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CONTRA COSTA
HEALTH SERVICES

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The Honorable Donald Rucker, MD,
National Coordinator for Health Information Technology,
US Department of Health and Human Services
200 Independence Ave. SW
Washington, DC, 20201

Comments submitted at: https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement

Re: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2

Dr. Rucker:

Contra Costa Health Services appreciates the opportunity to comment on ONC's Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2. We provided comments on the related 21st Century Cures Act NPRM from ONC and CMS in separate comment letters.

Contra Costa Health Services , a department of Contra Costa County in California's San Francisco Bay Area, includes a Medicaid Managed Health Plan with 200,000 members, a 162 bed Regional Medical Center with 40k annual emergency room visits, outpatient clinics with 500k annual visits, Detention Health Services to our county jail population, Behavioral Health including a psychiatric emergency and inpatient services, Emergency Medical Services, Hazardous Materials Department and Public Health Department that serves the entire population of 1 million county residents. As a safety net organization, we focus on serving Medicaid, uninsured, and homeless populations in our county.

We fully recognize the value of Health Information Exchange to our patients and to our system's ability to meet clinical quality targets. We currently participate in robust exchange of health information, having exchanged almost 11 million standards-based exchanges of full patient records since we implemented our Electronic Health Record in 2012. Our exchange rates are steadily increasing, having exchanged 3.9 million records in 2018, and typically send 100k records a month and receive 200k records per month, including exchanges with the VA, SSA and Department of Defense, and Carequality participants. Geographically have exchanged records with entities in all 50 states, including 1,618 Hospitals, 1,421 Emergency Departments, and 37,004 Clinics as of March 2019.

Contra Costa Health Service commends ONC for their proposals to harmonize networks' permitted purposes and the data available for exchange. We also support the security and privacy standards in the MRTC required for participation in TEFCA.

TEFCA, USCDI and API proposals in the related 21st Century Cures NPRMs will radically reshape our national health IT infrastructure. Taken together, TEFCA and the NPRMs will promote: (1) nationwide provider access to their patients' health information, (2) individual access to their health information electronically without any special effort, (3) population level data exchange, (4) open and accessible application programming interfaces (APIs), (5) penalties for information blocking not covered by the seven exceptions.

While these goals are laudable, the scope of these policies will require significant refinement and massive investment of work to be operationalized. They will need clarification in scenarios where several regulations seem to be at cross purposes. For our comments, we will address topics in the order mentioned in TEFCA Draft 2 document.

Exchange Modalities (p.13)
We support QHIN Targeted Query, which is similar to our current set up, and support QHIN Message Delivery, which will be helpful to promote deployment of shared provider directories that would improve adoption of modalities such as DirectX messaging.

However, QHIN Broadcast Query is wasteful of bandwidth resources and recalls pre-Google web browser searches that returned a random assortment of information. QHIN Targeted Query that queries key trading partners that make up a majority of matches, for example the top ten trading partners that make up 99% of HIE, will achieve huge amounts of benefit. We also use National Record Locator Service, which is not a broadcast query, and effectively fills the gap on the other 1%.

Exchange Purposes (p.14)
We thank the TEFCA Draft 1 for including Treatment, Payment, Health Care Operations, Public Health, Individual Access (per HIPAA) and Benefits Determination, since our operations includes many of these diverse purposes and initially our Health Plan held back from HIE because of an internal determination that HIPAA did not cover the purposes of Payment and Benefits Determination within our EHR vendor's HIE "rules of the road". We support the modification of the Common Agreement to require only the subset of Utilization Review under Payment Purpose.

We would appreciate that TEFCA clarify how to reconcile this reasonable requirement with the CMS Medicare and Medicaid Programs: Patient Protection and Affordable Care Act NPRM's aggressive requirements (in section III Patient Access Through APIs) that Health Plans make the following information available to patients via an API within a single business day: CMS requirements are more difficult that TEFCA's, and we would prefer as a single onramp to HIE that the regulation explicitly state that data be exchanged within TEFCA's framework.

- Patient Claims and Encounter Data
- Provider Directory Data
- Clinical Data including Laboratory Results
- Drug Benefit Data, including Pharmacy Directory, and Formulary data

The Common Agreement's Relationship to HIPAA (p.15)
We would like to comment that the statement in the second paragraph overlooks a major gap in the framework: "Many non-HIPAA entities, such as the developers of smartphone apps, offer useful and efficient services to individuals who elect to use them as a means to access their EHI."

Let us imagine a future where apps can deliver care that aligns with the IOM's criteria of "Safe, Timely, Effective, Efficient, Equitable and Patient-Centered."

However "useful and efficient" the services rendered, their efficiency derives from inequitable privacy arrangements outside of Health IT. Non-HIPAA covered IT corporations have fended off regulation as referenced in Shoshana Zuboff's recent book The Age of Surveillance Capitalism. https://www.publicaffairsbooks.com/titles/shoshana-zuboff/the-age-of-surveillance-capitalism/9781610395694/.

Google and Facebook have appropriated unrestricted use of its users behavioral data, hidden beneath an infinite regress of "Terms of Agreement" that allow the sale of our data to 3rd parties. Non-HIPAA internet corporate giants have redefined concepts of privacy in their favor, resisting regulatory oversight proposed by the Federal Trade Commission in 2000 (https://www.ftc.gov/reports/privacy-online-fair-information-practices-electronic-marketplace-federal-trade-commission). Non-HIPAA covered IT companies continue to breach less stringent non-HIPAA privacy rules. (https://www.ftc.gov/system/files/documents/reports/privacy-data-security-update-2018/2018-privacy-data-security-report-508.pdf).

When the FCC issued rules to protect Meaningful Choice of consumers from Internet Service companies in November 2016, https://www.fcc.gov/document/fcc-releases-rules-protect-broadband-consumer-privacy These guidelines aimed at limiting internet service provider's ability to track all their users. These privacy protections were overturned on March 28, 2017. https://www.washingtonpost.com/news/the-switch/wp/2017/03/28/the-house-just-voted-to-wipe-out-the-fccs-landmark-internet-privacy-protections/?noredirect=on&utm_term=.e3872f6ad9cf

The TEFCA committee must clarify how meaningful is Meaningful Choice when Health IT is an island of privacy is protected by regulation, surrounded by an ocean of surveillance.

Our key concern remains the ONC's 2015 Edition CEHRT criteria that mandates allowing patients to use an app of their choosing to view/download/transmit their Electronic Health Information. The 2015 Edition enshrines in regulation the assumption that apps and their users will be appropriately self-regulating. We question this assumption when existing Terms of Agreement for apps and internet services have no language that resembles TEFCA Draft 2's "**Meaningful Choice and Written Privacy Summary**" (p.17), nor conduct their operations in accordance with **Principle 2 – Transparency** (p.26). The Privacy Lab at Yale has published a series of research reports documenting hidden trackers embedded in popular apps. https://privacylab.yale.edu/trackers.html

No EHI Used or Disclosed Outside the United States (p.18)

Furthermore, when a QHIN allows an individual to access their EHI with an app of their own choosing, as mandated by ONC's 2015 Edition CEHRT criteria, this will make implementation of MRTC Draft 2 requirement **2.2.11 No EHI Outside the United States** (explained on p.18 and MRTC p.45) impossible to determine. We repeat the data documented by the Privacy Lab at Yale

demonstrates that apps will instead share data in hidden and unknown channels. Aside from undermining Meaningful Choice, there will be no way for entities to verify whether EHI is used or disclosed outside of the United States when connected to any app.

As part of their business model non-HIPAA covered IT companies mine users behavioral data gained by surveillance to build apps that "offer useful and efficient services." Please clarify what regulations will verify the national provenance of an app-of-a-patient's-own-choosing, how a QHIN can verify and audit data an app discloses to third parties within or without the United States, including any EHI released to the app. This vulnerability is present whether or not the EHI uses **Security Labeling** (p.18). The most a QHIN can assure is whether it reasonable determines that another QHIN stores EHI within the United States.

Principle 5 – Access: Ensure that individuals and their authorized caregivers have easy access to their EHI. (p.29)

TEFCA Draft 2 needs to claim jurisdiction over non-HIPAA IT entities that produce Health Apps. Require all health apps have Terms and Conditions that align with TEFCA Draft 2's "**Meaningful Choice and Written Privacy Summary**" (p.17).
Require that health apps meet all the principles of the Trusted Exchange Framework (TEF) Draft 2.
Require health apps comply with an appropriate set of MRTCs.

Please revise TEFCA to fix this huge chasm in the health information privacy landscape: currently all transparency, meaningful choice and regulation ends where the app begins. This informs our comments on the following principle.

Principle 6 – Population-Level Data: Exchange multiple records for a cohort of individuals at 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. (p.30)

We appreciate support the goal stated in Principle 6 of TEFCA Draft 2. We agree that the standards to support this use case are not yet mature. We would ask that future TEFCA developments that envision the use of APIs to transfer EHI would seriously address alternatives to the use of apps as intermediaries of such transactions unless and until the concerns we mentioned previously about apps are addressed. Direct QHIN to QHIN interactions via APIs will support verifiability that all entities to the transmission of EHI are compliant with the TEFCA framework.

In conclusion, we thank the ONC for this opportunity to comment on TEFCA Draft 2, and hope our comments are helpful to the committee's deliberations.

Sincerely

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