Possibility of FDA Regulation of Health Information Technology Looms Large

Pharmacies and Their Vendors Worry About Quality

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The push for hospitals to implement health information technology (HIT) systems, driven in part by Medicare and Medicaid incentives (and penalties), has affected pharmacy systems. It will continue to do so, as the definition of “meaningful use” is expanded to incorporate more required tasks related to medications. Everyone who works in a hospital pharmacy will be affected by how the federal government regulates these new technologies, including both hardware and software. Retail pharmacies, even though they are not being pressured by incentives, are also concerned about how new regulations would affect mobile medical devices (e.g., glucose monitors for diabetes management and home-based monitors for hypertension), medication management, and medication reconciliation at transitions of care.

Organizations such as the Pharmacy e-Health Information Technology (e-HIT) Collaborative are communicating with a work group within the Department of Health and Human Services (DHHS) Office of the National Coordinator for Health Information Technology (ONC), which will soon be making recommendations to Congress concerning HIT; the FDA will be paying close attention too.

Surescripts is also concerned about the failure of some pharmacy system vendors to oversee the quality of their products. The company provides the electronic prescribing (e-prescribing) backbone that software vendors “plug into.” Those vendors sell “plugged-in” e-prescribing systems directly to end-user pharmacies.

David Yakimischak, Executive Vice President and General Manager of e-prescribing at Surescripts, says that the company has worked hard to encourage its vendors to adopt quality programs in an effort to reduce pharmacy errors. He explains:

Vendor responsiveness has been relatively random. Quality and patient safety performance does not appear to play heavily in end-users’ purchasing decisions. Our conclusion is that in the absence of new incentives and penalties, there is currently little or no business case for vendors to make significant investments in high-quality patient safety programs.

The FDA is under Congress’s mandated deadline of January 2014 to produce a regulatory framework for HIT. The key issues are whether the FDA should be allowed to regulate all HIT (as it does for medical devices) or whether some HIT (especially software with which pharmacists and physicians interact with a system to make clinical decisions or observations) should even be regulated at all. Some in the drug-distribution chain think that systems requiring clinical intervention should be certified, but not regulated, by a non-federal body (such as The Joint Commission) and that the ONC should oversee the certification process. The ONC already has a few years of experience in certifying HIT that is eligible for incentives (which go to the purchasers, such as hospitals), as decreed by the American Recovery and Reinvestment Act of 2009 (the “stimulus bill”).

The National Committee for Quality Assurance (NCQA), The Joint Commission, or RAC (formerly, the Utilization Review Accreditation Commission) have track records in the rigorous accreditation of health care software.

The American Hospital Association (AHA) thinks that hardware and software products should be regulated based on the risk they pose to patients. Key factors to be considered include the potential for harm, the degree of harm, and the extent to which software is automating and/or guiding clinical decision-making.

Linda E. Fishman, Senior Vice President of Public Policy Analysis and Development at the AHA, says: “For example, when drug dosage data are sent from an order entry system to a pharmacy information system, it is crucial for safety that both the data points and their units of measure are accurate within each system and across systems.”

Last February, the Bipartisan Policy Center, a think tank created to meld Democratic and Republican views, published a paper called An Oversight Framework for Assuring Patient Safety in Health Information Technology. The report stated: “The FDA’s current regulatory approach for medical devices is generally not well suited for health IT.”

The report recommended that HIT products be divided into three categories according to the relative risk to patients and the opportunity for clinical intervention:

- **Highest risk**: Products for which there is no or little opportunity for clinical intervention represent a high risk of patient harm. The FDA currently regulates medical devices, designated as Class I, II, or III. Class I includes devices that pose the lowest risk to patients, and Class III devices are associated with the greatest risk. The FDA would continue to regulate all of these devices.
- **Lowest risk**: The software supports the administrative and operational aspects of health care but that is not used in the direct delivery of clinical care. Population analytics,
back-office billing systems, claims-payment systems, and prescription drug-refill reminders are examples of software that is not utilized for patient-specific treatment or diagnosis. The Bipartisan Policy Center recommends no additional FDA oversight for this category.

• Intermediate risk: Products in this category (e.g., clinical software) can be used to recommend a course of care. Very few participants in the debate, at least on the industry side, think that this category should be regulated by a federal agency.

Meanwhile, the ONC’s ability to translate its considerable HIT experience into political weight in any upcoming battle with the FDA over new regulations is compromised by the absence of a national coordinator, given the departure of Farzad Mostashari, MD. The position needs to be filled quickly—for many reasons.