



Via Electronic Submission to: www.regulations.gov

June 12, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: [Docket No. FDA-2014-N-0406] Proposed Strategy and Recommendations for a Risk-Based Framework for Food and Drug Administration Safety and Innovation Act Health Information Technology; Request for Comments

Dear Sirs:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative, we are pleased to submit comments in response to the April 16, 2014, *Proposed Strategy and Recommendations for a Risk-Based Framework for Food and Drug Administration Safety and Innovation Act Health Information Technology; Request for Comments*.

The Pharmacy HIT Collaborative (the Collaborative) has been involved with the agencies developing the national health information technology (HIT) framework since 2010. The Collaborative is supportive of the proposed strategy and recommendations to improve the safety of HIT through safely designed and implemented systems. Pharmacists provide patient-centered care and services, maintain various patient care records, and as part of the integrated health care team, they are directly involved with other health care providers and patients in various practice settings. Pharmacists are in a strategic position to help improve patient safety, especially, through HIT.

The following are our responses to the questions asked concerning the proposed priorities and recommendations for a risk-based framework:

A. Promote the use of quality management principles

- 1. What essential quality management principles should apply to health IT? How should they apply to different stakeholders and at different stages of the health IT product lifecycle?***

Pharmacy Health Information Technology Collaborative

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The Pharmacy HIT Collaborative supports and recommends the application of quality measures developed by government and nongovernment quality and standards organizations to health IT, including those organizations representing the pharmacy profession. We refer the agencies to standards and principles developed by organizations such as the Pharmacy Quality Alliance (PQA), the National Quality Forum (NQF), and the National Committee for Quality Assurance (NCQA). Pharmacists providing patient care look to these organizations, particularly PQA, NQF, and NCQA to develop independent quality principles.

2. *How do we assure stakeholder accountability for adoption of quality management principles? Is there a role for a non-governmental, independent program to assess stakeholder adherence to quality management principles? Is there a role for government?*

The Pharmacy HIT Collaborative believes that one way to assure accountability for adoption of quality management principles for the safe design and systems development of health IT is through accreditation and certification. In the pharmacy profession, nongovernmental organizations providing such include the Joint Commission, Center for Pharmacy Practice Accreditation (CPPA), and OASIS (a nonprofit, international consortium that promotes industry consensus and produces worldwide standards for security, privacy, content technologies, cloud computing, etc.). Other organizations include: the Accreditation Commission for Health Care (ACHC), the Agency for Health Care Research and Quality (AHRQ), and URAC (formerly the Utilization Review Accreditation Commission). These organizations research, develop and maintain standards of quality for health care and health care systems.

In its role as a payer, we believe the government should develop quality measures that are used to incentivize payments and payment systems. We believe that the Office of the National Coordinator should play an adequate role outlining the national strategy and promote adoption of standards and best practices.

B. Identify, develop, and adopt standards and best practices

1. *Are the identified priority areas for standards and best practices the proper areas of focus? If not, what areas should be prioritized?*

The Pharmacy HIT Collaborative agrees that the identified priority areas are the appropriate ones.

2. *How can the private sector help facilitate the development and adoption of applicable health IT standards and best practices? Is there a role for a nongovernmental, independent program to assess product and stakeholder adherence to standards and best practices? Is there a role for government?*

The Pharmacy HIT Collaborative believes that one way to assure accountability is through standards development and accreditation. As indicated in our response to the first proposed priority, there are numerous nongovernmental programs currently doing this. In the pharmacy profession, nongovernmental organizations providing such include the ACHC, Joint Commission, CPPA, OASIS, and URAC. Another important organization is the AHRQ. These organizations research, develop and maintain standards of quality for health care and health care systems.

C. Leverage conformity assessment tools

- 1. What conformity assessment tools, if any, should be incorporated into a risk-based health IT framework? How should they apply to different stakeholders and at different stages of the health IT product lifecycle? How can adoption of and adherence to conformity assessment programs be promoted?***

The Pharmacy HIT Collaborative believes the accreditation and certification process should be incorporated into a risk-based health IT framework. As indicated in our previous responses, there are numerous nongovernmental programs currently doing this. In the pharmacy profession, nongovernmental organizations providing such include the ACHC, Joint Commission, CPPA, OASIS, and URAC. Another important organization is the AHRQ. These organizations research, develop and maintain standards of quality for health care and health care systems.

- 2. Should interoperability be tested? How should tests to validate interoperability be conducted? Should interoperability standard(s) be adopted and used for conformity assessments (i.e. develop a functional standard that specifies interoperability characteristics that could be used for conformity assessment)?***

The Pharmacy HIT Collaborative supports and encourages interoperability testing and standards adoption for use in assessments. In some areas, this is a common practice, especially on the payer side. Pharmacy business partners who exchange payment information must go through scenario testing. One of the reasons for this testing is to ensure the safety and validity of the medication information being exchanged. Standards to transmit claims information also are tested. The pharmacy profession is moving toward this direction with clinical information. An example of this is electronic prescribing. E-prescribing systems must be able to handle the information being tested. DEA's Electronic Prescribing of Controlled Substances (EPCS) audit/certification process and rules for pharmacy systems and physician EHR software companies became effective in June 2010, with DEA approving several categories of third-party audit/certification organizations, as well as the subsequent addition of individual eligible audit/certification organizations.

3. *How should the intended user (e.g. health care provider, consumer, etc.) affect the type of conformity assessment performed?*

The Pharmacy HIT Collaborative believes health care providers, consumers, and other intended users should affect conformity assessments performed by reporting errors and safety issues to federally listed patient safety organizations (PSO), as well as reporting such issues to the accreditation and certification groups who performed the assessments. Such patient safety organizations include the Institute for Safe Medication Practices (ISMP) and Alliance for Patient Medication Safety Patient Quality Commitment (PQC) program.

When health care providers and consumers connect electronically to access medical information, they need to be able to report medication errors or problems either directly within the HIT system being used or to a PSO.

4. *How should conformance assessment results be communicated to stakeholders?*

The Pharmacy HIT Collaborative recommends that conformance assessment results be communicated to stakeholders by posting such results and certifications seals, if applicable, on providers' websites or through website lists showing which systems, products, services, organizations, etc., are certified and meet conformance standards. Using certification seals, for example, can assure users that the HIT systems meet certain standards.

5. *Is there a role for a nongovernmental, independent health IT conformity assessment program? Is there a role for government? Should the ONC Health IT Certification Program be leveraged to protect patient safety through the use of conformity assessment tools?*

The Pharmacy HIT Collaborative believes the government should have limited oversight, as long as there are approved nongovernmental organizations performing conformity assessments. One area in which the government may be involved concerns payer issues (e.g., fraud and abuse). The government's role is to support standards and accreditation groups. The ONC Health IT Certification Program should allow current state health department processes for patient safety to remain in place.

D. Create an environment of learning and continual improvement (proposed Health IT Safety Center included in this section)

1. *What should be the governance structure and functions of the Health IT Safety Center, in order for it to serve as a central point for a learning environment, complement existing systems, facilitate reporting, and promote transparent sharing of adverse events, near misses, lessons learned, and best practices?*

The Pharmacy HIT Collaborative recommends that the governance structure follow that of the PSOs. The Health IT Safety Center also should work with organizations, such as the Collaborative, using their expertise and knowledge to make more HIT-related safety information available. The Collaborative's founding organizations represent pharmacists in all patient care settings and other facets of pharmacy, including pharmacy education and pharmacy education accreditation. The Collaborative's associate members represent e-prescribing and health information networks, a standards development organization, transaction processing networks, pharmacy companies, system vendors, and other organizations that support pharmacists' services.

2. How can comparative user experiences with health IT be captured and made available to the health IT community and other members of the public to promote learning?

To promote learning and sharing with the health IT community and the public, the Pharmacy HIT Collaborative believes that capturing user experiences with health IT needs to be done at the system vendor level and the FDA and made available through venues where health IT systems can be rated. Two such venues, the Center for Medicare & Medicaid Services (CMS) Online Survey, Certification and Reporting (OSCAR), and OASIS, are currently being used to share and rate health IT care systems. OSCAR is being used to rate long-term care and is an open source cluster application resource. OASIS is being used for rating home health care and is a nonprofit, international consortium that promotes industry consensus and produces worldwide standards for security, privacy, content technologies, cloud computing, etc.

The Collaborative recommends exploring such resources further for use in health IT and by the Health IT Safety Center that will be established.

3. How can the private sector help facilitate the development of a nongovernmental process for listing selected health IT products? What types of products and information should be included? Should the results of conformity assessments, such as conformance with certain clinical or privacy and security standards, be included?

As mentioned above, the private sector is currently using third party resources, such as OSCAR and OASIS, for garnering consensus on standards, security, and rating health IT systems and making results available for public viewing. The pharmaceutical and IT communities, including HL7, recently announced a collaboration on OASIS clinical trial data standard for content management systems to advance interoperability for exchanging clinical trial content in the cloud (<https://www.oasis-open.org/news/pr/pharmaceutical-and-it-communities-collaborate-on-oasis-clinical-trial-data-standard-for-cont>).

The Collaborative recommends exploring such resources further for use in health IT and by the Health IT Safety Center that will be established.

4. In terms of risk management, what type of safety-related surveillance is appropriate for health IT products categorized as health management functionality? What continued or expanded role(s), if any, should the ONC Health IT Certification Program play in the safety-related surveillance of health IT products?

The Pharmacy HIT Collaborative believes risk management should come through PSOs and the FDA, including PSOs gathering appropriate data related to the safety of health IT products. ONC should work with PSOs to make appropriate data available to the public.

5. What role should government play in creating an environment of learning and continual improvement for health IT?

The Pharmacy HIT Collaborative believes the government should support and work through PSOs in creating an environment of learning and continual improvement for health IT.

E. Clinical decision support

1. What types of CDS functionality should be subject to the health management health IT framework? Which types should be the focus of FDA oversight?

The Pharmacy HIT Collaborative believes that CDS functionalities that operate without health care provider's direct involvement should be subject to the health management health IT framework and FDA oversight. If a health care provider is directly involved in the decision-making and recommended action, then FDA oversight would not be needed. For example, if a medical device (e.g., home blood pressure) displays a measurement and from that measurement the CDS is alerting the patient to take some action (e.g., lower or increase medication dosage) without getting advice from a health care provider, then FDA should have oversight.

2. How should the following priority areas identified in the health management health IT framework be applied to CDS categorized as health management health IT functionality?

- a. Quality management principles.**
- b. Standards and best practices.**
- c. Conformity assessments.**
- d. Learning environment and continual improvement.**

The Pharmacy HIT Collaborative recommends that all of the priority areas be applied to CDS. They should be applied through the following:

- a. Pharmacy quality organizations
- b. Standards and quality organizations and professional associations
- c. Certification and accreditation process
- d. PSOs

Pharmacy professional associations, as noted previously, oversee all of these areas for the practice of pharmacy and help distribute information to practitioners.

3. *Are there additional safeguards for CDS, such as greater transparency with respect to CDS rules and information sources that are needed to appropriately balance patient safety and the promotion of innovation?*

In the practice of pharmacy, pharmacy professional organizations, such as the Pharmacy HIT Collaborative members, e.g., American Society of Health-System Pharmacists (ASHP) and American Pharmacists Association (APhA), develop and oversee best practices for CDS. The resources and guidelines provided by these organizations support pharmacists engagement in health care quality initiatives that balance patient safety and improve patient outcomes.

4. *Does the certification of CDS functionalities, such as those functionalities currently certified under the ONC Health IT Certification Program, sufficiently balance patient safety and the promotion of innovation?*

As noted in question 2, the Pharmacy HIT Collaborative believes that applying priorities a-d, as recommended in our comment, also are needed to ensure CDS functionality has that balance between patient safety and the promotion of innovation, in addition to the ONC Health IT Certification Program. This is particularly critical with regard to CDS as it is used with medical devices. As we discussed previously, if a device (e.g., pacemaker, blood pressure, etc.) is making CDS without a health care provider's involvement, then oversight and testing is needed.

5. *How can the private sector help assure the facilitation of the development, application and adoption of high quality CDS with health management health IT functionality in lieu of a regulatory approach? What role, if any, should government play?*

Many private sector, professional health care organizations (e.g., pharmacy) have developed high quality CDS for health management health IT functionality, which have been adopted by their respective practitioners.

As discussed previously, the Pharmacy HIT Collaborative believes that CDS functionalities and health systems that are operating on their own and without a health care provider's direct involvement should be subject government oversight. If a health care provider is directly involved in the decision-making and recommended action, then government oversight would not be needed.

The Pharmacy HIT Collaborative's vision and mission are to assure the nation's healthcare system is supported by meaningful use of HIT, the integration of pharmacists for the provision of quality patient care, and to advocate and educate key stakeholders regarding the meaningful use of HIT and the inclusion of pharmacists within a technology-enabled integrated health care system. The Collaborative was formed in the fall of 2010 by nine pharmacy professional associations, representing 250,000 members, and also includes seven associate members from other pharmacy-related organizations. The Pharmacy HIT Collaborative's founding organizations represent pharmacists in all patient care settings and other facets of pharmacy, including pharmacy education and pharmacy education accreditation. The Collaborative's Associate Members represent e-prescribing and health information networks, a standards development organization, transaction processing networks, pharmacy companies, system vendors and other organizations that support pharmacists' services. For additional information, visit www.pharmacyhit.org

On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the *Proposed Strategy and Recommendations for a Risk-Based Framework for Food and Drug Administration Safety and Innovation Act Health Information Technology; Request for Comments*.

For more information, contact Shelly Spiro, Executive Director, Pharmacy HIT Collaborative, at shelly@pharmacyhit.org.

Respectfully submitted,



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