



October 20, 2021

To: The Leadership of Sequoia Project

Submitted via Email

From: Deven McGraw
Lead, Data Stewardship & Data Sharing, Ciitizen Platform
Invitae Corporation

Re: Elements of Common Agreement Comment Letter

Dear Leaders on the Sequoia Project,

Invitae thanks the Sequoia Project and the Office of the National Coordinator for Health IT (ONC) for this opportunity to provide comments on the required data elements of the Common Agreement and commends the work of both entities in their efforts to improve interoperability of electronic health information. In 2016, Congress directed ONC to develop or support a trusted exchange framework to enable nationwide electronic health information exchange. Almost five years later, we are pleased that the Trusted Exchange Framework has a proposed timeline for implementation of 2022. We recognize the impact that the Common Agreement will have on establishing the electronic data infrastructure for health information networks and systems and believe that the work that ONC and the Sequoia Project are currently doing will have a lasting impact on our healthcare system's ability to share electronic health information to improve individual and population health.

Invitae is one of the largest and fastest growing medical genetics companies in the United States with the mission to make comprehensive genetic information part of mainstream medicine to improve healthcare for everyone. This includes making genetic testing more accessible and more affordable to all who can benefit. We look forward to working with the Sequoia Project and the ONC to ameliorate barriers to accessing results and information that benefit patients throughout their care journey.

Ciitizen, an Invitae company, is on a mission to empower the world's 7 billion citizens to have complete control of their health data; to share it with whomever, whenever, and wherever they want. With a focus on empowering sick patients, Invitae's Ciitizen online platform democratizes health care by putting data ownership and control back in the hands of patients — the stakeholders most highly motivated to collect it, use it, and share it liberally to save their own lives and the lives of others just like them. The Trusted Exchange Framework and Common Agreement, once fully implemented, should help individuals seamlessly obtain their health



information — including genetic information — from anywhere they’ve received care in the U.S. through a single query.

We offer the following comments on the initial elements of the Common Agreement:

Individual Access Services

We are pleased to see the inclusion of “individual Access Services” (IAS) as an Exchange Purpose for the Trusted Exchange Framework (TEF). We strongly agree that IAS should be a required purpose for exchange, and that this requirement would be part of the Common Agreement among Qualified Health Information Networks (QHINs) as well as a required flow-down provision for TEF Participants and Subparticipants. Under the HIPAA Privacy Rule, all disclosures of protected health information are within the discretion of covered entities (and business associates, to the extent permitted by their business associate agreements), but disclosures to individuals at their request are required to be honored, except in rare circumstances. In addition, the federal information blocking rules prioritize the ability of patients — acting on their own or through chosen third-party apps — to obtain their electronic health information. It is critical that any national network for the exchange of health information similarly prioritize the ability of individuals to seamlessly access their health information.

Although Invitae’s Ciitizen platform envisions directly querying the TEF on behalf of individuals on the platform, we also support the proposal that any QHIN, Participant or Subparticipant could launch an IAS query to the network on behalf of individuals with whom they have a direct relationship, as long as the purpose of these queries is to obtain information for use by the individual (see comments below regarding which types of queries should be considered to be for “individual access”).

We agree that providers solely providing IAS should not be required to respond to queries for any of the other Exchange Purposes, although such providers should be able to provide a response at the request or with the consent of the individual. For example, individuals using the Ciitizen platform may seek to exchange information with their health care providers through the TEF.

However, a Participant or Subparticipant that exchanges data for multiple purposes should be required to respond to all of the Exchange Purposes, and additionally, we disagree with the requirement that IAS service providers be “non-HIPAA” covered in order for responses to non-IAS to be voluntary. It is possible for an entity that is solely providing IAS to be covered by HIPAA. Many individuals will choose apps that are offered by their health care provider or health plan, and that app, as a Participant or Subparticipant, should be able to query the TEF for IAS. These apps should also be able to decline to respond to a query for information for non-IAS purposes with respect to data they hold as an IAS provider.

We further recommend that the Common Agreement make clear that consent from an individual to access their health information can be collected digitally via an E-SIGN Act compliant means. The proposed elements of the Common Agreement note that consent should be acquired in a manner that is in compliance with HIPAA, but HIPAA does not require electronic signatures to be accepted. The TEF will not facilitate appropriate exchange of EHI if consent from individuals, where it is required, must be obtained in person or through wet signatures.

As a final note, we urge the Sequoia Project and ONC to clarify that queries for IAS must be for the purpose of obtaining health information for the individual to control. The HIPAA Privacy Rule permits disclosures of protected health information to third parties with the authorization of the individual; however, those disclosures frequently are not to provide the individual with copies of, and control over, their health information, even though they are “authorized” by the individual. It will be critical that IAS does not become a pipeline for disclosures of information that may be authorized by the individual but are not for one of the Exchange Purposes.

Privacy and Security Requirements

We agree that for the TEF to be successful there will need to be minimum requirements for privacy and security. However, it will be critical that these requirements be set in a way that does not discriminate against providers of IAS (for example, through identity proofing and patient matching requirements that are beyond what is commonly deployed by health care system entities for providing individuals with their health information or exchanging information for treatment purposes).

In addition, while we agree that compliance with the HIPAA Security Rule is an appropriate standard for the TEF, compliance with “most of” the HIPAA Privacy Rule makes little sense for providers of IAS that are not otherwise covered by HIPAA. The Privacy Rule’s litany of permitted uses and disclosures is a poor fit for third party apps that serve individuals. Instead, those apps should not disclose health information except with the consent of the individual. We suggest that Sequoia and ONC look to multi-stakeholder best practices for protecting health information in third party apps — such as the CARIN Alliance’s Code of Conduct — in setting standards for third-party apps engaged by individuals. Further, security incident notifications should be consistent with existing breach notification obligations (whether HIPAA or HITECH, depending on the entity involved) and should focus on threats to the TEF vs. internal threats. We note that the existing definition of security incident aligns with the HIPAA breach notification definition but is inconsistent with the threshold for breach notification for personal health apps and related entities under HITECH. As a result, Sequoia and ONC should consider defining a security incident consistent with HITECH for apps that are covered by those provisions.

Information Required to be Exchanged

We strongly support a broad description of required information that must be exchanged by TEF participants for the Exchange Purposes. For IAS, the information required to be shared in response to a query should be any electronic protected health information that meets the definition of “designated record set” under the HIPAA Privacy Rule. This should include genetic information in the records of any TEF participant, whether or not there are data standards for this information and whether or not the requested information is “structured” or “unstructured.” If it is information that is commonly being exchanged for treatment purposes by QHINs, Participants, and Subparticipants, it should be available for IAS queries, and Sequoia and ONC should work to expand the information that should be available through the TEF.

Intersection with federal information blocking rules

It is understandable why the TEF is being initially proposed as a voluntary framework, but the TEF should be a key strategy to facilitate interoperability and portability of electronic health information consistent with the 21st Century Cures Act and the federal information blocking rules. Consequently, we urge ONC to move quickly to use its Cures Act authority to define what is not information blocking to incentivize participation in the TEF. We similarly urge that the TEF and Common Agreement be structured in a way that supports compliance with these rules.

In addition, many of the QHINs, Participants, and Subparticipants in the TEF will be “actors” under the information blocking rules, and a significant subset of those entities will be business associates under the HIPAA Privacy Rule. To maximize participation in the TEF, it will be critical for ONC to work with the HHS Office for Civil Rights to assure that the Exchange Purposes can occur via all participants in the TEF, regardless of potentially conflicting language in business associate agreements. In other words, parties to a business associate agreement should not be able to use that agreement to limit what can be exchanged via the TEF by entities that are “actors” under the information blocking rules, so long as the exchange of information is otherwise permitted by applicable law.

Representation of IAS Providers in TEF Governing Bodies

Providers of IAS services like the Ciitizen platform should be represented in governing bodies for the TEF. To date, input from IAS service providers has been sought through general public comment opportunities but the Common Agreement Workgroup membership was limited to those entities with the potential to qualify as QHINs. Since many of the Common Agreement provisions will flow down to Participants and Subparticipants, and the TEF is expected to be useful for Exchange Purposes that include IAS, we believe it is fundamental to the success of the network that governing bodies include a broader range of stakeholders intended to use and benefit from the TEF.

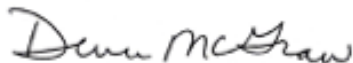
Additional Questions

Sequoia and/or ONC should provide more details on what scenarios fit into the bucket of exchange of “nonhealth information” among Non-HIPAA Entity IAS providers.¹ The participants in the network will be health care entities, or entities requesting health information - and IAS services should be for the purpose of enabling individuals to obtain their health and medical record information.

Invitae and Ciitizen thank the Sequoia Project and ONC for considering comments from stakeholders. We believe that this discussion can provide an opportunity to move toward the democratization of health data in a manner aligned with established Privacy and Security rules, while enabling flexibility in the provision of patient consent using mechanisms permitted by the E-SIGN Act. Allowing for both HIPAA and non-HIPAA compliant entities that provide IAS services to not respond to non-IAS requests for data controlled by patients enables a broader range of entities to give patients control over their health information. Clarifying what is meant by “information blocking” and including a broad range of stakeholders in TEF Governing Bodies will improve representation of the diverse data entities covered by this Agreement. We believe that it is imperative for ONC to use the power and ability granted to them by the 21st Century Cures Act to contribute to creating a Trusted Exchange Framework and Common Agreement that focuses on patient controlled data sharing.

If there are any questions, please reach out to Deven McGraw at deven.mcgraw@invitae.com.

Sincerely,



Deven McGraw,
Lead, Data Stewardship & Data Sharing, Ciitizen Platform
Invitae Corporation

¹ “TEFCA Information would not be limited to health information, in that there may be instances where non-health information is sent between QHINs for an Exchange Purpose. For example, a Non-HIPAA Entity Individual Access Service Provider that is not a health care provider may request information from another Non- HIPAA Entity Individual Access Service Provider that is not a health care provider.”