DirectTrust The most trusted name in health information exchange

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DirectTrust Comment to ONC on the Draft for the Trusted Exchange Framework and Common Agreement, TEFCA

As President and CEO of DirectTrust.org, Inc. (DirectTrust), a large, inclusive, and diverse health IT industry alliance non-profit, it is my pleasure to comment on behalf of our membership on the recent TEFCA documents published by ONC.

Address Direct exchange and "push" interoperability as an important mechanism of health information exchange: We applaud the intent of this framework and common agreement to further advance the interoperable exchange of electronic health information. However, the omission from the documents of the importance of the Direct interoperable "push" model implies that "query" for a patient's medical information is all that is needed to achieve the interoperability goals of the 21st Century Cures Act. In reality, both are needed. Pull or "query" is important. But a real time "push" model such as that accomplished by Direct interoperability supported by the DirectTrust trust framework is also critical to meeting the Cures Act HIT provisions, and to the achievement of best practice patient care.

The DirectTrust community has developed a single, one-to-many, "on-ramp" for health care stakeholders to participate in nationwide health information exchange for "push" transactions via Direct messaging and attachments. Since its inception just over 5 years ago, DirectTrust members have collectively developed a health information network that reaches over 110,000 health care organizations and 1.6 million end users as participants, with transactions nearing 170 million over the past year 2017. In short, it is proven and it works.

We want to point out just a few of the numerous use cases widely adopted and appropriate for securely "pushing" electronic health information via Direct. Examples include:

- real time acute facility discharge messages, including from the ER, to the patient's ambulatory care team
- "closed loop referrals" (when placing a referral to another healthcare provider or service, then the return of the results from a service or encounter)

- ad-hoc communication among individual providers, other health care team members, patients, and caregivers.

These and a growing list of other use cases requiring and benefiting from bi-directional communications cannot be accomplished in a timely manner or within complex, high-acuity workflows using only a "pull" model which requires significant staffing and effort. But they are *critical* components of a responsive, coordinated and patient-centered healthcare system. Health care providers need and deserve a combination of electronic "push" interoperability with "query" technology to provide the full gamut of interoperation of clinical information systems.

The robust state of adoption of Direct exchange and its significant development as a standard for secure and interoperable health information exchange is in large part a result of the early support that DirectTrust received as the recipient of a Cooperative Agreement with, and funding from, ONC under the "Exemplar Health Information Exchange Governance Entities Program" between 2013-2015. The primary mandate charged to DirectTrust by ONC under the agreement was the establishment of a large "trust community" that would scale nation-wide for the trust relationships needed for provider and patient confidence in sharing of protected health information (PHI), such that individual parties to the exchanges would not need to engage in expensive and time-consuming one-to-one negotiations or agreements regarding policy and controls for privacy, security, and trust in identity. Instead, all participating parties would rely upon assurance grounded in a common framework of technical standards, trust policies, and best practice requirements, voluntarily agreed to and enforced. This has been accomplished through robust accreditation and audit of services and semi-annual testing of HISP providers; a brief legal agreement known as the Federated Services Agreement; and constant oversight by DirectTrust, its volunteer Committees and Board of Directors.

In public statements, ONC personnel have explained that "push" messaging is not included in the TEFCA rules because it is working well today: "…(T)he mechanism that DirectTrust has set up is working well, mission accomplished; we don't need to touch this." (Genevieve Morris, January 18, 2018).

We agree with Ms. Morris' statement, of course, but by not explaining this decision in writing within the TEFCA documents explicitly, the ONC may unintentionally suggest that it believes that only query-based interoperable health information exchange is important and worthy of promotion within the TEFCA rule set, or that Direct exchange will not benefit from further support by ONC. The latter is distinctly incorrect. As we have noted in our recently published "Consensus Statement: Feature and Function Recommendations to Optimize Clinician Usability of Direct Interoperability to Enhance Patient Care," usability of Direct exchange in many EHR products remains awkward, imperfect, or ignored outright. Features and functions to support easy use of Direct messaging for providers ought to remain a high priority for support by ONC. We believe this is an unwarranted oversight on the part of ONC, and one that we hope will be corrected.

Recommendation: It therefore serves the interests of all parties to health information exchange that in the "Overview" section of the Trusted Exchange Framework and Common Agreement documents, you

include reference now and in the future to the importance of secure "push" communication of electronic health information provided via Direct under the coordination and governance of DirectTrust to the nation's path forward, first and foremost for patient care and second to meet regulatory requirements, and that ONC briefly explain why the Trusted Exchange Framework Part A and Common Agreement Part B shall apply only to "query" technology.

Raising awareness of identity management for scalable trust: The TEFCA rules appropriately raise awareness of the importance of certificate-based identity management and assurance. DirectTrust has developed an effective and sustainable Public Key Infrastructure (PKI) to achieve efficient identity proofing along with essential support services for interoperability such as trust anchor bundles for trusted certificates and accreditation programs, to enable scalable distribution of trust throughout the health care industry. DirectTrust's Certificate Policy, HISP Policy and other supporting policies are fine-tuned to the needs of the health care industry.

DirectTrust's PKI maintains the flexibility to address other use cases within health care besides those for Direct exchange. While due diligence should always be performed on the applicability of DirectTrust's PKI to use cases contemplated in the full scope of TEFCA, engagement between DirectTrust and the FHIR community has identified opportunities to develop scalable certificate-based authentication at scale through use of the DirectTrust PKI. ONC and the chosen RCE should encourage and support these efforts to ensure the value-added that this use of the DirectTrust trust framework for identity offers.

DirectTrust is ready and willing to facilitate scalable trust within the qualified HIN architecture envisioned in the TEFCA documents, and to work with any candidates for the RCE cooperative agreements and with ONC to collaborate. Such collaboration would save significant resources by avoiding the establishment of a completely new PKI for the purposes and tasks included in TEFCA.

Additional comments and talking points from DirectTrust members:

There are still questions to be answered, and further clarification to be provided related to TEFCA. The following summarizes DirectTrust member observations, question, and concerns, offered for ONC consideration and discussion during this process:

- General observations: While the DirectTrust framework shares many of the same core principles and goals outlined within TEFCA and should be considered as reference to a successful model for how to establish a trust framework, the fact remains that query-based exchange involves a much more complicated set of use cases given such topics as consent management, and impacts of state law and contract variance (e.g. opt-in vs. opt-out). Similar models, such as those of establishing Qualified Entities within the New York eHealth Collaborative attempt to address these additional complexities and should be investigated.

  There is a general concern about the high ambition, required scale, and top-down characteristics of the plans for TEFCA as currently laid out by ONC, which to some appear as "over-reaching."

While none of our members have expressed disagreement with the laudable overall goals of the Common Agreement, there is significant doubt about the ability of the industry to accommodate the new administrative burdens, find funding to comply with new requirements for "on ramp" exchange technology, and to manage new privacy mandates across the range of permitted uses, in the time frames anticipated. There are also questions as to ONC's ability to sustain the effort to see TEFCA through to completion over a period of several years given budget and personnel cuts to ONC.

The success of DirectTrust has been achieved by the members themselves driving to achieve shared goals through a voluntary and very collaborative process. TEFCA seems to have introduced goals and requirements directed by government and ultimately monitored and enforced by a private sector RCE, versus naturally created by members of the community. While this approach is not inherently problematic, it warrants special consideration in order to maximize participation and outcomes. It is recommended that ONC allow the RCE, in combination with the anticipated QHIN participants to together define the path to achieve the stated goals, and the pace at which it is implemented to create a similar environment. Furthermore, we would recommend further opportunities to weigh in on this process through additional comment periods as it has been difficult in this short time frame for stakeholders to fully understand the operational needs and consequences of this proposal.

The multiple record download and bulk data transfers use case has the potential to generate very large concurrent activities for systems receiving these types of requests. Can eHealth Exchange and FHIR (still an immature standard) grow to handle the volume of exchanges being contemplated by TEFCA? Prioritization of use cases may be necessary to enable steady growth in the amount and types of transactions to aide in preventing initial overburden of participant systems.

None of these concerns should be construed as negative criticism. They do, however, suggest that refinement and a good deal more industry stakeholder consensus about achievable implementation of TEFCA is warranted.

- Permitted uses: There is concern about the additional burdens that might be placed upon participants in QHINs to meet the permitted use requirements, and that these requirements might have a negative downstream effect on participants being willing join a QHIN or an HIE that is a member of a QHIN. Does ONC anticipate that compliance with the TEFCA would require participants to validate the legitimacy of a querying entity's purpose for the request? Covered entities that are participants in HIEs have HIPAA obligations to verify the authority of the entity requesting electronic health information. They are also subject to the minimum necessary requirements under HIPAA. Covered entities may only disclose the minimum amount of information necessary for a particular purpose. It is not clear how participants, or HIE or QHINs on their behalf, will be able to operationalize these permitted uses and meet these legal requirements. How would the purpose of a request, e.g. for public health or research, be made

manifest to the queried parties?

It is unclear how QHINs would operationalize a validation process for a query's stated purpose. For example, how would a QHIN know whether a requesting entity had a legitimate research project? The TEFCA says research in "peer-reviewed journals" but there is no way to know at the time of the data request that a study will end up in a peer-reviewed journal.

The permitted purposes represent several broad use cases, some of which are not commonly in use today for HIE. This is contrary to the "minimum set of conditions" language in 21st Century Cures. It will be a huge lift for most HIEs to accommodate all the permitted purposes in the short term. A better approach may be starting with 1-2 priority purposes – i.e. Treatment, Health Care Operations – and add more purposes to the TEFCA's requirements over time, as QHINs demonstrate success.

- Participation agreements at local levels: There is concern regarding costs associated with changing local HIE participation agreements. All contracts governing participation in an HIE that is a member of QHIN would need to be updated within 12 months of signing the Common Agreement. Changes would almost certainly be substantive given that many participation agreements now in place do not normally permit some of the required permitted uses, e.g. research or large aggregations of data for public health or population management, as well as the TEFCA's provisions around secondary use, fees, and non-discrimination.

  Few, if any, existing networks could comply with the TEFCA's provisions today. Complying with the TEFCA's non-discrimination policy and other provisions will necessitate re-negotiating HIE's existing contracts with potentially thousands of healthcare providers. This would be not only a time-intensive and costly process, but would inevitably lead to providers dropping out of HIEs, given that many providers may take issue with the broad permitted purposes for which their data must be exchanged under the TEFCA. If many of the successful regional or state HIEs lose providers through this process, ONC's goals will not be achieved. We encourage ONC to study the costs and impacts of this policy (similar to what would be required for a rulemaking) and make that information available before proceeding.

- Non-discrimination and privacy policy questions: There is a concern that it might be unreasonably difficult for a participant in a QHIN to conduct due diligence and protect their members' interests in privacy and security given the duty under TEFCA to not limit exchanges, and that this policy would cause participants to completely relinquish control over where their data are sent. The "imperative to share" would require that the QHIN be assessed against privacy and security standards of, for example, a large payer participant, as well as other covered entities that participate. It would also require that each participant be responsible for investigating privacy breaches that occur to its members PHI in the Trusted Exchange Framework – though the members' data could be disclosed by multiple entities. Given the

national nature of this initiative, some wonder if there is a better solution here – one that does not create privacy liability for entities disclosing PHI to the QHIN that could cause member confusion in the event of a breach.

HIPAA allows for data to be exchanged in certain permitted purposes, but does not mandate their exchange for all those purposes. Under HIPAA, providers are the ones who make judgment calls about what is an appropriate use of data and maintain security and privacy controls. The TEFCA turns around this paradigm, *mandating* exchange for certain purposes instead of simply *allowing* it. This puts providers out of control of the flow of their patients' data, and shifts the burden to QHINs.

- Concerns with business model issues: The TEFCA's provisions on fee limitations seem to exclude for-profit business models (i.e. vendor-based networks) from becoming a QHIN – was this ONC's intent? Even if QHINs are only meant to be non-profit HIEs, limiting fees to those which are cost-based may impact these networks' sustainability plans. Even if they do not seek to recoup a profit, HIEs may want to set fees such that they could develop a surplus to reinvest in technology development, etc.

- Process for common agreement and updates: The process for revising the TEFCA appears to be delegated to an ONC grantee, the RCE, who would be a private-sector entity. In this scenario, rules and requirements that affect health information exchange for the country would be modified or updated with no notice and comment process to collect feedback from the stakeholder community in an open and transparent way, no regulatory impact assessment, and no guaranteed feedback loop. This is deeply troubling to the HIE community given the potential impact of the TEFCA on their business models and sustainability.

Given the scope and importance of the TEFCA's vision and potential impact, DirectTrust urges ONC to allow the stakeholder community additional opportunity for public comment. Specifically:

(1) Opportunity to comment on the TEFCA after anticipated regulations regarding information blocking are released later in 2018, given the relationship between information blocking and the content of the TEFCA. It is difficult to respond thoroughly to either document in isolation, and many in the community are wondering whether non-compliance with the TEFCA will impact an entity's status as an "information blocker" or not.

(2) Opportunity to comment after the publication of the revised Common Agreement. We understand that ONC plans to issue a revised Common Agreement, likely after awarding the RCE. At such time, ONC should open an additional comment period so the community can react to the revised provisions.