HiMSS Electronic Health Record Association

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Wellsoft Corporation

August 23, 2017

Donald Rucker, MD
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Rucker,

On behalf of the 30 member companies of the Electronic Health Record Association (EHRA), we are pleased to offer our comments to the Office of the National Coordinator for Health Information Technology (ONC) on the 21st Century Cures Act (Cures) Trusted Exchange Framework and Common Agreement. We appreciate this opportunity to provide input on establishment of a framework for the exchange of health data across networks.

Our comments outlined on the attached document encourage ONC to make the framework voluntary, with future work building upon existing standards and technology approaches for interoperability. Our comments focus primarily on:

1. Our support for secure exchange and non-discrimination in data-sharing.
2. Urging ONC to build upon the important investments and progress that have been made by stakeholders, versus introducing major mid-course changes which would lead to disruption.
3. Emphasizing that participation in the trust framework should be voluntary.
4. Noting that some comment areas proposed by ONC seem to extend beyond Cures requirements; these should be clearly stated as ONC policy goals, as opposed to statutory requirements.

Thank you for this opportunity to comment. We look forward to continuing to work with ONC and other stakeholders to advance secure data exchange and support patient care through the best use of electronic health records.

Sincerely,

Sasha TerMaat
Chair, EHR Association
Epic

Richard Loomis, MD
Vice Chair, EHR Association
Practice Fusion

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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

Comment Areas	
Comment Area 1: Standardization	**Adhere to industry and federally recognized technical standards, policies, best practices, and procedures.** EHRA emphasizes that important work and investments have been made by developers, HIEs, exchange consortia, providers, payers, and other stakeholders in technical standards and technology approaches for interoperability and encourages future work by ONC to build upon and not undermine or reduce the value of this foundation. For example: 1. HHS has previously signaled through EHR certification (2014 Edition, 2015 Edition) an ongoing investment in HL7's C-CDA as the document standard for interoperability. This standard, which has been undergoing periodic revision based on community feedback, can be applicable for many use cases including provider-to-provider transitions, public health use cases, patient access to health information (VDT), and bulk extracts for EHR conversions or other purposes. 2. For "push" use cases, Direct has gained traction for provider-to-provider communication as a transport mechanism, typically using documents as payload but capable of including HL7 V2 or other content as well, while HL7 V2 messages continue to support a variety of interoperability use cases within and across organizations to exchange data where format is not relevant. 3. For "pull" use cases, IHE document query standards are the most popular with established large scale infrastructures. With the maturing of FHIR, IHE has extended its profiling with complementary FHIR-based document level query profiles (MHD). FHIR based RESTful serviced APIs are emerging using the Argonaut implementation guidance for data element level queries, while IHE has further defined profiles in that space (QEDm) and is providing the ability to combine both document and data element level queries (mXDE) for clinician and patient access. 4. For authentication, we note that Direct Trust, Car*e*Quality, the CommonWell Health Alliance, and the Surescripts National Record Locator Service (RLS) have existing technologies and frameworks that allow for scalable authentication of participants that ONC can look to and recognize as part of an overall trusted framework. 5. For patient access to health information via an APP, ONC has not previously identified a standard in certification, but we see HL7 FHIR and the associated Argonaut profiles as the most commonly used standards-based approach. 6. Developers, providers, and other stakeholders have also implemented and aligned on various ONC-identified/specified industry data element and data set (i.e., C-CDS) standards.

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August 23, 2017

	7. ONC should properly evaluate complaints of non-compliance with the Trusted Framework before reaching conclusions of information blocking. Even with relatively mature standards, vendors frequently must do work that is additive to a trust framework's requirements to enable exchange. For example, HIEs and registries frequently ask for items above and beyond the baselines through testing and implementation requirements. In addition to health IT developer investments in these standards and associated technology approaches, healthcare providers have already invested in purchasing and upgrading to health IT that supports these standards and to aligning their workflows and data capture to populate these formats. Also, EHR developers and others in the industry have invested in and engaged with a variety of rapidly accelerating exchange/trust networks and frameworks, including CommonWell, eHealth Exchange, Carequality, the CARIN Alliance, and DirectTrust. We note that there has been important progress among both these exchange approaches (e.g., CommonWell connecting to Carequality and Surescripts RLS being available through Carequality) and their use of a variety of standards (e.g., both IHE document query profiles, HL7 C-CDA, and HL7 FHIR profiles) within the same exchange model. Taken together, all of the investments by stakeholders are clearly pointing in the right direction and are advancing cross-organizational and intra-organizational interoperability as well as improving patient access. It is critical that ONC work on a set of core principles that enable meta-governance that a Trust Framework should support, thus building on the existing work. All the while, ONC should recognize that variations beyond the core principles are appropriate considering the different but overlapping purposes of various trust frameworks, rather than seek to make major mid-course changes or defining a single industry trust framework intended to replace the evolving and proven models now in place. Such non-productive disruption would lead to wasted investments in a time of constrained resources, slow current progress, and send a message that industry investments in interoperability are perennially at risk to changing policy priorities.
Comment Area 2: Transparency	**Conduct all exchange openly and transparently.** Applicable exchange models should involve transparency regarding trust framework principles and agreement/contract provisions relevant to participants and other affected stakeholders. The trust framework should be voluntary. Failure to adhere should not be considered de facto information blocking when other methods are used to exchange information. Additionally, ONC should avoid conflating a trust agreement with specific service agreements or network agreements and not seek to draft such detailed agreements. Rather, its focus should be on core principles that various Trust Frameworks should support to enable essential consistency across networks.

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Comment Area 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.**
	EHRA supports this general principle, although we recognize that providers and other exchange partners may wish to negotiate such provisions (especially for cooperation) in ways that distinguish between different HIPAA and other data categories/uses, particularly for purposes beyond treatment in support of direct patient care.
	The EHRA's EHR Developer Code of Conduct recognizes that data should follow the patient, and developers who have adopted the Code of Conduct agree to:
	• "Enable, to the greatest extent possible, our clients to exchange clinical information with other parties involved in the care of a patient, including those using other EHR systems, through standards-based technology."
	• "Work with our clients to facilitate export of patient data if a client chooses to move from one EHR to another."
Comment Area 4: Security and Patient Safety	**Exchange electronic health information securely and in a manner that promotes patient safety and ensures data integrity.**
	EHRA supports this general principle. Developers who adopt the Code of Conduct "are committed to developing and implementing our software, services, and business practices in ways that protect patients' privacy through the secure and trusted handling of protected health information (PHI)." Additionally, they agree:
	• "We are committed to following best practices for handling PHI or other confidential information when we are stewards of such information."
	• "We will adopt relevant standards for protection of electronic PHI. Such actions may include, but are not limited to, use of industry standards for encryption, hashing, or access control."
	• "We will make available to our clients information about our approaches to privacy and security."
	• "We will provide our clients with information on best practices for using our products to support their privacy and security responsibilities."

Comment Area 5: **Access**	**Ensure that patients and their caregivers have easy access to their electronic health information.** It is important to note that not all exchange frameworks will be focused on either patients or caregivers, depending on design or use case, but we agree the overall system should meet this goal. Additionally, we see a need to clarify "caregiver" in this context: a patient's clinician, a family member or friend, or both?
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.** We note that this comment area is not called out in the statutory language of Cures. We seek clarification on the statutory basis for this approach, and how it may relate to initiatives already in place through quality measures and enabling access to certain claims data that is already progressing in this space. Not every use case or exchange participant will have the same capability or need for sending multiple records. While it is our understanding that existing and emerging exchange standards can send multiple records upon authorized requests, we suggest that this not be a requirement for all networks, rather for networks that aim to support this capability.
General **Comments:**	**Stakeholders may submit additional comments in this section that do not fit in the above categories. Alternatively, commenters may submit their comments in their entirety in this category if they choose. We note that while we encourage use of the above comment areas, it is not required.** The comment areas put out by ONC seem to extend beyond what is specifically required under Cures. It will be important to distinguish between statutory requirements and ONC policy goals. ONC should utilize, reference, and permit existing trust frameworks and recognize that these may have different elements based on varying use cases, goals, and participants. *ONC should focus on identifying and facilitating a sufficient set of private sector trust agreements and facilitate coordination where needed, focused on core principles, rather than specifying a single overarching framework and eliminating variations across existing agreements.* Centralized and federated models can work together; there is no need to require a centralized technical or organizational architecture for interoperability. Measuring progress toward the effectiveness of trusted frameworks is helpful, but we caution that such measurements should be nimble and a byproduct of existing data rather than new data collection. We point to EHRA's comments on ONC's Interoperability Measurement Framework regarding industry interoperability measurement efforts for further context as well.

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August 23, 2017

	Work beyond the capabilities of current standards (or piloting new standards) should be encouraged. It will be important that innovation or variation within the exchange ecosystem not be limited.