February 19, 2018

Don Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services
Hubert Humphrey Building, Suite 729
200 Independence Avenue SW
Washington, DC 20201

Dear Dr. Rucker:

Enclosed are the comments of the eHealth Initiative (eHI) on the ONC Draft Trusted Exchange Framework (TEF) and the U.S. Core Data for Interoperability (USCDI). eHI is in a unique position to comment and offer insight on this issue. Our viewpoints are broad and consensus-based. We are the only independent non-profit, multi-stakeholder coalition dedicated to improving the quality, safety, and efficiency of healthcare through the use of technology and health information. Moreover, eHI's work and its membership have built needed coalitions and moved the health IT field forward at critical junctures.

We look forward to continuing this progression and working with you, the Recognized Coordinating Entity (RCE) and other key federal government and private sector participants on this and other *21st Century Cures Act* implementation issues. eHI will have fresh thoughts and recommendations to provide in the future, given our recently launched initiatives in the related areas of: technology and analytics, value and reimbursement and workflows to improve the provider and patient experience. Our key comments are below.

If you have any questions or need clarification, please contact me at jennifer.covich@ehidc.org

Sincerely,

Jennifer Covich Bordenick
Chief Executive Officer
eHealth Initiative

Overarching Comments

- **Baseline Fundamentals and Scope**: Overall, eHI supports ONC's approach to the draft TEF and U.S. Core Data for Interoperability (USCDI), which seek to address multi-stakeholder needs with: a single set of rules from which to operate, pursuing a more efficient approach to sharing, building on existing initiatives and simplified provider access to exchange networks. We caution however, that the scope and pace of these initiatives are very ambitious, perhaps overly so.

- **Sustainability**: eHI stresses the need to ensure that the TEFCA processes, including the RCE and the QHIN, are financially sustainable and not overly dependent on federal funding.

- **Common Agreement and Technical Detail Shift**s: eHI recommends that much of the technical detail, including specific standards references, should be moved from the TEF and subsequent legal agreement (the CA) to RCE use-case specific implementation guides.

- **Wide Participation and Forward Progress:** To ensure wide participation in this new framework, early wins will be needed. To achieve such success will require more flexibility to build from existing exchange capability and a phasing-in of the permitted purposes and use cases supported.

- **RCE:** The RCE focus on the private sector and private sector standards is very positive. eHI emphasizes that the RCE should have significant independence from ONC with transparent accountability (including to ONC) and governance that engages all stakeholders, and particularly end-users.

- **Inclusion of the Patient/Caregiver Voice:** We commend the inclusion of a Framework principle around "Access" that ensures individuals and authorized caregivers have easy access to their health information (Principle 5). In efforts to execute this principle, it is important that the voices of these patients and their caregivers be at the table when working to improve their access and contributions to their health information. And, as individuals' access grows, it will be important for them to be presented information in a way that helps them understand their care record.

- **Population Health:** Population health (i.e., bulk data access) is identified as a priority goal, but eHI believes it may need to have some guardrails placed around it to limit both strains on bandwidth and to ensure privacy and implementation of a "minimum necessary" approach to data access. In public presentations, for example, ONC has identified which filter criteria would be appropriate and which would not.

- **Qualified Health Information Networks (QHINs):** eHI points out the need to ensure that there are enough QHINs (that enough will be eligible and interested in that role) to provide sufficient query coverage and access to various stakeholders. For example, it is not clear that the plan to exclude single state Health Information Exchanges (HIEs) or vendor networks from being QHINs is needed.

- **Open APIs:** The role of open, standards-based APIs as expressed in the documents are positive overall, but it must be acknowledged and reflected that applicable standards are still maturing. eHI believes that an ability should be built in to the TEF and Common Agreement to enable TEFCA participants to validate that "apps" are secure and conform with existing privacy laws.

- **Requests**: The obligations of those who receive a request are detailed in the document, but eHI points out, there is less discussion of the obligations of those who make a request. More information about the request may be needed for the respondents to adequately assess whether they can share information consistent with existing privacy laws.

- **Information Blocking and Compliance:** eHI is concerned that the combination of detailed flow-down obligations, linked to information blocking enforcement and certification-based compliance could complicate exchange, especially with the USCDI addition of an expanding set of data elements that providers will be responsible for exchanging.

- **USCDI:** The idea of standards maturity model is in the U.S. Core Data for Interoperability (USCDI), as well as this step wise approach to moving towards the 21st Century Cures "all data" goal, is welcome, but the 12-month turnaround and large number of new anticipated concepts may be overly ambitious. eHI emphasizes that it is not sufficient to name a standard They need to have full implementation guides that are piloted, used in production, and adopted through successful demonstration of their usefulness.