.g., premarket authorization, QSRs, postmarket surveillance, etc.). Requirements for section 513(g) petitions, including contents and user fees ($3,490 for FY 2014), are described in an April 2012 final guidance. FDA intends to respond to 513(g) petitions within 60 days of receipt.

Interested entities should also be on the lookout for and consider submitting comments in response to forthcoming statements of agency policy. (For example, after the FDA/ONC/FCC report is finalized later this year, FDA is expected to begin issuing substantive guidance in draft form, including guidance specific to CDS software.) Public comment periods offer stakeholders an important opportunity to influence agency regulations and/or guidance before such requirements are finalized.

In light of the above-described congressional interest in the regulation of health IT, manufacturers should also stay apprised of legislative activity that would change the FDA’s authority to regulate health IT.

Editor’s note: This article was written prior to the FDA’s June 20, 2014 issuance of draft guidance in which the agency expressed its intent to exercise enforcement discretion with respect to MDDS devices, medical image storage devices, and medical image communications devices.

6. 21 C.F.R. § 880.6319.
7. 21 C.F.R. § 870.2910.
9. 21 C.F.R. § 892.2050.
10. 21 C.F.R. § 862.2100(a).