Pharmacy Health Information
Technology Collaborative

August 25, 2017

Office of the National Coordinator
Department of Health and Human Services
330 C St., SW, Floor 7
Washington, DC 20201

Re: 21st Century Cures Act Trusted Exchange Framework and Common Agreement

Dear Sir or Madam:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (the Collaborative), we appreciate the opportunity to submit comments regarding the *21st Century Cures Act Trusted Exchange Framework and Common Agreement,* as follow up to the July 24, 2017, kick-off meeting.

The Collaborative has been involved with the federal agencies, including the Office of the National Coordinator (ONC), developing the national health information technology (health IT) framework since 2010.

Pharmacists provide person-centered care and services, maintain various secure 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 users of health IT and are especially supportive of interoperability standards incorporating Health Level Seven (HL7), SNOMED CT, RxNorm (National Library of Medicine), National Council of Prescription Drug (NCPDP) SCRIPT, and NCPDP Real Time Formulary and Benefits (currently under development). The Collaborative supports the use of these particular standards, which are important to pharmacists for use in providing specific person-centered care and services to patients. Moreover these particular standards would help in reaching the trusted exchange framework's goal of nationwide interoperability.

Our comments regarding the six specific topic areas are below.

Comment Area 1: Standardization
Adhere to industry and federally recognized technical standards, policies, best practices, and procedures

The Pharmacy HIT Collaborative supports adherence to recognized technical standards, policies, best practices, and procedures for the exchange of electronic health information. However, these will not be enough to achieve the goal of widespread interoperability as these facets vary within participating groups, vendors, and health care providers. With the many private sector efforts in this area, we continue to have a disparate health IT framework that creates barriers to achieving widespread interoperability.

To achieve full interoperability under the 21st Century Cures Act, a national standard and a common agreement with respect to health information technology within the trusted exchange framework needs to be adopted. Without a national standard and common agreement, existing industry technical standards, policies, best practices, and procedures may run the risk of not being compatible with the new trusted framework once it's developed, especially since adoption of this framework by the private sector would be voluntary for those not participating in the Merit –based Incentive Payment System (MIPS), meaningful use, alternative payment models (APMs), or other federal value-based payment programs.

Pharmacists are users of health IT and are especially supportive of interoperability standards incorporating Health Level Seven (HL7), SNOMED CT, RxNorm (National Library of Medicine), National Council of Prescription Drug (NCPDP) SCRIPT, and NCPDP Real Time Formulary and Benefits (currently under development). The Collaborative supports the use of these particular standards, which are important to pharmacists for use in providing specific person-centered care and services to patients. In addition, these particular standards would help in reaching the trusted exchange framework's goal of nationwide interoperability.

The ONC has a critical role to play in developing a consensus and the support to ensure full network-to-network exchange of health information with the new trusted exchange framework nationally. We believe one of the starting points to develop a consensus is to define what a trusted exchange framework is, how it will operate, how it will be implemented. The Act does not define trusted exchange framework.

Comment Area 2: Transparency
Conduct all exchanges openly and transparently

The Collaborative supports exchanges operating openly and transparently. Critical to achieving open and transparent exchanges is ensuring that information blocking is discouraged and does not occur with vendors or health care providers, including removing barriers that may constitute or be perceived as information blocking. The existence of information blocking currently is a concern of the Collaborative and its members. As users of health information technology, pharmacists in all practice settings need unhindered access to the exchange and

use of electronic health information. Establishing trust in this framework will be vital to its success. There will need to be true accountability in this regard.

We recommend that ONC continue to analyze gaps and identify and make available the best solutions to curtail information blocking. The Collaborative also believes it may be necessary to rethink the HIPAA Privacy Rule under this new paradigm. HIPAA is often used as a way to block information sharing.

Comment Area 3: Cooperation and nondiscrimination
Collaborate with stakeholders across the continuum of care to exchange health information, even when a stakeholder may be a business competitor

As noted in comment area 2, establishing trust applies to this area, as well, and will be key to collaborating with stakeholders across the continuum of care, particularly with regard to collaborating with a business competitor. Concerning the latter, this may be a paradigm shift for some and could necessitate a change in business models. Existing requirements with regard to cooperation and non-discrimination in data exchange arrangements vary across organizations.

Comment Area 4: Security and Patient Safety
Exchange electronic health information securely and in a manner that promotes patient safety and data integrity

The Collaborative believes that ensuring patient security and safety in the electronic collection and exchange of health information is of the utmost importance. Protecting patient information is paramount. One area of concern that needs to be kept at the forefront of discussions of a trusted exchange framework is cybercrime, which is a fast-growing challenge.

As this process moves forward, the Collaborative recommends establishing common identity proofing practices and requiring multi-factor authentication for all patient and provider access to the trusted exchange framework and health IT systems, particularly with regard to the various means of accessing health IT systems and electronic health information. Access to health IT systems via mobile phones, email, online services, and other electronic avenues is becoming more commonplace. We believe such may occur with the trusted exchange framework. Although security may be implied, it would be helpful to have that specifically indicated as part of the trusted exchange framework, particularly in today's environment.

Comment Area 5: Access
Ensure that patients and their caregivers have easy access to their electronic health information

The Collaborative supports establishing assurances that patients and their caregivers have easy access to their electronic health information. At the same time, and as we noted in comment area 4, easy access also needs to ensure patient security and safety in the electronic

collection and exchange of health information, especially with regard to cybercrime. This is also an area in which it may be necessary to rethink the HIPAA Privacy Rule regarding electronic exchanges of health care information. HIPAA could be a barrier.

Comment Area 6: Data-Driven Choice.
Exchange multiple records at one time to enable identification and trending of data to lower the cost of care, improve the health of the population, and enable consumer choice
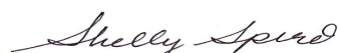
The Collaborative supports the exchange of multiple records at one time. This is also an area in which it may be necessary to rethink the HIPAA Privacy Rule regarding electronic exchanges of health care information. HIPAA could be a barrier.

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The Pharmacy HIT Collaborative's vision and mission are to assure the nation's health care system is supported by meaningful use of health IT, the integration of pharmacists for the provision of quality patient care, and to advocate and educate key stakeholders regarding the meaningful use of health IT 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 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.

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On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the *21st Century Cures Act Trusted Exchange Framework and Common Agreement.*

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

Respectfully submitted,

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