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

Re: Qualified Health Information Network (QHIN) Technical Framework (QTF) Draft 2

To whom it may concern:

Health Gorilla is pleased to provide comments in response to the Qualified Health Information Network (QHIN) Technical Framework (QTF) Draft 2. We applaud the current focus of ONC to push interoperability forward, building upon innovation from current industry interoperability frameworks and networks, along with interoperability focus from CMS in its recent proposed rule, and the requirements from Congress in the 21st Century Cures Act. We are encouraged by the significant improvements made in draft 2 of the QTF.

Yet, we are concerned that some of the specifics of ONC's proposals within QTF may hinder the progress that has already being made in the industry when one considers the time period between the 21st Century Cures Act to Q1 of 2022 and the release of the Common Agreement, and the rapid pace of innovation. Specifically, we urge the ONC to reconsider its direction in certain areas set forth herein to best comply with the Congressional mandate to "develop or support a Trusted Exchange Framework" (emphasis added) by surveying the work that has already taken place and is continuing to take place in the industry today. We ask that the ONC play a supporting role rather than starting over and developing a Trusted Exchange Framework, and continue pushing forward nationwide interoperability, while still following the additional congressional mandate to "avoid the disruption of existing exchanges between participants of health information networks."

It is our hope that these comments provide support for a roadmap that ensures current industry efforts toward interoperability are considered and fully leveraged so that they truly fulfill the potential of the TEFCA and 21st Century Cures Act 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 secure interoperability platform 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 for the Puerto Rico Department of Health. Health Gorilla operates as the interoperability 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 an interoperable health care system that enables patients, providers, payors, and others to have access to secure medical information in a way that bolsters the progress that has been made in the ten (10) areas below.

QHIN Message Delivery

Option 1: Require QHIN Message Delivery

One of the main purposes of TEFCA is to have an Electronic Health Information (EHI) securely follow patients when and where it is needed. QHIN Message Delivery was added in TEFCA Draft 2, as a critical aspect needed for the achievement of the broader ONC goals. QHIN Message Delivery is necessary to ensure the continuum of care for a patient, and that relevant information is sent to identified care facilities and providers. QFT Draft 1 specified both the HIE XCDR as the standard and listed Direct and FHIR as alternative/emerging standards. However, the QTF Draft 2 limited the standard to the IHE XCDR profile, removing the option for alternative/emerging standards.

Health Gorilla looks forward to the inclusion of a FHIR standard, and has submitted relevant feedback in the FHIR roadmap section. By adopting existing standards and concepts already familiar to software developers outside of healthcare, FHIR reduces the learning curve, makes real-time interoperability easier, and enables faster and simpler application creation. Finally, FHIR adopted principles of reuse, performance, usability, fidelity, and implementability to align with the three overarching goals of the ONC in developing a Trusted Exchange Framework (TEF) and a Common Agreement. As a result, and because it has been systematically adopted in this space, we ask that the XCDR Profile and the FHIR standard be available at the same time.

Specifically, FHIR is used by all major vendors in their consumer facing applications. While SMART on FHIR was the initial hotbed for innovation, we have only begun finding value in the broader use of the FHIR standard. For these reasons and others that we will discuss, SMART on FHIR (“FHIR”) have been adopted by most of the major healthcare participants in the marketplace.

Many more health systems around the country are innovating and have already incorporated FHIR enabled technologies, starting in 2017, and have continued to expand upon this progress with the FHIR protocol generally.

This includes some of the more prominent health systems, which began innovating with FHIR apps to provide clinical care in the United States years ago. Specifically, these include Boston Children’s Hospital, CoxHealth, Duke Medicine, Geisinger Health, Healthcare Corporation of America, Intermountain Healthcare, Ochsner Health System, Partners Healthcare, and University of Utah Health have incorporated and continue to expand upon their use of the FHIR protocols.

Other innovators followed suit, such as Apple’s personal health record (PHR) feature, called Health Records, that uses FHIR to aggregate existing patient-generated data in the Health app with data from electronic medical records at more than 500 hospitals.

Additionally, many of the top EHR vendors have already incorporated support for FHIR into their products and are beginning to roll out the technology to healthcare institutions. Epic currently has well over a hundred sites with patient facing FHIR support, and previously stated that they expected a majority of their sites to be FHIR enabled by the end of 2018. Cerner has said that they expected nearly all of their in-patient sites, and many ambulatory sites to become FHIR enabled in 2018. Allscripts FHIR enabled their 2017 releases of three of their EHR products. Other EHR companies are also in the process of building SMART support into their products. (www.smarthealthit.org.)

To summarize, Message Delivery is a critical success factor to achieve the goals of the ONC and should absolutely be required in the final version of the QTF. To do that effectively, the QTF must include the use of FHIR as an option. Without FHIR as an option or as an alternative, it will force innovative leaders in the industry that have progressed significantly by tackling the issues of availability and accessibility via FHIR to slow, or worse abandon, these superior and innovative efforts to adopt the current IHE XCDR profile. Therefore, Health Gorilla advocates strongly for the inclusion of FHIR as an alternative/option because it is a widely used and standard, as set forth above, and it continues to be integrated within TEFCA, and specifically with the QHIN Message Delivery exchange.

Roadmap for FHIR in TEFCA

TEFCA Draft 2 referenced FHIR as an alternative/emerging standard to facilitate the national exchange of data. QTF Draft 2 removed FHIR, stating that "although the healthcare industry has started to explore new exchange methods, such as Representational State Transfer (REST) application program interfaces (APIs) and standards like Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®)3, there is still work to be done in operationalizing these approaches at the scale of QHIN-to-QHIN exchange."

The FAST Exchange Metadata Using RESTful Headers project, sponsored by the FHIR Infrastructure Work Group, is currently working to provide a model of FHIR data exchange through an intermediary (QHIN to QHIN). The intention of this Group is to publish an Implementation Guide, however, the timeline for publication is unknown because the timeline for Submit for STU Ballot in May of 2021 was postponed without a newly defined timeline.

We are mindful and cognisant of the existing challenges for the broad adoption of FHIR. We strongly believe the FHIR standard addresses needs in the industry, and we expect to see the rapid adoption of the standard continue to grow exponentially, especially with the national network of exchange created by TEFCA. With those points in mind, we strongly suggest that the FHIR exchange should be listed as an optional standard of exchange in the final version of the QTF. Given current industry focus on FHIR based exchange as discussed herein, patient access to data, and the recent CMS and ONC proposed rules requiring FHIR APIs from providers and payor, it is seems that the market at large would be hampered if TEFCA limits its "on- ramp" to query and push messaging, without inclusion of those FHIR APIs. As such, it

could be argued that it may run afoul of the Congressional mandate to "avoid the disruption of existing exchanges between participants of health information networks."

A major concern with "Information Blocking" in the recent ONC proposed rule is how provider organizations will deal with the potentially massive burden of vetting consumer apps. Consumer apps need to be included in TEFCA. Once an app has been "validated" as TEFCA-compliant, and is live on a QHIN (directly, through a Participant, etc,) any other QHIN must exchange with that consumer app at the patient's direction. We advocate for QHINs to certify patient apps. Once certified by one QHIN, all QHINs should respect the certification of the patient app. An information blocking exception could be added such that if a patient uses an app that is not a party of the TEFCA (bound to the Common Agreement), the provider could not be an information blocker for refusing to exchange with that app.

Without FHIR inclusion for consumer apps in TEFCA, and without that exception, every provider organization will be required to individually vet every possible consumer app. That task is entirely infeasible/ impossible. A vetting of apps through QHINs, under the direction of the RCE and ONC, would properly remove that burden from the provider organizations (and payors, and anyone else a consumer app would want information from,) allowing patients to trust that any consumer app of their choosing will be able to connect, as long as it is "certified"/"TEFCA compliant"(or whatever label is given to those apps.)

Health Gorilla has been an early adopter of FHIR, and has built an interoperability platform where Participants can code against Health Gorilla's published APIs for easy "on-ramp" to the national exchange of data. Health Gorilla's rapid and accelerated growth is a testament to the industry's desire to use FHIR APIs for the exchange of health data. Health Gorilla is far from alone in the current market. As explained above, FHIR became the standard of most major healthcare systems, EHR vendors, and innovators, such as Apple, years ago.

By adopting existing standards and concepts already familiar to software developers outside of healthcare, FHIR reduces the learning curve, makes real time interoperability easier, and enables faster and simpler application creation. Finally, FHIR adopted principles of reuse, performance, usability, fidelity, and implementability that align with the three overarching goals of the ONC to develop a Trusted Exchange Framework (TEF) and a Common Agreement.

Given the above, we strongly advise that elements that should be included in the TEFCA FHIR Roadmap include the following:

1. Add a requirement to allow SMART on FHIR end-points for patient access in the directory for each relevant QHIN (as required by CURES Act) as **required** in the final version of the QTF
2. Inclusion of FHIR standards in final version of the QTF as **optional** for both Message Query and Message Delivery

3. Release a timeline for required use of the FHIR standards for both Message Query and Message Delivery

Removal of RLS and eMPI Requirement

In developing a Trusted Exchange Framework (TEF) and a Common Agreement that meets the industry's needs, one of ONC's high-level goals was to support nationwide scalability.

Therefore, it is clear that requiring RLS and eMPI on the QHIN level works towards the larger picture and the express intention of the QTF to govern the data exchange between QHINs, while imposing minimal requirements on the structure and operations internal to QHINs, its Participants and Subparticipants. Without these protocols, additional and unnecessary barriers will be imposed upon QHIN participants exchanging data in the Trusted Exchange Framework.

Currently, the QTF Draft 2 specifies the technical underpinnings for QHIN-to-QHIN exchange and certain other responsibilities described in the Common Agreement. It described the precondition that each QHIN has either a Record Locator Service (RLS) OR Enterprise Master Patient Index (eMPI) OR the ability to query all of its Participants for a patient lookup within the timeout limitation as specified in the QHIN Service Level Requirements Policy (pending.) While the volume of the data exchanged within the TEFCA model is yet to be known, it is important to be cognizant that the QTF Draft 2 describes the requirements that must support nationwide scalability. The QHIN Service Level Requirement Policy will serve as the final measure on whether a multi-layered exchange without an RLS OR eMPI meets the standard set forth by the ONC and the RCE. Additionally, the Constraints for Participants and Subparticipants do not include requirements around the timeliness of responses of Participants and Subparticipants. If the requirements of RLS and eMPI are not imposed on the QHIN, then additional requirements would need to be passed onto Participants and Subparticipants.

Therefore, clearly requiring RLS and eMPI on the QHIN level is the best choice to meet the express goals of the QTF as set forth herein, and allow the QTF to govern the data exchange between QHINs, while allowing the best and most effective communication internal to QHINs, its Participants and Subparticipants.

Patient Matching

Clearly, there needs to be a minimum on patient matching to ensure that there is confidence that the right patient record is being pulled. There needs to be matching on at least the standard elements of PHI under C.F.R. Section 164.514(b)(2), along with matching based upon data validated algorithms, and a robust de-duplication process for accurate record aggregation.

Industry discussion has occurred around the publication and standardization and minimum and maximum bars for patient matching, based on the acceptable risk for each permitted purpose. In the current industry, a trusted framework does not exist, which results in each entity making up their own policies around patient matching. The end result is a fragmented system where an

argument can be made that information blocking is occurring, based on interpretations around appropriate patient matching.

Health Gorilla acknowledges the complexity of the problem. We propose that the final version of the QTF includes standards and requirements to address the minimum and maximum bars for patient matching, per a permitted purpose. For example, commonly exchanged elements of patient name, date of birth, sex, address, and phone number require one standard to define how each element should they be weighted, the comparison and handling of differences in data values, as well as non-standard values that can in included to augment patient matching. There are of course many more examples and differing standards. This is a problem so notable there have been many industry workgroups that have worked on this issue in the past, including the Sequoia Project's whitepaper, A Framework for Cross-Organizational Patient Identity Management.

Leaders in the industry, while not in a position to disclose intellectual property, can report that they are able to accomplish patient matching at an extremely high success rate with current technology. A trusted exchange network can only be accomplished by creating the standards and requirements to address the minimum and maximum bars for patient matching, per permitted purpose.

User Authentication and Identity Proofing

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 entity 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 addressed identity proofing standards. The Minimum Required Terms & Conditions (MRTCs) Draft 2 contains policies around identity proofing. It 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 QTF Draft 2 as a stand alone document 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." QTF Draft 2 falls short of addressing the act of identity proofing individuals, and fails to include a reference to National Institute of Standards (NIST)

Digital Identity Guidelines, NIST 800-63-3. The requirements of identity proofing to the QHIN, Participant, or Participant Member to whom the Individual has a Direct Relationship is not addressed in QTF Draft 2. This is a major gap that must be addressed.

With the pending release of the Common Agreement, there is no assurance that the intention and policy contained in TEFCA Draft 2 will be included in the final version of TEFCA. To ensure a secure and trusted framework, policy and technology standards are necessary. The QTF needs to supply policy on how identity proofing under National Institute of Standards (NIST) Digital Identity Guidelines, NIST 800-63-3 is captured and then 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.

C-CDA 2.1

The documentation and standards published for the implementation of the Trusted Framework and Common Agreement have been thoughtful in utilizing the existing and trusted standards to ensure the highest adoption of TEFCA. Health Gorilla applauds the ONC and RCE for specifying the C-CDA 2.1 as the expected standard for all patient information. The QTF also addresses that for Document Retrieve responses not in C-CDA 2.1 format, QHINs MUST convert the response to C-CDA 2.1. This ensures the trusted framework has adopted the most recent standard that includes improvements in interoperability in the current healthcare marketplace.

Mutual Server Authentication - QHIN to participant

The QTF Draft 2 specifies the technical underpinnings for QHIN-to-QHIN exchange. The QTF stops at defining only the QHIN-to-QHIN exchange and does not specify the interactions for QHIN to participants. Furthermore, it states as long as QHINs are able to achieve the required functional outcomes within their networks, they generally have the operational flexibility to select appropriate standards and approaches consistent with the needs of their business environments.

As QTF-010 is written today, it defines the mutual authentication methods for both QHIN-to-QHIN exchange, and it prescribes the mutual authentication methods for QHIN to Participant exchange. TLS 1.2+ for Mutual Server Authentication is appropriate for the QHIN-to-QHIN exchange.

The QTF should be consistent and only define QHIN-to-QHIN authentication methods. QHIN to Participant authentication should be left to each QHIN to determine the appropriate mechanism, based on the QHIN operational model. If the ONC and RCE feel that to ensure the secure and trusted framework, then the QHIN to Participant authentication needs to be specified, and it should be permitted to be based on OAuth 2.0 without mutual TLS authentication. In complex

modern architectures, load balancers are usually in place that terminate TLS, and would cause interoperability, which is the fundamental opposite of TEFCA's goal. Also, as an example of further support, Internet Engineering Task Force (IETF) suggests that application-level encryption might be a better overall approach compared to mutual TLS.

Health Gorilla asks that the QTF move the process forward and to exclude the mutual TLS requirement to ensure interoperability, and to recognize the standards being widely used today. Requiring mutual TLS for QHIN to Participants communication will be a step backwards, and exclude HINs, like Health Gorilla, who have built a sophisticated network based on OAuth (JWT bearer token) FHIR standards.

Directory Services

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

The QTF Draft 2 specifies the technical underpinnings for QHIN-to-QHIN exchange and certain other responsibilities described in the Common Agreement. 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.

It is critical that the RCE maintain their 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.

The Directory Service model described in QTF Draft 2, where all QHINs will download the local copy of the RCE directory for exchange, 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.

Health Gorilla proposes a distributed model for the management of the directory services with the same end result for the QHINs.

1. Each QHIN maintains their own Directory of Participants which serves as source of truth, and is responsible for ensuring the accuracy of the directory.

2. RCE is responsible for maintaining directory of participating QHINs, but does not act as source of truth for QHINs' participants
3. Alternative 1: QHINs can load other QHINs' directories, and are responsible for aggregating the directories into a local copy, stored by each QHIN.
4. Alternative 2: RCE can load, aggregate and store a secondary copy of all QHINs' participants in RCE local directory. In this case, the QHINs could load the RCEs directory for a local copy to avoid querying each individual participant QHIN directory.

Advocate for broader exchange of data

One of the main purposes of TEFCA is to have an Electronic Health Information (EHI) securely follow patients when and where it is needed. TEFCA Draft 2 allows for data use under a new category of "Quality Assessment & Improvement," which is defined as "support for various quality initiatives, including outcomes, clinical guidelines, patient safety, population-based activities, protocols, case management, care coordination, etc."

The current focus of ONC to push interoperability forward, building upon innovation from current industry interoperability frameworks and networks, along with interoperability focus from CMS in its recent proposed rule, and the requirements from Congress in the 21st Century Cures Act make data based improvements on patient care possible.

In the 21st Century Cures Act (Sections 4003(b)(9)(A) & 4003(b)(9)(B)(i)), the ONC is given the task to "develop or support a Trusted Exchange Framework" (emphasis added). Section 4003(b)(9)(F)(iii) goes on to specifically state that "the Trusted Exchange Framework and common agreement...shall take into account existing Trusted Exchange Frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between participants of health information networks."

We believe population-level data (here "population management" as defined as all of the uses for which TEFCA Draft 2 allows under the "Quality Assessment and Procurement" use case) exchange will be mission critical to many of the goals of an interoperable healthcare ecosystem, and that data regarding population management is absolutely the only path to lead to the vast improvement of patient based health care in the United States.

On December 15, 2017, in a meeting funded by and including the ONC, the Computational Health Informatics Program (CHIP) and the SMART Team at Boston Children's Hospital hosted a meeting in Boston focused on emerging standards for population level data export from health information systems using Health Level Seven® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®). This meeting brought together key stakeholders from across health care, including representatives from payers, providers, health systems, and electronic health record (EHR) developers, and technology innovators.

One of the key goals of this meeting, a meeting that was cited frequently during the Congressional Debate regarding the CURES Act, was to understand the existing and planned

population level data use cases of ONC, payers, analytics and population health software vendors, EHR developers, and other parties to guide the technical roadmap in this area.

In one study, Google acquired 10,000 images of eyes used to detect diabetic retinopathy. The company then developed and validated a deep learning algorithm that reviewed these images—and outperformed ophthalmologists in detection accuracy. This shows the potential of large data sets combined with powerful AI and machine learning technologies (as time goes on, these technologies have improved and become more prolific.)

“With the emergence of FHIR there is now an opportunity to standardize transferring data, which will reduce the costs of these networks and make them sustainable. Further, an automatic data export that is part of an electronic medical record could become a core function of the health system. This would provide data liquidity and enable population health analytics.” (The Intersection of Technology and Policy: EHR Population Level Data Exports to Support Population Health and Value/ [Executive Summaries], Dec 17, 2017, Page 7.)

Right now, socioeconomic disparities in health in the United States are large, are persistent, and appear to be increasing over recent decades, despite the general improvements in many health outcomes due to access and overall quality of care. The most advantaged American men and women experience levels of longevity that are the highest in the world. However, less advantaged groups experience levels of health comparable to those of average men and women in developing nations of Africa and Asia or to Americans about half a century ago (Berkman and Lochner, 2002). Furthermore, these wide disparities, coupled with the large numbers of people in these least-advantaged groups, contribute to the low overall health ranking of the United States among developed, industrialized nations.

A major opportunity for TEFCA to improve the overall health quality of the entire United States population now rests on our capacity to either reduce the numbers of the most disadvantaged men, women, and children in the highest risk categories or to reduce their risks for poor health by using population management data. With the ability to use and access data for population health management, the combination of technology and data can help bring significant health concerns into focus and address ways that resources can be allocated to overcome the problems that drive poor health conditions in the population. We all have a stake in population health in America today. Once there is transparency and insight into patients by using population management data, we will begin to understand populations, have greater insight into the lines between a population management/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, and 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 "Quality Assessment & Improvement" data and any related and defined data use cases have the broadest possible definitions and uses.

Mandatory response for accepted exchange purpose

Another aspect of building a trusted framework is having the certainty that queries will be responded to when data is requested for permitted uses under current healthcare law as well as what is prescribed by the Common Agreement. The current landscape of health information exchange has had limited success in facilitating the national exchange of information for non-treatment purposes. Existing networks and consortiums such as eHealth Exchange, Carequality, and CommonWell are demonstrating very limited willingness to respond to queries for information when non-treatment permitted purposes are listed, with each entity working to address the problem, through policy workgroups and incentivized pilots.

The QTF Draft 2 constraints for Participants and Subparticipants currently does not specify the conditions by which participants and Subparticipants must respond to queries. With the pending release of the Common Agreement, there is no assurance that the requirement of responses for allowable permitted purposes will be addressed. Without such direction, there is a strong likelihood the lack of trust in today's landscape will be assumed in the TEFCA model of national exchange. Therefore, a mandate is absolutely essential on data exchange for all identified and approved purposes.

To achieve the spirit of TEFCA, and to fully realize a trusted exchange, we strongly request the ONC and the RCE include concrete policy addressing that when queries are received with an accepted exchange purpose, and data exists, then the entity must respond to the query with the information.

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

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