Ohio Health Information Partnership
Health Information in a Heartbeat

June 17, 2019

Donald Rucker, MD
National Coordinator for Health Information Technology
Office of National Coordinator
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Rucker:

I am responding to the Office of National Coordinator's (ONC) Draft 2 of the Interoperability Framework TEFCA released April 19, 2019. I represent the Ohio Health Information Partnership and its HIE, CliniSync. We currently connect 156 hospitals, thousands of ambulatory providers, 500+ post-acute care sites and numerous social service agencies. We have a longitudinal community health record (CHR) which includes information on 14 million unique patients. Therefore, under the proposed definitions in TEFCA 2, CliniSync could potentially act as both an HIN and a QHIN. We feel that we have good perspective on the interoperability goals set out in the 21st Century Cures Act and ONC and how to achieve them.

We believe that even though there are clarifying details laid out in this version of TEFCA, much of the framework can't be fleshed out until a Recognized Coordinating Entity (RCE) is appointed. Therefore, the full analysis would need to wait until the RCE is in place and governing policies are developed. We feel that even though there are more details in this version of TEFCA than the original version, much of the framework won't be fleshed out until a Recognized Coordinating Entity (RCE) is appointed.

It is critical that as the TEFCA program for national interoperability begins, all parties stay focused on the exchange of data for treatment. There are many potential use cases that are commendable to meet certain aims in the health care system. These should all be secondary to making the clinical data available at the point of care for treatment. Support for treatment should be the primary aim of any interoperability initiative.

Here are some of the areas that the Ohio Health Information Partnership addressed in the first draft of TEFCA and our response to how the issues have been addressed in TEFCA 2.

- Minimum Necessary: We are strongly supportive of ONC's approach to "Minimum Necessary" in Draft 2 [Minimum Required Terms and Conditions (MRTC) Term 7.19]. We feel that the concept of minimum necessary must be the underpinning of any interoperability initiative. By making "Minimum Necessary" a separate term and condition, it focuses the need to incorporate Minimum Necessary into any technical, security and governance structure established under TEFCA.

- Exchange Purposes:

    - ONC has removed the requirement that "Research" be a permitted purpose that would require QHINs to make data available to anyone involved in a peer-reviewed research paper. We strongly support this change to remove the research requirement.
    - In addition, ONC has narrowed the Payment and Operations exchange purposes to limit them to Quality Assessment and Improvement, Business Planning and Development, and Utilization

Review. We feel this more focused approach will make the initial interoperability efforts easier to achieve.

- ONC has removed the requirement that QHINs need to allow testing of APIs for phone apps across the system. We support this change. We feel that the discussion about APIs should not occur until CMS and ONC have had the opportunity to put into place a new procedure for vetting the security of these apps.

- **Timing for Adoption of Compliant Agreements and Technical Requirements:** ONC has expanded the timeline for bringing contract terms with Participants into compliance with TEFCA and has allowed another 6 months' time (now 18 months) to adopt required new technology. We support these timeline changes.

- **Inclusion of Directed Exchange as an Exchange Modality Using Message Delivery:** We support Message Delivery as a form of exchange under TEFCA. Depending on the use case, message delivery may be a more appropriate form of exchange for the data requested.

- **Patient Access to Data through an HIN and Use of APIs to Access:** In *Principle 5 "Access: Ensure that Individuals and their authorized caregivers have easy access to their EHI,"* ONC states that HINs have a duty to give patient access to data. ONC is also requiring that HINs make data available through APIs using third party apps that "comply with the applicable data sharing agreement requirements." We feel that the discussion about APIs should not occur until CMS and ONC have had the opportunity to put into place a new procedure for vetting the security of these apps. Although additional restrictions on apps appear in other CMS/ONC regulations proposed this year, the reality is that there is no established review process. This area is critical when the system being exposed contains medical data from patients around the country. Any such breach would be catastrophic. The data exchanged via discrete data transfer through APIs can put an enormous technical load on a provider's EHR system to the level of millions of "knocks" each month. ONC and CMS should review technical challenges before making API integration a requirement.

  Besides the technical issues around access by third party vendors, there is also the issue of data ownership. Many HIEs, such as CliniSync, do not own the clinical data; they only act as the transmitting agent. If patient access is driven instead through providers and existing patient portals and these providers are participants in TEFCA, then there can be widespread patient access. This can be facilitated through contracts with EHR vendors who can work with the app developers to grant access at the provider level.

- **Meaningful Choice for Patient Segregation of Data:** We agree that patients should have the right to decide what data should be shared with other providers. However, technically this is not always feasible. Before a process is adopted for data segregation, we would urge ONC to review what data should be covered (just 42 CFR Part 2 data or a broader data source?). Recognizing that there is a full-scale initiative at the Congressional level to repeal Part 2 and replace it with HIPAA, it may be better to see what happens this legislative session to better understand what should be done technically to segregate data.

- **Exchange of Patient Panel Data for Population Health:** As ONC accurately points out, "the standards to support this use case are not mature enough for widespread implementation." We would agree, especially since the scope of the data to be transferred for population health and the mechanism have not been identified. We have special concerns around use of APIs for this data transfer (as ONC proposes) because of the same security issues addressed above. Population Health should rightfully continue as a developing use case and not an initial requirement for HINs.

Thank you for the opportunity to participate in this discussion.

Sincerely,

Dan Paoletti, CEO

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