Pharmacy Health Information Technology Collaborative

Via Electronic Submission to: exchangeframework@hhs.gov

February 20, 2018

Office of the National Coordinator for
Health Information Technology
U.S. Department of Health and Human Services
300 C St., SW, Floor 7
Washington, DC 20201

Re: Draft Trusted Exchange Framework

Dear Sir/Madam:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we are pleased to submit comments for the *Draft Trusted Exchange Framework.*

Pharmacists are users of health IT and are supportive of interoperability standards, especially those utilizing certified EHR technology (CEHRT). The Collaborative supports use of these particular standards which are important to pharmacists for working with other health care providers, transitions of care, allergy reactions, immunization historical and administered, immunization registry reporting, medications, medication allergies, patient problems, smoking status, reporting to public health agencies, clinical decision support services/knowledge artifacts, drug formulary checking, and electronic prescribing (including new versions).

The Collaborative has been involved with the federal agencies, including the Office of the National Coordinator (ONC) and the Centers for Medicaid and Medicare Services (CMS), developing the national health information technology (HIT) framework since 2010.

The following are our comments regarding the *Draft Trusted Exchange Framework.*

Part A – Principles for Trusted Exchange

The Collaborative supports the six core principles of the Trusted Exchange Framework and Common Agreement (TEFCA) by which Qualified HINs, as well as HINs, and other data sharing arrangements are used for the exchange of electronic health information and to facilitate interoperability.

Principle 1 (A)– Adhere to industry and federally recognized technical standards, policies, best practices, and procedures

The Collaborative supports this principle, especially the use of Consolidated Clinical Document Architecture (C-CDA) developed by HL7, as indicated as an example in principle 1(A) and Fast Healthcare Interoperability Resources (FHIR) in Principle 1(B). The Collaborative has a suggested edit to the reference of C-CDA: Page 14 refers to it as consolidated clinical data architecture rather than consolidated clinical document architecture.

Although the ONC states in Principle 1(A) that "Qualified HINs and their participants should adhere to federally adopted or recognized standards," this appears to indicate that adherence to these standards is voluntary. The word "should" implies alternative standards, which may or may not be certified or compatible to achieve interoperability across networks, that could be used in TEFCA. It is not clear if making adherence voluntary is the ONC's intent. As currently proposed, voluntary adherence appears throughout each of the principles.

Given the work that has been done the past few years by the ONC, the CMS, and the myriad of stakeholders to move existing programs forward using certified technologies and standards to facilitate interoperability, the Collaborative recommends that adherence to federally adopted or recognized standards be required for TEFCA.

Principle 2: Transparency: Conduct all exchange openly and transparently.

Although the Collaborative is supportive of this principle, we have concerns that adherence is voluntary and all participant agreements for permitted purposes, as the ONC mentions, may not support all of the HIPAA permitted purposes. As we noted in Principle 1(A), adherence to the core principles should be required for participating in TEFCA. Voluntary adherence could decrease success of the goals set by TEFCA, especially, for achieving interoperability. The Collaborative also recommends that all TEFCA participant agreements for permitted purposes be compliant with HIPAA and support HIPPA permitted purposes. The privacy and security of patients is paramount.

Principle 3: Cooperation and Non-Discrimination: Collaborate with stakeholders across the continuum of care to exchange electronic health information, even when a stakeholder may be a business competitor.

There are two areas in this principle that the Collaborative asks the ONC to examine more critically and address further: information blocking and the rescission of net neutrality. Information blocking and limiting the sharing of data are a concern to pharmacists and the Collaborative. The ONC should state definitively that any form of information blocking is prohibited for participation in TEFCA, emphasizing that federal law (21st Century Cures Act passed by Congress) bans this practice. Principle 3 does not specifically ban information blocking, and as noted in Principles 1 and 2, appears to indicate that adherence to this principle

is voluntary as follows: "Likewise, Covered Entities should not implement technology in a manner that permits limiting the sharing of data." This statement does not specifically prohibit a covered entity or any participant from doing such. Stating someone should or should not conduct a certain activity is not the same as requiring them to adhere or comply.

The recent rescission of net neutrality may affect this principle, as well as Principles 5 and 6, and may have the unintended consequence of allowing a form of information blocking. The Collaborative strongly encourages the ONC to look into this concern, if it has not already begun to do so.

Principle 3 states, "Qualified HINs may not use methods that discourage or impede appropriate health information exchange, such as throttling the speed with which data is exchanged…." Additionally, the ONC posits, "Fees and other costs should be reasonable and should not be used to interfere with, prevent, or materially discourage the access, exchange, or use of Electronic Health Information within a Qualified HIN or between Qualified HINs." Although Qualified HINs possibly may not do this, now that there is no longer net neutrality, Internet Service Providers (ISPs) may inadvertently become the impediment through the slow and priority access fast lanes that will be created and the higher fees charged for using the priority access fast lanes. Higher fees could also be passed on to end users, including patients, to access their health information. Please see our comment section: Net Neutrality Repeal.

Principle 4: Privacy, Security, and Safety: Exchange Electronic Health Information securely and in a manner that promotes patient safety and ensures data integrity.

The Collaborative supports Principle 4, ensuring the integrity, privacy, security, and safety of patients with regard to electronic data exchange of health information.

Principle 5: Access: Ensure that individuals and their authorized caregivers have easy access to their Electronic Health Information.

The Collaborative believes Principle 5 may also be directly affected by the rescission of net neutrality. Principle 5(A) states: "Do not impede or put in place any unnecessary barriers to the ability of patients to access and direct their Electronic Health Information to designated third parties." As we commented in Principle 3, the repeal of net neutrality may have the unintended consequence of being an impediment to the access and flow of electronic health information, especially, for patients. It will be contingent on how ISPs implement fast and slow lanes that are under consideration and the fees that may be charged for using fast lanes. Please see our comment section: Net Neutrality Repeal.

Principle 6: Data-driven Accountability: Exchange multiple records for a cohort of patients one time in accordance with Applicable Law to enable identification and trending of data to lower the cost of care and improve the health of the population.

As noted previously, Principle 6 may also be directly affected by the rescission of net neutrality. The repeal of net neutrality may have the unintended consequence of being an impediment to the flow of multiple patient records. ISPs control the flow of information and data. It will be contingent on how ISPs implement fast and slow lanes that are under consideration and the fees that may be charged for using fast lanes. Please see our comment section: Net Neutrality Repeal.

Part B – Minimum Required Terms and Conditions for Trusted Exchange

The Collaborative supports the terms and conditions outlined for developing the Common Agreement for TEFCA to establish common authentication, a common set of rules for trusted exchange, a minimum core set of organizational and operational policies to enable the exchange of electronic health information, and a single "on-ramp" for stakeholders. Of particular importance for pharmacists and the Collaborative are the required adherence to standards for privacy, security, and identity proofing. The Collaborative supports the use of FHIR in these standards.

3. Standardization

The Collaborative supports the use of FHIR and ultimately HL7 for query/pulls in 3.1.5 Population Level.

4. Transparency – 4.3 Disclosures for Patient Safety, Public Health, and Quality Improvement Purposes.

The Collaborative especially supports "(iii) reporting of EHR-related adverse events, hazards, and other unsafe conditions to government agencies, accrediting bodies, patient safety organizations, or other public or private entities that are specifically engaged in patient quality or safety initiatives."

5. Cooperation and Non-Discrimination – 5.2 Non-Discrimination

The Collaborative has concerns regarding the repeal of net neutrality and its potential affect on subsection 5.2.2. This subsection states that a Qualified HIN shall not unfairly or unreasonably limit exchange or interoperability with any other Qualified HIN by sending EHI at different speeds (sometimes referred to as data throttling) or slowing down the rate at which such EHI is sent. As we pointed out previously, ISPs control the flow (speed) of information and data over the Internet. Although this is entering into an unknown area, it will be contingent on how ISPs implement fast and slow lanes that are under consideration and the fees that may be charged for using fast lanes. Please see our comment section: Net Neutrality Repeal.

6. Privacy, Security, and Patient Security

The Collaborative supports the standards and requirements for privacy, security, and patient security and agrees that is paramount to implementing TEFCA.

8. Data-driven Choice

The Collaborative supports the use of HL7 for 8.1.1 query/pulls for 8.1 Population Level Data. Although subsection 8.1 indicates "the standard referenced in 4.1.5 being formally adopted by HL7," Part B of this document does not include a subsection 4.1.5. It is not clear whether 4.1.5 applies to 4. Transparency, or if this is a typo and is meant to refer to 3.1.5, which contains identical language. We ask the ONC to clarify.

9. Participant Obligations

The Collaborative supports the requirements for Participant Obligations, especially those for privacy, identity proofing, authentication, and security breach notifications.

Net Neutrality Repeal Impact

The Collaborative strongly encourages and recommends that the ONC examine the potential impact of the net neutrality repeal on TEFCA, if it has not already begun to explore this area. The ending of net neutrality could go well beyond the average Internet user's day-to-day experience. It is our concern that repealing net neutrality may have a substantial negative impact on the health care arena, health IT that is reliant on the Internet, and the sharing of health care data via the Internet. Health care programs and providers could find their abilities to provide and share health care data with others slowed if they are not in a position to pay for prioritized access (fast lanes). ISPs could become information blockers, an unintended consequence, as they control the flow of information and data, which would impede achieving the interoperability goals established by the ONC for the use of health IT nationwide. Information blocking is an issue that Congress addressed by including a prohibition of such in the 21st Century Cures Act.

ONC Inquiry Regarding Prescription Drug Monitoring Programs (PDMPs)

The Collaborative believes that a single "on ramp" to data within the 49-state PDMPs could help broaden use and access to the exchange of controlled substances prescriptions, particularly, as a national, centralized PDMP does not exist, and provided all of the states agree to such access; however, an on ramp may not necessarily address and resolve some of the issues surrounding PDMP usage (e.g., real-time interoperable databases among states; real-time response for validating accurate data; standard sets; etc.). Missouri is the only state that has not adopted PDMP because of privacy concerns expressed by state legislators. St. Louis County, however, adopted and implemented its own PDMP.

The Collaborative is familiar with two groups working to achieve improved interoperability of the states' PDMP programs: the National Council for Prescription Drug Programs (NCPDP) and the National Association of Boards of Pharmacy (NABP).

The National Council for Prescription Drug Programs developed a detailed plan to standardized PDMPs nationally "to better track and deter abuse of controlled substance prescriptions. The plan leverages NCPDP's Telecommunication and SCRIPT Standards in use industry-wide"[1] and addresses real-time interoperability, standard sets, and data integrity issues.

The National Association of Boards of Pharmacy (NABP) has moved in this direction and provides single access to the majority of the states PDMPs. NABP's PMP InterConnect links 45 of the 49-state and St. Louis County PDMPs to facilitate sharing of prescription data across state lines.[2] States participating are required to sign a memorandum of understanding (MOU). "If practitioners, pharmacists or other PMP users wish to obtain multistate PMP data, they are required to contact their home-state PMP directly, as access is granted through the specific state PMP. The state must be participating in PMP InterConnect in order for the individual to obtain multistate data."[3] California, Florida, Nebraska, and Washington have not signed on. It appears at least 45 states may have resolved state law issues regarding interstate connectivity and sharing of data across state lines.

The Collaborative strongly supports the development and adoption of standards, such as NCPDP's Telecom and SCRIPT and HL7's FHIR, which will help close interoperability, workflow, and real-time reporting gaps associated with PDMP.

Additional Questions for the ONC

After reviewing the *Draft Trusted Exchange Framework*, a few other questions remain. The Collaborative asks the ONC to comment on the following:

How will the Trusted Exchange Framework and Common Agreements be monitored for compliance?

If a participant is found to be noncompliant, what action will the ONC take (e.g., warnings, penalties)?

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[1] "NCPDP's Recommendations for an Integrated, Interoperable Solution to Ensure Patient Safe Use of Controlled Substances," white paper, Version 2.1, November 2016. https://www.ncpdp.org/Education/Whitepaper?page=2

[2] https://nabp.pharmacy/initiatives/pmp-interconnect/

[3] https://nabp.pharmacy/initiatives/pmp-interconnect/faqs/#how-to-connect

Is the Trusted Exchange Framework design flexible enough to accommodate new technologies being developed that could be used to advance? One technology that is now being touted as a possible solution to some interoperability issues in health care is blockchain. Although currently making its way into the financial industry (Bitcoin is one its earliest and larger users), recent reports state that blockchain has strong applicability for health care and health information.

Is the FDA coordinating its REMS Platform Initiative with the ONC to ensure full interoperability with the Trusted Exchange Framework once REMS is operational? This will be important to those in health care, especially pharmacists, who may be required to use both. The Collaborative submitted REMS comments on January 31, 2018, to the FDA, asking this same question.

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The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members, including those in pharmacy education and accreditation. The Collaborative's membership is composed of the key national pharmacy associations involved in health information technology (HIT), the National Council of Prescription Drug Programs, and nine associate member encompassing e-prescribing, health information networks, transaction processing networks, pharmacy companies, system vendors, pharmaceutical manufacturers, and other organizations that support pharmacists' services.

As the leading authority in pharmacy health information technology, the Pharmacy HIT Collaborative's vision and mission are to ensure the U.S. health IT infrastructure better enables pharmacists to optimize person-center care. Supporting and advancing the use, usability, and interoperability of health IT by pharmacists for person-centered care, the Collaborative identifies and voices the health IT needs of pharmacists; promotes awareness of functionality and pharmacists' use of health IT; provides resources, guidance, and support for the adoption and implementation of standards driven health IT; and guides health IT standards development to address pharmacists' needs. 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 *Draft Trusted Exchange Framework.*

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

Respectfully submitted,

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