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The Sequoia Project, the TEFCA Recognized Coordinating Entity
Mariann Yeager, CEO
8300 Boone Blvd. Suite 500
Vienna, Virginia 22182

Re: Elements of the Common Agreement and QHIN Eligibility Criteria

To whom it may concern:

Health Gorilla is pleased to provide comments in response to the Elements of the Common Agreement and QHIN Eligibility Criteria. We applaud the ONC and RCE for beginning to define the infrastructure model and governing approach for the Trusted Exchange Network. Health Gorilla has provided specific comments where clarification and additional information is needed. The goal of the Common Agreement is to establish a floor of universal interoperability across the country for health care. For that goal to be achieved, clear policy is required across all sections, to ensure all actors are held to the same level of accountability.

Yet, we are concerned that some of the specifics in the Elements of Common Agreement may hinder the progress that has already been made in the industry. Specifically, we urge the ONC to reconsider its direction in certain areas to best comply with the Congressional mandate to "develop or support a Trusted Exchange Framework" (emphasis added) by surveying the completed and in-progress work across the industry today. We ask that the ONC embrace the coordinator role, focusing on helping federal and industry partners successfully achieve their missions, through supporting and improving upon completed work, rather than starting over and developing a net-new Trusted Exchange Framework. This will allow a continued push forward on nationwide interoperability while still following the additional congressional mandate to "avoid the disruption of existing exchanges between participants of health information networks".

Health Gorilla is supplying comments on the following five (5) sections.

- Exchange Purposes

- Individual access services (IAS)
- Governing Approach and Cooperation and Nondiscrimination
- Directory Services
- QHIN Eligibility Criteria

It is our hope that these comments provide support for a roadmap that ensures current industry efforts toward interoperability are considered and fully leveraged to fulfill the potential of the TEFCA and 21st Century Cures Act. ONC's three primary goals for developing or supporting a Trusted Exchange Network are to: 1) provide a single "on-ramp" to nationwide connectivity, 2) have Electronic Health Information (EHI) securely follow patients when and where it is needed, and 3) supports nationwide scalability. These goals must be met without hindering the incredible innovation around EHI in healthcare, bolstered by best practices, interoperability, analytics and AI. Progress is currently being made every day by leaders in the field and TEFCA has the potential to expedite the speed of innovation.

Founded in 2014, Health Gorilla is a health information network that enables the entire healthcare ecosystem to seamlessly exchange health data. Health Gorilla powers health care organizations around the world, helping them deliver high-quality value-based care. The Health Gorilla platform makes it easy for providers to bi-directionally exchange their patients' information with other organizations. As a result of our ease of use and expertise, we are working with some of the largest vendors with the largest amounts of healthcare data in the United States, and this experience is surging forward. For example, we currently work with a wide array of vendors used by provider organizations in the US and Puerto Rico. Health Gorilla has integrated clinical data from enterprise EMRs like Epic, Cerner, and Meditech, ambulatory EMRs, to laboratory information systems, health information networks, radiology systems, and enterprise data warehouses. Health Gorilla also has a vast network of integrated labs, including national labs like LabCorp and Quest, and local labs throughout the United States. Part of the reason for the demand is the ease of use, security, accuracy, compliance, and the complete structured and longitudinal record of care per patient across all healthcare verticals.

To highlight a recent example of Health Gorilla tackling a project that is broad in scope, we are currently the sole source provider of an island-wide Health Information Exchange Network for the Puerto Rico Department of Health. Health Gorilla operates as the health information network solution, connecting payors, labs, providers, patients, and public health officials. This HIE has brought forward a new era of interoperability to Puerto Rico, with an established network to achieve the objectives of streamlining care, reducing costs, empowering patients and providers, and giving public health officials the data they need to act decisively on broader trends, including responding to COVID-19.

Furthermore, Health Gorilla has been recommended as the only clinical exchange portal that met functional and security criteria for public health departments by the Duke University Interoperability Report. Published in May of 2020, and authored by the former ONC head and

former CMS administrator, the Report credits Health Gorilla, “which is both a Member of CommonWell and an Implementer on Carequality, currently provides query access to all acute-care sites on both networks, and maintains its own set of services (MPI and RLS) and capabilities (event notifications) that could increase utility for public health”.

We look forward to meeting with you to further our discussions about the value of a commercial health information network that enables patients, providers, payors, and others to have access to secure medical information in a way that bolsters the progress made in the five areas below.

Exchange Purposes

We applaud the ONC and RCE listing the six Exchange Purposes in the Elements of the Common Agreement. All six are absolutely essential to achieve the overarching goals of TEFCA and the 21st Century Cures Act. To support those goals, all certified QHINs MUST support all six exchange purposes to truly create the “networks of networks” architecture. Without that, fragmentation would exist and the Trusted Exchange Framework would not be possible. Full adoption of the six exchange purposes creates a floor of universal interoperability across the country.

We show support for the statement that QHINs must certify the allowable exchange purposes for each Participant and Subparticipant. We feel it is absolutely an essential function to achieve the Trusted Exchange Framework. Health Gorilla applies strict network governance today to our existing network of Participants and Subparticipants; ensuring the exchange purpose, use case, and the appropriate use of data allowable by applicable regulations. We seek additional requirements and policy on how this requirement can be consistently applied by all QHINs, to ensure appropriate certification of all Participants and Subparticipants across the “network of networks” architecture. Clear policy and contractual terms are necessary to ensure each actor in TEFCA is held to the same standard, and all actors can trust the integrity of the Trusted Exchange Framework.

The Elements of the Common Agreement defines the terms “Treatment,” “Payment,” and “Health Care Operations” generally as having the same meaning as they do under the HIPAA Privacy Rule. In current networks and consortiums, the broad HIPAA definitions have created ambiguity, requiring additional policies to define organizational types and allowable actions within each exchange purpose. Further definition will help to govern the accelerated growth of the digital health market, which continues to improve the industry and change the way we think about the delivery of healthcare. Additionally, the Elements of Common Agreement states that the Trusted Exchange Network can be used by non-HIPAA covered entities. The definitions and policy must scale to non-HIPAA covered entities and address the specifics of the broader exchange of health information, all while using HIPAA regulations as the foundation. Finally, we suggest that definitions and requirements be included in the flowdown agreements, making all actors contractually obligated to adhere to the same standards. The exchange purposes provide the foundation of exchange in the Trusted Exchange Framework. By applying further definition

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and including the definition as part of the flow down agreement, it strengthens the foundation of the Trusted Exchange Framework.

We thank you for retaining the exchange purpose of Benefits Determination. We see huge potential in utilizing the Trusted Exchange Network to solve many of the problems and inefficiencies faced today around Benefits Determination. However, we challenge the definition of Benefits Determination. The Elements of the Common Agreement limits the definition to any "federal, state, local, or tribal agency, instrumentality, or other unit of government as to whether an individual qualifies for government benefits for any purpose other than health care". We feel strongly that a broader definition is needed; expanding the definition to include qualified private entities (pension plans, employer long-term disability plan, life insurance, etc). We ask that the ONC play a supporting role and follow the Congressional mandate to "avoid the disruption of existing exchanges between participants of health information networks". Existing health information networks, including Health Gorilla, provide technical solutions to qualified private entities for Benefits Determination by utilizing the technical solutions described in QTF Draft 2 for managing consent and patient authorization. The ONC and RCE should absolutely create policy to allow for the broadest exchange of data possible within the defined exchange purpose of Benefits Determination.

The Elements of the Common Agreement states the RCE plans to work with stakeholders to identify additional Exchange Purposes over time, as appropriate. We applaud the ONC and RCE for this commitment. A major opportunity of TEFCA is to improve overall health quality for the entire United States population. The ability to access data for population health management, combined with innovations in technology, can help bring significant health concerns into focus; ultimately transforming the way resources are allocated to overcome the problems that drive poor health conditions. We all have a stake in population health in America today. Once there is transparency and insight into population management data, we will begin to better understand populations, have greater insight into the lines between a preventative and a medicine focus on health care services, and create a population health focus on the broader determinants of health. Specifically, among other things, we will begin to discover the identification, understanding, and segmentation of populations, how to redesign services for that population, and how to deliver those services at scale. Once we have those insights, the United States healthcare system as a whole will be able to require organizations to understand and address the broader social, environmental, and behavioral determinants of health in order to achieve better outcomes, improve the care experience, and control total cost.

Making the transfer of population management level data a reality is the opportunity of a generation. Without it, while we will have a faster, accurate, and more secure patient record, the delivery mechanisms of healthcare in the United States will remain at a transactional level. Care, quality, and cost will not change significantly enough to place America on the map as a leader in the field by "making [widespread and powerful] data-based improvements on patient care possible". Therefore, we ask that the ONC continue to consider expanded exchange

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purposes and any related and defined data use cases that have the broadest possible definitions and uses.

Individual Access Services (IAS)

The Elements of the Common Agreement addresses Individual Access Service (IAS) Provider with the definition of “each QHIN, Participant, and Subparticipant that offers Individual Access Services”. We ask the ONC and RCE to clarify and provide more information on how the role is defined. The Elements of the Common Agreement makes the statement “a QHIN, Participant, or Subparticipant would be allowed, but not required, to offer IAS to Individuals with whom they have a Direct Relationship”. Health Gorilla believes the Direct Relationship with the individual is the first step in establishing the underpinnings of the Trusted Exchange Network in support of the IAS Exchange Purpose. Additionally, we ask for clarification on a QHIN’s role in IAS. Will each QHIN need to establish themselves as an IAS Provider, if they connect Participants or Subparticipants that operate as an IAS Provider? Will each QHINs need to validate the identification mechanism performed by Participants or Subparticipants that operate as an IAS Provider? Additional policy is needed on the role of the IAS Provider, and how Direct Relationships and the IAS Provider role will be governed across the “network of networks" architecture.

One of the overarching goals of ONC is to have Electronic Health Information (EHI) securely follow patients so that EHI can be used when and where it is needed. To ensure the security of the trusted framework, identity proofing technical standards and policies enforcing the use of such standards are necessary for individuals to fully access their information through TEFCA. In a multi-layered “network of networks” architecture, the exchanging entity responding with TEFCA Information (TI) is likely many layers removed from the IAS Provider that completes the identity proofing. To facilitate a Trusted Exchange Framework, all entities must trust the identification verification standards utilized across the exchange of TI.

TEFCA Draft 2 previously contained policies and standards for identity proofing. The Minimum Required Terms & Conditions (MRTCs) Draft 2 states that prior to the issuance of access credentials, an Individual User shall be required to verify his or her identity at a minimum of IAL2 with the QHIN, Participant, or Participant Member to whom the Individual has a Direct Relationship. The publication of the Elements of Common Agreement and QTF Draft 2, as stand-alone documents, lost the references to these standards and the policy around identity proofing. Quoting QFT Draft 2, “a QHIN, for example, needs to know and record the identity of any Subparticipant or user attempting to query for or send TI. Because there may be a multi-layer hierarchy of Subparticipants under each Participant, the QHIN relies on each entity to obtain and share authentication information about those ‘downstream’ from it, and is therefore further removed from the QHIN in the hierarchy”.

Both the Elements of the Common Agreement and QTF Draft 2 fall short of addressing the act of identity proofing individuals, and fail to include a reference to National Institute of Standards

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(NIST) Digital Identity Guidelines, NIST 800-63-3. The requirements of identity proofing to the QHIN, Participant, or Subparticipant to whom the Individual has a Direct Relationship is not addressed in the Elements of the Common Agreement nor QTF Draft 2. This is a major gap that must be addressed. To ensure a secure and trusted framework, policy and technology standards are necessary. The Common Agreement needs to supply policy on how identity proofing under National Institute of Standards (NIST) Digital Identity Guidelines, NIST 800-63-3 is performed and governed. The QFT Final Version must then supply technical standards on how that information is captured and communicated in the IHE XUA profile. NIST 800-63-3 IAL2 identity guidelines set a higher degree of trust where many federal agencies and healthcare organizations today are expected to meet these standards. We ask that this issue is concretely addressed in the Common Agreement to ensure the accuracy and security of the identity proofing standards.

Governing Approach and Cooperation and Nondiscrimination

We commend the ONC and RCE for including initial elements of the Governing Approach and Cooperation and Nondiscrimination. To fully create a Trusted Exchange Network, a strong governing approach will be needed to ensure all parties are operating within the confines of the Common Agreement. The described Transitional Council will need a strong voice to bring stakeholder feedback to the RCE. The RCE would be wise to utilize the Transitional Council and subsequent Governing Council as a resource to address known challenges, gaps, and future improvements of TEFCA. Disputes and challenges to TEFCA should be expected. In anticipation, the ONC and RCE included the Cooperation and Nondiscrimination section. Health Gorilla applauds the elements listed, and encourages the ONC and RCE to formalize and expand the requirements of how all scenarios will be addressed, and to include the requirements in both the Common Agreement and flowdown terms.

Directory Services

The directory service is quintessential to the development of a trusted framework. It is a key function that enables the exchange of TEFCA Information and creates transparency and visibility for the actors in the national exchange of data.

The Elements of the Common Agreement states the RCE would maintain an RCE Directory Service to support exchange of information between and among QHINs, Participants, and Subparticipants. The QFT Draft 2 expands on the function and purpose of the RCE in the management of directory services. The RCE's role in TEFCA is to serve as the governing health information network exchange through the Common Agreement. The currently proposed directory service model has the RCE playing an additional technical and governing role in the exchange. This structure does not serve one of ONC's primary goals of creating a framework that supports nationwide scalability.

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It is critical that the RCE maintain its role as the governing body and not facilitate a technical role for the exchange of TI. A clear separation between the governing body, and the owner of a critical technical component, is necessary for the RCE to maintain the authority of the role, as awarded by the ONC.

Furthermore, it is Health Gorilla's opinion that the model for directory services has the RCE serving as a single point of failure. As a key technical function, the scalability of directory services management should be carefully considered and single points of failure must be avoided at all costs. In contrast, and as a better practice, a distributed model, with delegated authority to QHINs for directory services management, reduces the risk and employs a model that scales to the continued growth of national exchange. This must be considered as an update to the structure of directory services in the QTF, as this change would greatly benefit the QHINs and the healthcare community served through the TEFCA information exchange.

In the QFT feedback, Health Gorilla proposes a distributed model for the management of the directory services with the same end result for the QHINs and Trusted Exchange Network. We encourage the ONC and RCE to adopt the proposal.

QHIN Eligibility Criteria

The QHIN Eligibility Criteria was released as a supplement to the Elements of the Common Agreement and identified five general eligibility criteria along with specific requirements for each criteria.

Criteria four (4) states each Signatory must demonstrate "the organizational infrastructure and legal authority to comply with the obligations of the Common Agreement and a functioning system to govern its health information network. In addition, Signatory must demonstrate it has the resources and infrastructure to support a reliable and trusted network". Health Gorilla fully supports this criteria. It addresses the importance of the QHIN role and the functional aspects required of the role. However, Health Gorilla challenges the inclusion of requirements 4.a.i, 4.a.ii, and 4.a.iii. The Common Agreement establishes the infrastructure model and the governing approach for the Trusted Exchange Network. The flowdown terms and conditions specified in the Common Agreement enforce the governance of the network, and create consistency between all parties. With the legal framework and governing approach put in place by the Common Agreement, there is no need for each QHIN to have a network governance body composed of participants. Each QHIN should be allowed to operationalize a network governance program that ensures compliance to the Common Agreement, and align with the organization's business model. Requirements 4.a.iv and 4.a.v create this flexibility.

Furthermore, requirements 4.a.i, 4.a.ii, and 4.a.iii are unnecessarily restrictive, and eliminate any commercial HIN from being eligible for a QHIN Designation. These requirements significantly narrow the scope of eligible organizations. If commercial organizations have the

appropriate network governance, legal framework, and technical means, there is no reason they can't fulfill the role of QHIN in the Trusted Exchange Network.

Finally, Health Gorilla applauds the ONC for including the provisional status in the QHIN Eligibility Criteria. The provisional status creates latitude and flexibility in the QHIN model. We ask for more information on specific policies the RCE would use to designate a QHIN on a provisional basis. The current QHIN Eligibility Criteria is general with statements including unclear words such as, "demonstrates the likelihood of being able to satisfy all such criteria during the course of the provisional status". A minimum bar must be defined on what satisfies a provisional status. Without a minimum bar, there is the potential of eroding the trust in the Trusted Exchange Network.

We thank you in advance for your time and consideration of these critical issues. Health Gorilla is happy to provide additional information or answer any questions, and we look forward to meeting with you to further the meaningful and thoughtful goal of how best to improve healthcare in the United States.

Sincerely,

DocuSigned by:
Steve Yaskin
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Steve Yaskin