Pharmacy e-Health Information Technology Collaborative

VIA Electronic Submission to: http://www.regulations.gov

June 26, 2013

Steve Posnack,
Director, Federal Policy Division
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Bldg., Suite 729D
200 Independence Ave. SW
Washington, DC 20201

Re: Food and Drug Administration Safety and Innovation Act (FDASIA): Request for Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology

Dear Mr. Posnack:

On behalf of the membership of the Pharmacy e-Health Information Technology Collaborative, we are pleased to respond to the *Request for Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology*.

The Pharmacy e-HIT Collaborative is supportive of the continued use of electronic health information exchange across providers and patients, as well as strategies that are effective and feasible to further advance and promote interoperability and health information exchange, and ensure the protection of patient data collected and shared through electronic means, including mobile devices and mobile medical apps. We agree that a coordinated approach and oversight between the health care industry and federal regulators is critical to the successful, safe use of health information technology (HIT) that is being adopted.

The Pharmacy e-HIT Collaborative is actively engaged with the Office of the National Coordinator for HIT (ONC) and others in the development of a national strategy and framework for health information exchange. We commend the FDA, ONC, and FCC for moving forward with the request from Congress to thoughtfully examine the regulatory framework concerning HIT and extending the opportunity to HIT

stakeholders to provide comments and recommendations for creating the risk-based regulatory framework and strategy health information report.

The following are our comments to the questions posed in two of the three areas for this RFC.

1. Taxonomy: What types of health IT should be addressed by the report developed by FDA, ONC, and FCC?

The Pharmacy e-HIT Collaborative recommends that the report include employing standards developed by the American National Standards Institute (ANSI), the National Council for Prescription Drug Programs (NCPDP), and Health Level Seven (HL7), platform uniformity, and applicable guidelines developed by professional health care associations for mobile devices and telehealth. Additionally, discussion and recommendations concerning the development of safe, secure mobile medical apps and other internet-based health care apps used in health care delivery, and privacy protection for patients and patient information collected and exchanged through HIT and mobile medical apps should be addressed in the report.

As patient-centered, health care providers, pharmacists capture and monitor their patients' health information through mobile medical devices. Examples of areas in which pharmacists and patients use mobile medical devices include: glucose monitoring/diabetes management, at home hypertension monitoring/management, medication management, and medication reconciliation at transitions of care.

It is important that the producers of mobile medical devices and mobile medical apps be encouraged to certify that their products follow and meet acceptable HIT standards and platforms for the collection, exchange, and protection of patient health information, as well as ensuring patient safety and well-being in the use of these devices and information to support positive health outcomes. The Pharmacy e-HIT Collaborative recommends that product developers follow nationally recognized standards and guidelines (e.g., ANSI). Several organizations that have developed recognized and accepted national guidelines are members of the Pharmacy e-HIT Collaborative and are listed at the end of our comments. We encourage the FDA, ONC, and FCC to contact these groups for further information.

The development and introduction of mobile medical and health care apps for smart phones and other mobile devices is accelerating. In the January 2013 issue of *Medicine on the Net*, an e-newsletter published by HealthLeaders Media, it was reported that the FDA indicated there were 17,288 health and fitness apps on the market in mid-2012, along with 14,588 medical apps. Many of these apps have no oversight that can attest to their effectiveness and safety.[1]

The January 2013 article also stated "mobile apps for diabetes management are a hot spot in the app world." The FDA approved the first iPhone-enabled glucose meter for sale at retail in May 2012.[2]

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[1] *Medicine on the Net,* e-newsletter, HealthLeaders Media, January 2013, www.healthleadersmedia.com.

[2] Ibid.

In response to the proliferation of mobile medical apps, the FDA issued a draft guidance document for Mobile Medical Applications on July 21, 2011 (the FDA anticipated having the guidance finalized by the end of FY' 13). In its overview, the FDA noted: "As is the case with traditional medical devices, mobile medical apps can pose potential risks to public health. Moreover, mobile medical apps may pose additional and different risks due to the unique characteristics of the platform."[3] FDA also states that this guidance clarifies and outlines its current thinking and that it "will continue to evaluate the potential impact these technologies might have on improving health care, reducing potential medical mistakes, and protecting patients."[4]

At that time, the FDA also stated that it "intends to apply its regulatory requirements solely to a subset of mobile apps that it is calling mobile medical applications or 'mobile medical apps.'"[5]

As the FDA draft guidance points out, there are concerns with mobile medical apps, which the Pharmacy e-HIT Collaborative also shares in regard to usage, platforms, and standards that apply to specific health issues and management in which the patient should be interacting with a health care provider when using a mobile medical app. There is a strong potential for patient safety issues in this area.

We encourage the report to include more research and oversight recommendations for mobile medical apps, detailing specific concerns about the usage, platforms, and standards, and how these apps may affect patient outcomes, delivering health care services by health care providers, and ensuring patient safety. Since the FDA raised concerns about mobile medical apps in its draft guidance, the report should include updates of any activity by the FDA to finalize its draft guidance document, as well as any activity in applying its regulatory requirements.

Lastly, protecting patient information collected via mobile medical devices and apps is paramount, as this is the direction patients, health care providers, and HIT are moving. Development of an HIT framework in this area needs to ensure that any patient information transmitted to or received by a mobile device and using mobile medical apps is protected and patient privacy secured.

The FCC is currently considering new rules to protect information stored and received on mobile devices and is expected to vote on the proposal on June 27, 2013. The proposal, however, appears to focus on phone calls and phone numbers placed or received on a device, the duration of calls, and the geographic location where calls were made and not the type of personal information that is being transmitted, received, or exchanged. Thoughtful consideration and discussion need to be given by the FCC to HIT and patient privacy in this regard.

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[3] *Mobile Medical Applications,* Draft Guidance for Industry and Food and Drug Administration Staff, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, issued on July 21, 2011, page 5-6.

[4] Ibid., page 6.

[5] Ibid., page 4.

2. Risk and Innovation: What are the risks to patient safety posed by health IT and what is the likelihood of these risks? What factors or approaches could be included in a risk-based regulatory approach for health IT to promote innovation and protect patient safety?

The Pharmacy e-HIT Collaborative believes that the risks to patient safety in HIT are allowing products that are not held to any standard to enter the market. Assuring that vendors developing technology and related products follow nationally recognized guidelines, such as ANSI standards, is critical. The FDA has already acknowledged some risks to patient safety and the public health in its July 2011 guidance concerning mobile medical apps.

As the FDA also has statutory authority regarding medical devices and other related products, it could develop and implement minimal regulatory guidelines based on recognized and accepted industry standards. Incorporating such uniform standards into regulation would help to promote innovation and protect patient safety.

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The Pharmacy e-HIT Collaborative, including pharmacy professional associations, the Pharmacist Collaborative (formerly PSTAC), Medication Therapy Management (MTM) intermediaries, and NCPDP, are defining guidelines and standards related to the pharmacist's role in HIT. Pharmacists in all practice settings provide several patient-centered services electronically. It is evident that access to HIT solutions can enhance the pharmacist's ability to improve the overall medication-related safety and quality of patient care in coordination with other health care providers and improve patient outcomes.

Formed in the fall of 2010, the Collaborative's vision and mission is to assure the nation's healthcare system is supported by meaningful use of HIT and 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's goals seeks to ensure HIT supports pharmacists in health care service delivery, achieve integration of pharmacists and pharmacies into health information exchanges, and advocates pharmacist recognition in HIT programs and policies.

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 networks, a standards development organization, transaction processing networks, pharmacy companies, system vendors and other organizations that support pharmacists' services. The Collaborative was founded by nine pharmacy professional associations representing over 250,000 members and includes seven associate members from other pharmacy related organizations. For additional information, visit www.pharmacyhit.org

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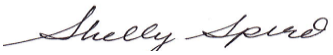
On behalf of the Pharmacy e-HIT Collaborative, thank you again for the opportunity to comment on *FDASIA Request for Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology*. For more information, contact Shelly Spiro, executive director, Pharmacy e-HIT Collaborative, at shelly@pharmacyhit.org.

Respectfully submitted,



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