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Re: Draft Trusted Exchange Framework (TEF)

Submitted electronically to exchangeframework@hhs.gov

Dear Dr. Rucker:

The Sequoia Project is pleased to submit comments on the Office of the National Coordinator (ONC) Draft Trusted Exchange Framework (TEF). We appreciate the careful consideration that ONC is giving to this process and to the comments from stakeholders.

The Sequoia Project is the non-profit, 501(c)(3) organization that houses several independently governed health IT interoperability initiatives, including the eHealth Exchange network and Carequality. Our comments on the Draft TEF are based on our organization's significant experience supporting large-scale, nationwide health data sharing initiatives. Through these initiatives, we serve as an experienced, transparent and neutral convener of public and private-sector stakeholders to address and resolve practical challenges to interoperability, including in-depth development and implementation of trust frameworks and common agreements. This work extends to several crosscutting projects, including patient matching, improving the quality of clinical documents exchanged, and other matters prioritized by these stakeholders.

Our team's decades of combined experience implementing national-level health IT interoperability, including our track record of supporting and operationalizing federal government interoperability initiatives, such as our sponsorship of the eHealth Exchange, provide a unique perspective on various aspects of the Draft TEF. This experience is especially relevant to the design and operation of the Recognized Coordinating Entity (RCE). See Appendices 1 and 2 for more detail on RCE design and our initiatives.

Our comments are organized as follows:

- Summary comments on the draft Trusted Exchange Framework (TEF);
- Appendix 1: Suggested criteria for RCE design;
- Appendix 2: Pertinent background on The Sequoia Project's relevant initiatives; and
- Appendix 3: Detailed technical comments on the draft TEF.

The Sequoia Project comments, based on our deep experience in developing and implementing such agreements, are aimed at helping ONC strengthen the final TEF and successfully carry out its implementation. *Our shared overall aim is to improve the health and health care of patients, consumers, and our nation through more seamless access to health information.*

Overview

The Sequoia Project appreciates ONC's efforts to implement provisions in Title IV, Section 4003 of the 21st Century Cures Act (Cures). These provisions call for ONC to convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework and common agreement (TEFCA) among health information exchange networks. We applaud ONC's engagement with stakeholders and its intention to leverage the private sector in this process.

We especially note legislative language and congressional intent that the TEFCA is to *take into account existing trusted exchange frameworks and agreements* used by health information networks to *avoid disrupting existing exchanges* between participants of health information networks. We also agree with and appreciate the *voluntary* nature of the TEFCA.

In our comments, we highlight:

- Lessons learned and pertinent best practices from The Sequoia Project and its initiatives, such as Carequality and the eHealth Exchange (See especially Appendix 2);
- Suggestions for RCE-selection and operational criteria drawn from The Sequoia Project's experience as a national convener of diverse stakeholders on health information exchange policy and our direct experience developing innovative models to support electronic health information exchange (See Appendix 1);
- The need, consistent with congressional intent, to avoid reversing progress and disrupting existing exchange;
- The importance of ensuring that the Draft TEF does not assume/impose more uniformity in the health data exchange space than is needed to successfully implement the proposed use cases and permitted purposes. Careful and deliberate allowance for variation will accommodate current and future organizational and technology models;
- Ways in which the proposal can be made more flexible, with the ability to support innovation and adapt to a rapidly changing market, which we believe is consistent with the clear intention of ONC, the Department of Health and Human Services, and the Administration;
- Areas where the proposal may be too prescriptive and also where it is not specific enough to achieve operational success; and
- Opportunities to reduce complexity, risk to ONC goals, and regulatory and compliance costs for the federal government, providers, and exchange and technology organizations.

It will be important for ONC to take into account comments received on this Draft TEF in its finalization of the TEFCA portion of its forthcoming proposed rule addressing various 21st Century Cures provisions. In addition to developing the TEFCA and that rule in parallel and with consistent intent, we further advise that this new proposed rule not extend regulatory controls into areas where a more voluntary, stakeholder-driven model will be most effective by reflecting and taking advantage of the diversity of experience in the exchange community.

Overall, we encourage ONC to build on, support and, critically, not disrupt existing trusted exchange frameworks and common agreements already in broad use by health information networks, such as the eHealth Exchange, and by frameworks to interconnect networks, such as the Carequality Interoperability Framework. These initiatives have already demonstrated the ability to achieve high levels of operational, standards-based patient data exchange. For example, The Sequoia Project has a clear track record of supporting successful large scale, nationwide health data sharing. The success of this work is evidenced by the connectivity and volume of query-based exchange supported by the eHealth Exchange health information network and with the Carequality Framework.

For nearly a decade, the eHealth Exchange network's common agreement has supported the exchange needs of private and public partners as well as the ability to accommodate evolving technologies, use cases, and other interoperability needs. Today, the eHealth Exchange enables information to be exchanged for 120 million individuals among four federal agencies (Department of Defense, Veterans Health Administration, Centers for Medicaid and Medicare Services, and Social Security Administration), 47 regional and state health information exchange networks, 75 percent of U.S. hospitals, 70,000 medical groups, 8,300 pharmacies, and 3,400 dialysis centers. Although Carequality has supported live exchange for only 1.5 years, its acceleration of connectivity and exchange of data is unique to the history of interoperability and a model that should be emulated. Already, Carequality connects over 600,000 physicians across more than 34,000 clinics and 1,200 hospitals. The volume of clinical data exchanged accelerates monthly, with more than 2 million clinical documents exchanged in December 2017 alone.

The frameworks and agreements behind these initiatives are already delivering real interoperability at scale. We believe that learning from and building on the experience that went into these frameworks and agreements will be essential to the success of the TEFCA in expanding on the work already underway. One of the Carequality Framework's particular strengths lies in the flexibility afforded by the use of implementation guides to enforce use case-specific requirements, rather than incorporating all requirements in the single, underlying legal contract. We believe that this model of *separating use case-specific requirements from the Common Agreement* would serve ONC well in implementing the TEFCA and meeting our shared goals.

Summary Comments

Our summary comments are below and our detailed and technical comments are in Appendix 3.

1. *We support the overall intent, high-level approach, and policy goals of the Draft TEF.*

We share ONC's high-level goals for expanding interoperability while building on the existing infrastructure and trust frameworks that support nationwide health data sharing. We also agree with the intent to simplify end user access to exchange networks. Clearly, achieving interoperability has been more difficult and is taking longer than desired. We have been on the front lines of advancing electronic health data exchange and widespread interoperability since 2008 and fully appreciate the progress as well as the challenges that remain. Based on this experience, we believe that a critical success factor for the TEFCA will be the ability to work in close collaboration with the healthcare sector to support coordinated

implementation, while remaining flexible and adapting as implementations mature and the market continues to innovate and evolve.

2. ***We are encouraged by the Draft TEF's focus on private-sector standards and organizations, including the central role of a Recognized Coordinating Entity (RCE) to achieve effective interoperability.***

We support ONC's intention to build on existing private-sector models and to leverage existing standards rather than undertaking the long and expensive process of creating new standards. Building on existing models and standards will help minimize disruption to existing initiatives that are effectively advancing interoperability, which is consistent with congressional intent. Such an approach will lower the costs for all involved, which is particularly important since our experience underscores the significant investment required to create the strategic, operational and administrative infrastructure required for a viable information exchange ecosystem. Our experience also underscores the need for implementation of the TEFCA, including the RCE, to occur under long-term sustainable business models. These models should not be overly reliant on federal funding, which, over time, is subject to the constraints of the budget process and competing priorities.

3. ***As ONC works with the RCE to finalize and implement the TEFCA, we urge ONC to adjust its proposed approach to prioritize minimal disruption of existing exchange initiatives and networks that are on a trajectory consistent with both 21st Century Cures provisions and TEFCA goals, while eliminating barriers to their success.***

- a. We believe that such a commitment to minimal disruption is consistent with congressional intent, the statute, and ONC's initial statements of its approach to the TEFCA.
- b. To that end, we ask that ONC specifically allow and plan for a transition period in which TEFCA implementation can proceed along with the continued normal operations of organizations that become TEFCA participants, whether the RCE, QHINS, HINs/Participants, and End Users. It is essential to avoid a disruptive stalling of existing implementation efforts or stakeholder responses that "freeze" the market for interoperability and exchange as TEFCA implementation is phased in.

4. ***We are pleased that ONC intends to work with a private-sector RCE to consider comments received and to collaboratively create and implement the final TEFCA.***

- a. As we understand ONC's intentions, the TEF would be finalized by ONC and the RCE collaboratively and the Common Agreement (CA) would be developed by the RCE consistent with the TEF. We support such an approach.

- b. We encourage ONC and the RCE to engage with stakeholders in an open and transparent process, focusing on achieving a TEF that can support operational goals.
- c. It is essential that the RCE be a non-profit, 501(c)(3) that acts to lessen the burden of the government through its activities, has clear due process and transparency obligations, and balanced stakeholder consensus development processes.
- d. There needs to be additional work done to clearly identify the allocation of responsibility and authority between ONC and the RCE. ONC's role should be to ensure that the TEFCA meets congressional intent while giving the RCE sufficient latitude to operate in an efficient and effective manner in response to the rapidly changing health information exchange ecosystem.
- e. RCE accountability, implemented through its transparent governance processes (See Appendix 2), should be clear both to ONC and to its stakeholders, including QHINs, Participants, and End Users.
- f. Over time, ONC should consider shifting from a Cooperative Agreement to grant funding, to enable more flexibility and external accountability for the RCE as it demonstrates its success.

5. *We suggest that ONC focus on refining and articulating policy goals and principles, rather than on detailed agreement terms and technical requirements.*

We encourage ONC to work with the RCE within a defined time period to implement these policy goals in an operationally manageable set of terms, drawing on comments on this draft and ongoing public and implementation community input. In addition, it will be essential to build in a responsive change management process and the ability to iterate and incorporate learnings using an “agile” approach.

6. *We suggest that ONC allow a phased and modular implementation of the TEFCA.*

To help ensure non-disruptive implementation, we suggest that ONC work with the RCE to explicitly phase-in the TEFCA in a modular and predictable fashion, likely by use case, permitted purpose, and technology approach. The RCE, once established, should manage this phase-in using its processes of broad and transparent stakeholder engagement, in alignment with its work on use-case-specific implementation guides.

7. *Based on our years of experience as a coordinator for trusted exchange, we suggest that many of the provisions in the Draft TEF, as well as those envisioned for the Common Agreement, especially in Part B (Minimum Required Terms and Conditions), should be moved from the final TEFCA into use case-specific implementation guides.*

The rapidly evolving market and need to support innovation underscores the need for technology requirements to be maintained in implementation guides rather than the TEFCA. It can be very challenging to build all use case-specific terms into one legal agreement. Doing

so runs the risk that elements that work well for one use case are applied to others for which they are less appropriate. Implementation guides can be incorporated by reference into the final Common Agreement (CA), so that they are just as legally binding as the terms in the CA itself. They can also be updated more flexibly and frequently to reflect changes in technology and standards than would be desirable for an underlying legal agreement. This approach has had demonstrated success in Sequoia Project initiatives. We also ask that ONC clarify that only the Common Agreement is legally binding and that the TEF, including Parts A and B, is intended to provide guidance to development of the Common Agreement.

8. ***We recommend that ONC, as it works with the RCE to finalize the TEF, revise and expand the definition of a QHIN to enable more HINs to qualify and participate as QHINs so that a wide range of Participants and End Users are willing and able to connect to a QHIN.***
 - a. As currently defined, with a narrow, standardized and prescriptive definition, it is unclear whether any existing HIN could qualify as a QHIN due to the specific architecture prescribed for query-based exchange and the use cases contemplated (e.g., requirement for Connectivity Broker use, participant neutrality as defined by ONC, requirements for broadcast query capability and use). We and others in the field believe that such TEF provisions, as proposed, may discourage HINs from participating as QHINs.
 - b. The existence of too few QHINs could have several negative consequences, including excessive QHIN market power and too few recipients for queries and other exchange models.
 - c. One significant issue regarding QHIN viability and flexibility is the proposed provision in 5.4 of Part B that, except as required by HIPAA Rules or other applicable laws, QHINs may not enter into any agreement other than the Common Agreement (CA) with another QHIN that has also adopted the CA with respect to any query related to any of the Permitted Purposes. This requirement creates complications and is likely unworkable. As an example, this would prohibit agreements regarding any fees associated with queries, which are permitted under the CA subject to certain constraints. We suggest that additional agreements that are not in conflict with the CA be allowed.
 - d. We are also unclear whether there is sufficient demand going forward for the narrow definition of QHIN services among prospective Participants and End Users. Forcing such demand through likely pressures/incentives to sign the TEFCA, without adding flexibility, may result in added costs in the healthcare system and “bake in” a very specific architecture, with a likely reduction of innovation and experimentation.
 - e. We agree with the principle of participant neutrality, but also believe that the proposed ONC interpretation of this principle, in the Draft TEF and ONC presentations, will exclude existing HINs (for example a state-wide HIE or a vendor network) that already support query-based exchange at nationwide scale and that could engage in a TEFCA model as a QHIN, from being permitted to participate as QHINs. Excluding a single-state HIE but allowing two single state HIEs to

collaborate as a QHIN, or excluding a vendor network that has a Connectivity Broker and is willing and able to comply with the CA seems arbitrary.

Such an exclusion would force many providers and HINs to change from their existing approach, revise their architecture, and redirect transactions through a QHIN. For providers and HINs that leverage federated approaches, for instance, this requirement would likely add another layer of cost and overhead and could potentially disrupt current exchange, with little additional value from connection to a QHIN.

If the TEFCA achieves widespread acceptance and use, we can be confident that the market will offer solutions such that everyone who wants to participate in the exchange ecosystem will have a path for doing so. ONC need not add costly organizational layers for existing exchange participants in order to ensure options for all. Making QHIN status more accessible will only serve to make the market function more smoothly in this regard.

- f. In addition to broadening the eligibility criteria for QHINs, another way to encourage participation would be for ONC to work with the HHS Office of the Inspector General (OIG) to assure that organizations that become QHINs by signing the Common Agreement and abiding by all of its provisions, as well as QHIN Participants and End Users that are parties to agreements flowing down from the Common Agreement, are deemed by enforcement agencies to be in compliance with any information blocking regulations and requirements subsequently adopted by OIG.

9. *We suggest that flexibility on required standards and how they are defined at an implementation level is essential for the ability of the TEFCA framework to evolve over time.*

- a. We suggest that ONC revise and reduce the proposed reliance of the TEFCA on the ONC 2015 Certification Criteria and the Interoperability Standards Advisory (ISA). Such reliance does not reflect the underlying use cases/design elements for these documents. The ONC 2015 Certification Criteria were developed for use by electronic health record EHR and health information technology (health IT) developers rather than health information networks. In addition, the ISA, given its intended purpose, includes standards with a range of maturity and adoption levels, including, in some cases, alternative standards for the same use case. In addition, the ISA may not have the specificity needed to drive operational success.
- b. We believe that this issue can be well addressed if ONC sets broad policy guidelines and empowers the RCE, operating under appropriate processes, to finalize and maintain both the TEF and the Common Agreement and associated implementation guides. Such implementation guides could draw on the intent and applicable specifics from the 2015 criteria and the ISA while providing the selectivity and specificity needed for operational success. Work on the guides could also complement and support the phased, modular implementation approach we call for elsewhere in these comments.

10. We suggest that ONC work with the RCE, drawing on input from the industry, to determine where uniformity of architecture and approach is needed, and where policy goals can be achieved in a more varied environment.

- a. For example, although we strongly support simplified access to exchange networks and a single "on ramp" where feasible, we are not certain that a single on ramp across *all* identified use cases and permitted purposes, is necessary or appropriate when one considers certain specialized use cases or emerging models, like application programming interface (API)-based data access.
- b. To this end, we believe that ONC should permit specialized (by use case, permitted purpose, and technology) QHINs and ensure as well that Participants that have specialized missions can participate. Participants will work with QHINs that best meet their needs.
- c. We understand the importance to providers of simplified access to exchange networks for interoperability to be highly usable and affordable. We further believe that a uniform TEFCA, with high levels of participation, focused on specific use cases, can provide affordable, simplified access without seeking to impose a uniform architecture across the range of current and future exchange models (e.g., Direct, document-based query, HL7® Fast Health Interoperability Resources - FHIR® APIs, etc.).
- d. To this end, we encourage ONC to reevaluate the extent to which all QHINs must meet such a broad set of standardized requirements and assess the impact to innovation of such a requirement.
- e. Overall, the QHIN model and its application, including the focus on "broadcast queries," appears to be based in query-based document exchange experience and is likely not always applicable or optimal for FHIR API-based access, which will be relevant for all permitted purposes.
- f. Since most care is provided near where a patient lives¹, other architectures, such as federated networks, are quite viable to enable robust queries. Even if patients move or are "snowbirds," more targeted queries could be sufficient. We therefore believe that the *mandate* for broadcast queries (*as defined in the Draft TEF*) as the *default type of query*, which ONC already notes raises bandwidth considerations, is unnecessary. We do not dispute the value of broadcast queries, just whether or not they should be the mandated approach without the opportunity for judgement by the QHIN and its Participants. *We ask that ONC revisit this issue.*
- g. Requiring a single data exchange architecture for *all* covered use cases and permitted purposes, could impede innovation and may quickly become outmoded. For example, the focus on specific Connectivity Broker requirements to be a QHIN, including required use of a Record Locator Service (RLS) and support for all permitted

¹ According to the Dartmouth Atlas, "The use of health care resources in the United States is highly localized. Most Americans use the services of physicians whose practices are nearby." <http://www.dartmouthatlas.org/data/region/>

purposes and use cases, is likely too prescriptive in our experience, and may not be optimal for all permitted purposes and use cases, such as API-based interoperability, which is designed to work simply between systems, without complex brokers as intermediaries. In addition, does ONC intend for one organization to bundle all the required QHIN technology components? Such a requirement will likely add costs to the exchange ecosystem without clear evidence that this is the optimal model for exchange.

- h. The Draft TEF assumes that all providers and HINs need to use a particular centralized architecture to achieve effective and widespread exchange; however, most exchange to date uses other models, such as federated approaches, where vendors or others provide some of the services that would be reserved for/required of the QHINs.
- i. To this point, we note that Section 4003 requires ONC to pilot test the TEFCA and urge ONC to work with the RCE to design a pilot strategy, with the resulting pilot completed before the TEFCA is considered final.
- j. Consistent with this pilot test approach, we suggest that ONC work with the RCE to explicitly phase-in the TEFCA in a modular and predictable fashion, likely by use case, permitted purpose, and technology approach. The RCE would manage this phase-in using its processes of broad and transparent stakeholder engagement, including engagement with the QHINs. Phase 1 could focus on current, in-production exchange frameworks and networks and implement applicable TEF principles and Common Agreement provisions.

11. Based on real-world implementation experience, we recommend TEF terms should endure as reflected in the Common Agreement (CA), with implementation-level details evolving over time in implementation guides incorporated by reference into the Common Agreement.

- a. The current set of Draft TEF terms includes implementation-level technical, functional, work flow and use case details. In our experience, these details are often refined based on real-world implementations, which requires a nimble and efficient change management process that is linked to but distinct from the legal agreement.
- b. Including detailed common terms in one agreement can impose uniformity across use cases when it may not be necessary or desirable, and can lead to terms for one use case inadvertently applying to another in ways that don't make operational sense.
- c. We therefore recommend that the CA point to, and incorporate by reference, implementation guides and include a change management process to address changes.
- d. Implementation details should be specified with community involvement, especially QHINs and their Participants, and within the scope of specific intended use cases.
- e. In addition, it is important to distinguish use cases from agreement terms. Use cases should be defined as part of a prioritization process, with new use cases adopted through a change management process that includes input from stakeholders, the implementation community and ultimately end users (payers and providers).

12. As a general principle, it will be important to minimize/optimize the extent to which TEFCA parties (i.e., the RCE, QHINs, Participants, and/or End Users) are held responsible for actions and circumstances beyond their reasonable scope or control. For example, we question whether it is practicable for QHINs to be responsible for maintaining data quality when they don't themselves hold or generate the data being exchanged. Similarly, it may not be practicable for Participants to be responsible for ensuring that medications, allergies, and problems are up to date prior to exchanging these data.

In addition, ONC should not require an advance commitment to future or unspecified standards but rather should use the RCE's ongoing public-private engagement processes to identify and, as appropriate, require adherence to new standards. We urge ONC to work with the RCE to revise or eliminate provisions that have this effect.

13. We appreciate ONC's recognition of the bandwidth challenges that could accompany both broadcast queries and population-level queries and suggest that the TEFCA address this issue directly and provide a basis for technology and policy approaches that reduce bandwidth pressures, such as being clear on the ability to use asynchronous transfer.

We also suggest that ONC conduct pilots of these query models to assess issues such as standards readiness, bandwidth, and appropriate query filters, etc.

14. Some terms in the Draft TEF conflict with fundamental terms supporting large-scale exchange today and may result in unintended consequences.

- a. Section 4003(b) of Cures requires that the TEF not duplicate or disrupt ongoing activities in data exchange. After carefully reviewing the proposal and draft terms, most align with the terms supported by the healthcare sector today. There are several instances, however, that substantially differ and risk disrupting existing exchange or discouraging exchange. (We provide examples of such conflicting terms in our detailed comments in Appendix 3.)
- b. We urge ONC to work with the RCE to reduce complexity, cost, and burden to existing HINs and health data exchange models to minimize the extent to which they would need to amend their current agreements, participants, and data sharing infrastructures. The modular, phased-in implementation that we call for in these comments would be an important element of this approach. In a related vein, we suggest that ONC, as discussed in our detailed comments in Appendix 3, reduce the complexity of QHIN cost and fee tracking.
- c. We also urge that ONC look to extend the timing for required updates from up to 18 months (or even 24 months as applicable to specific circumstances), reflecting needed time to do the analysis, update agreements, implement technical changes, and, in the case of QHINs and HINs that involve governmental agencies, federal clearance and approval processes. ONC and CMS have recognized similar timing needs of greater than one year in ONC Certification and Meaningful Use/Medicare Incentive Payment System (MIPS) deadlines.

Conclusions

The Sequoia Project supports congressional intent and ONC's goals to leverage a TEFCA to enable interoperability among networks. We stand ready to work with ONC to refine and implement its Draft TEF. The years of experience of The Sequoia Project and our initiatives provide a unique vantage point and set of capabilities as well as active public and private-sector stakeholders. We are eager to make these resources available to ONC and submit these comments, which focus on needed revisions to the Draft TEF, in that spirit.

Most respectfully,



Mariann Yeager
CEO
The Sequoia Project

CC:

John Fleming, M.D., Deputy Assistant Secretary for Health Technology Reform
Genevieve Morris, Principal Deputy National Coordinator for Health Information Technology
Elise Sweeney Anthony, J.D., Director, Office of Policy
Steven Posnack, MS, MHS, Director, Office of Standards and Technology

Appendix #1: Proposed Desirable RCE Eligibility and Operational Criteria

Corporate Structure and General Capabilities

- Legal entity capable of contracting with ONC;
- Established and operated for the public benefit as evidenced by 501(c)(3) tax-exempt status from the IRS as an organization that lessens the burden on government;
- Can operationalize the TEFCA under current corporate and organizational structure (with feasible near-term revisions to structure as needed);
- Organizational ability to “wall off” non-RCE exchange initiatives to avoid any conflicts of interests;
- Financially stable;
- Relevant experience and operational capability; and
- Management and support infrastructure sufficient to manage the Cooperative Agreement.

Governance and Operations

- Governing body has authority to govern the RCE or establish an RCE governance structure;
- Balanced stakeholder representation;
- Effective size and balanced composition given mission and tasks;
- Formal, open, and transparent governance and operational process;
- Publicly available governance structure and process, work products, policies, agreements, and pricing;
- Active and ongoing stakeholder-focused engagement, communication, and education: (e.g. through regularly scheduled public calls, presentations, and other avenues);
- Publicized mechanisms for stakeholder and public input; and
- Mechanism for and experience with dispute resolution.

Multi-Stakeholder Engagement with Balanced Representation

- Active engagement of both private sector (multiple stakeholders) and government (multiple agencies); and
- Ability for diverse stakeholders to engage and have an active voice in the process for developing and maintaining policies, implementation resources, and governance.

High Level of Relevant Experience and Outcomes

- Experience as a national convener of diverse stakeholders/collaborative to advance health information exchange and interoperability;
- Experience working with federal agency partners, including under formal agreements;
- Currently supports operational exchange via a trust framework and common agreement, including experience with query-based exchange;
- Demonstrated track record with tasks required of the RCE, with outcome of such work in production at scale; and
- Existing relationships with likely QHINs and Participants.

Ability to Act in a Fair and Neutral Manner

- Owners or members cannot require the entity to act in their best interests as opposed to the public good or otherwise unduly influence the RCE;

- It is not invested in any specific technical architecture;
- The ability to be objective is imperative therefore the RCE may not advocate for specific industry stakeholder group(s);
- The RCE cannot be a trade association and similar organization that is required by its mission to advocate for the interests of their members;
- It is not under obligation to any technology vendor or type of system;
- Has taken specific and enforceable steps to address conflicts of interests; and
- Adopts a formal code of conduct for governing body members, staff, and leaders.

Appendix #2: Sequoia Project Initiatives

eHealth Exchange

The eHealth Exchange was initially incubated by ONC in 2008 as the Nationwide Health Information Network (NwHIN), the nation's first and largest public-private health data sharing network of its kind. Eight years after the first records were shared, this nationwide network continues to be the principal way in which federal agencies exchange health data with the private sector. Today, this robust network enables information to be exchanged for 120 million patients among four very large federal agencies (Department of Defense, Veterans Health Administration, Centers for Medicaid and Medicare, and Social Security Administration), 47 regional and state health information exchange networks, 75 percent of U.S. hospitals, 70,000 medical groups, 8,300 pharmacies, and 3,400 dialysis centers.

We project that approximately 100 million clinical document and quality measure transactions are exchanged every year (Note: due to the federated nature of the eHealth Exchange, exchange metrics are self-reported.)

The success of the eHealth Exchange can be attributed to its representative governance (i.e. network participants govern) and the common legal agreement, the Data Use and Reciprocal Support Agreement (DURSA) that enables trusted exchange relationships. Key elements of the DURSA include:

- Governance;
- Clear requirements applicable to all participants;
- Uniform privacy and security obligations;
- Minimal level of participation;
- Common agreement of the permitted purposes for which data can be exchanged;
- Respect for local network policies that specify types of authorized users and their rights;
- Future use of data received exchanged through eHealth Exchange;
- Compliance with well-defined technical specifications;
- Participant directory;
- Data Security Incident response and notification requirements;
- Participant Accountability for their actions as part of eHealth Exchange; and
- Mechanisms for updating the DURSA and eHealth Exchange Operating Policies and Procedures as legal and policy changes dictate.

This dynamic legal agreement and governance structure has been used effectively during the past nine years to adopt new and innovative use cases as the need arises, and currently supports more than one dozen use cases, including:

- Treatment/care coordination;
- Social Security Administration disability benefit determination;
Immunization;
- Consumer access;
- Encounter alerts;
- Prescription drug monitoring programs;

- Electronic lab reporting for public health; Syndromic surveillance;
- Life insurance determination; and
- Individual access to health information via a personal health record (PHR).

Going forward, the eHealth Exchange's governance model and DURSA provide the framework and process to support emerging value-based care models, API-based approaches to data sharing, consumer access, consumer directed exchange, and others to meet participant and market demands.

Carequality

As the eHealth Exchange network matured, so did the health IT industry and ecosystem. New and varied networks based on technologies, geographies, and other affiliations emerged, each operating independently with limited ability for data sharing among those networks. Leaders across the healthcare sector and government recognized a need to interconnect different data sharing networks and came together to develop an interoperability framework that would leverage, but not replace, the existing fabric of networks as well as accommodate coming innovations.

Carequality was conceived as a national-level, interoperability framework for trusted exchange between and among health information networks, programs, and services. It is important to recognize that Carequality itself is not a health data sharing network but provides the trusted exchange framework, through its common legal agreement and implementation guide, which enables participants in different networks to share data without having to join multiple networks.

The Carequality Interoperability Framework (the "Framework") was developed over two years with input from a broad array of stakeholders from across the healthcare continuum including: consumers, state and federal government, research, public health, behavioral health, long-term, post-acute care, hospitals and health systems, physicians, research, health IT vendors, and other stakeholders. The Carequality Interoperability Framework consensus process was designed to be extremely open and inclusive in both its governance process and implementation of the Framework that the governance process developed and now maintains. The Carequality Interoperability Framework is accessible to a wide range of organizations and implementers of the Framework including health information exchange (HIE) organizations, electronic health record (EHR) and HIE vendors, consumer application providers, and service providers to many parts of the industry such as payers.

These implementers agree to abide by a required common agreement, the Carequality Connected Agreement (CCA), which includes rules of the road for interoperable data sharing and enforce applicable standard terms on their network participants. By leveraging the CCA in combination with these existing network relationships, Carequality enables providers who participate in different data sharing networks to share data without having to establish separate legal agreements with each network, or worse, each partner. This approach significantly increases and accelerates connectivity on a nationwide scale.

Principles of trust and non-discrimination are the bedrock of the Carequality Interoperability Framework because the Framework accommodates widely disparate and sometimes even competing participants and service offerings. Each participant knows its rights and obligations and can trust that it understands the rights and obligations of all other participants. The technical specifications outlined by the Framework ensure that for each use case, participants can “speak a common language” no matter the source of the data. Carequality also provides operational support in the form of x.509 digital certificate services and a Healthcare Directory providing comprehensive information on participant organizations.

Carequality was created to respond to an identified need in the healthcare industry to promote interoperability among existing networks and different technology platforms. The rapid growth in the Carequality network-to-network exchange demonstrates that Carequality has successfully addressed the need. On July 1, 2016, a physician using one EHR system and a health system using another EHR system became the first participants to share health data under the Carequality Framework. Because the Framework allows a network to implement once and connect universally, the number of physicians has exploded in 18 months of live exchange to include over 600,000 physicians across 34,000 clinics and 1,200 hospitals. The volume of clinical data exchanged accelerates monthly, with more than 2 million clinical documents exchanged in December 2017 alone.

The Framework currently enables 50 percent of physicians to share beyond their own networks to coordinate care and other services across the country. Carequality is on a steady trajectory to connect the entire United States.

To summarize, the Carequality Framework leverages existing investments of its implementers to efficiently increase interoperability nationwide by using:

- A common set of rules and policy requirements for trusted exchange;
- A process for resolving disputes and questions of non-compliance with terms of a common legal agreement;
- Technical specifications for each supported use case that are distinct from and incorporated by reference into the common legal agreement; and
- Operational services for certificates and a participant directory.

The Carequality Framework and common legal agreement are deliberately independent of a specific architecture, data type, or use case. Today, the technical architectures for exchange include clinical documents for a host of purposes and patient-generated data. Current expansion plans include event notifications, APIs like FHIR resources, imaging, and others.