



June 17, 2019

Don Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator
U.S. Department of Health and Human Services
330 C ST SW
Mary Switzer Building; Office 7009A
Washington, D.C. 20201

Dear Dr. Rucker:

We thank you for the opportunity to respond to the second draft of the Trusted Exchange Framework and Common Agreement ("TEFCA 2.0") issued on April 19, 2019 by the Office of the National Coordinator for Health Information Technology ("ONC") of the Department of Health and Human Services ("HHS").

Surescripts was created with the purpose of serving the nation with the single most trusted and capable health information network to help increase patient safety, lower costs, and ensure quality care. Faithful to that purpose, Surescripts built and now operates the largest and the most comprehensive clinical health information network connecting health care organizations nationwide. While founded in 2001 as an e-prescribing network, our innovation has since allowed us to expand the scope of our network to reach organizations that connect pharmacists, physicians, payers, and patients. These organizations make up the Surescripts Network Alliance.

The Surescripts Network Alliance connects our electronic health record ("EHR") vendor, pharmacy, pharmacy benefit manager ("PBM"), and clinician customers – in addition to health plans, long-term and post-acute care organizations, and specialty pharmacy organizations – with 1.61 million healthcare professionals and 258 million patients in our master patient index, covering 79% of the U.S. population and 93% of insured patients. All of these stakeholders and participants in the Surescripts Network Alliance rely on Surescripts to easily and securely share health information. In 2008, Surescripts processed 17.7 billion clinical transactions, a jump of 29% from 2017.

These clinical transactions include not only routing of prescriptions and all of the associated e-prescribing transactions, but also include delivery of medication history records, real-time prescription benefit transactions, electronic prior authorizations, clinical direct messaging, and record locator & exchange messages. For instance, our Record Locator & Exchange service helped bring interoperability to life for thousands of healthcare organizations in 2018, giving clinicians access to nationwide health information exchange through a single connection at the point of care. Last year, our Record Locator & Exchange service was used by over 106,000 clinicians across all 50 states and

2800 CRYSTAL DRIVE
ARLINGTON, VA 22202
T: 703.921.2121 F: 703.921.2191

920 2ND AVENUE SOUTH
MINNEAPOLIS, MN 55402
T: 866.267.9482 F: 651.855.3001

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the District of Columbia, linking those clinicians to 108 million clinical documents, and allowing those clinicians to exchange 99 million care location summaries.

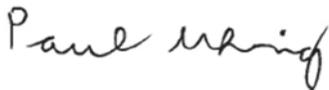
Please refer to our 2018 National Progress Report at <https://surescripts.com/news-center/national-progress-report-2018/>, which highlights the progress made last year across the Surescripts Network Alliance.

When we look at this vast exchange of actionable patient intelligence across care settings for purposes of treatment, we see interoperability in action – and in evolution. Our network strength is rooted in two core beliefs: (1) more actionable patient intelligence at critical points of care means better decisions, and (2) better decisions mean lower cost, higher quality, and increased safety. Guided by these beliefs, and further guided by our principles of neutrality, transparency, open standards, collaboration, and privacy, Surescripts is committed to saving lives, improving efficiency, and reducing the cost of health care for all.

We support and commend ONC in its commitment to fulfilling the requirements set forth by the 21st Century Cures Act signed on December 13, 2016 by President Obama. In our experience building and operating a nationwide interoperable network, we learned that even the most efficient and sophisticated network is useless without access to adequate health information to turn into actionable intelligence. We are aligned with ONC in its mission to break down information and technology barriers to improve healthcare, and in this letter offer recommendations to better accomplish this mission to support the interoperability goals of the nation.

Attached are our comments and recommendations for the various proposals within TEFCA 2.0. Specific actionable recommendations and suggestions are underlined. We thank you again for the opportunity to share our comments and would be pleased to answer any follow-up questions you may have.

Sincerely,

A handwritten signature in cursive script that reads "Paul Uhrig".

Paul L. Uhrig
Chief Administrative, Legal & Privacy Officer

TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT DRAFT 2

Comments and Recommendations

Surescripts commends ONC in its intent and drive to promote nationwide interoperability to ensure that individuals have access to safe, effective, and efficient healthcare. In brief, while we applaud the efforts of ONC to build on the first draft of the Trusted Exchange Framework and Common Agreement (“TEFCA 1.0”), we are concerned that there are still areas in the second draft of TEFCA (“TEFCA 2.0”) that remain overly broad and subject to multiple interpretations. Such breadth and ambiguity may have the effect of creating an unstable interoperability marketplace. TEFCA 2.0 also appears to impose specific standards and requirements on participants that may discourage major stakeholders in the industry from participating.

We have organized our comments into the following parts: (1) general comments to TEFCA 2.0; (2) comments on the Trusted Exchange Framework (“TEF”) Draft 2; (3) comments on Minimum Required Terms and Conditions (“MTRCs”); and (4) comments on the Qualified Health Information Network (“QHIN”) Technical Framework.

1. General Comments to TEFCA 2.0.

- 1.1.** We are grateful for ONC’s adoption of a phased approach in implementing TEFCA to encourage health information networks (“HINs”) to participate. As suggested in our comment letter to TEFCA 1.0, requirements that are overwhelmingly cost and resource prohibitive to HINs will be a barrier to participation and a barrier to creating both competition in the marketplace as well as the system contemplated by ONC for ubiquitous exchange among all providers. We are encouraged that ONC intends to work with the National Institute of Standards and Technology (“NIST”) and the industry on determining TEFCA use cases.
- 1.2.** In our comment letter to TEFCA 1.0, we supported ONC’s intent to build on existing private-sector models and leverage existing standards. We emphasized that building on existing models and standards would minimize disruption to existing initiatives that are effectively advancing interoperability and consistent with congressional intent. We urge ONC, however, to not build the foundations of TEFCA on standards that the industry and regulators are actively moving away from. As we emphasize later in this letter, ONC appears to be building TEFCA on the foundation of profiles that are or are becoming out-of-date (e.g., Integrating the Healthcare Enterprise Cross-Enterprise User Authentication (“IHE XUA”)). If ONC intends to impose certain exchange network infrastructural standards on QHINs, at their own cost, we believe that entities will more likely be incentivized to participate in TEFCA and become QHINs if they are asked to spend their limited resources in building upon modern standards and profiles, such as Health Level Seven (“HL7”) Fast Healthcare Interoperability Resources (“FHIR”), rather than overly complex and outdated profiles that today’s industry is phasing out of use.

- 1.3.** We applaud ONC's efforts to incorporate public comments to address gaps and uncertainty that were raised in the TEFCA 1.0. However, while ONC's TEFCA 2.0 clarifies certain definitions and expectations of TEFCA participants, TEFCA 2.0 still leaves many questions unanswered. For example, one of the components to the Common Agreement, which all QHINs will be required to comply with, is the Additional Required Terms and Conditions ("ARTCs"). On page 9 of TEFCA 2.0, ONC provides some provisions that may likely be covered under ARTC, such as determination of fee schedules and compliance; QHIN Application, Onboarding, and Designation requirements; a process for surveilling and testing QHIN compliance with the Common Agreement; an arbitration process for adjudicating non-compliance; and an audit-appropriate process for accepting and investigating complaints, and for suspending and potentially terminating a non-compliant QHIN. We are concerned that although ONC states that the Recognized Coordinating Entity ("RCE") will ensure that the ARTCs do not conflict with MRTCs, ARTCs that impose additional terms and conditions on top of MRTCs may unnecessarily restrict HINs from participating. Such unknowns (e.g., standards regarding adjudication for noncompliance; additional terms and limitations regarding QHIN fees) may cause low participation of HINs and/or further delay establishing an interoperable nationwide electronic health information exchange.
- 1.4.** In our comment letter to TEFCA 1.0, we asked ONC to consider focusing on refining and articulating policy goals and principles, rather than drafting specific agreement terms and technical requirements. Because networks in existence today have a plethora of arrangements, including downstream arrangements, we are concerned that specific terms and technical requirements imposed by ONC and/or RCE will affect such arrangements, and most likely cause low participation of HINs. Rather, as suggested in our comment letter, ONC should move many of the provisions from the TEF Draft 2, MRTC, and the QHIN Technical Framework ("QTF") into use case-specific implementation guides; the rapidly evolving market and the need to support innovation underscore the necessity of technical requirements to be maintained in implementation guides instead of the Common Agreement. We reiterate that ONC's and/or RCE's attempt to build all use case-specific terms into a legal agreement runs the risk of imposing elements that work well for one use case but are unsuitable for other use cases. Implementation guides can be legally binding if they are incorporated by reference into the final Common Agreement. ONC and the RCE may find this approach more helpful because updating implementation guides is easier than attempting to amend the underlying legal agreement. Additionally, implementation guides can be updated as needed to reflect the standards used by the industry.
- 1.5.** As stated in our comment letter to TEFCA 1.0, while we understand the intent of providing a single "on-ramp" to nationwide connectivity for providers, we are concerned that the focus on one on-ramp for all use cases could hinder innovation.
- 1.6.** In our comment letter to TEFCA 1.0, we suggested that ONC focus on fee transparency rather than imposing detailed commercial fee requirements. We are concerned that the

MRTC in TEFCA 2.0 includes very specific criteria concerning information exchange that will (i) materially alter HINs' agreements with existing customers, (ii) cause HINs to spend significant costs and resources to implement the provisions required to become a QHIN, and (iii) negatively affect the ability of entities to receive reasonable rates of return on their risk taking and investment. As we noted in our comment letter to TEFCA 1.0, any imposition on economic relationships by ONC or the RCE may result in fewer organizations participating as QHINs. Therefore, we ask ONC to define "reasonable fees" and/or clarify who determines "reasonable fees," such as the RCE, QHINS, a neutral third party, or the government. We also ask ONC to clarify how "reasonable fees" will be determined (e.g., industry practices; fair-market value).

- 1.7. We recommend that ONC consider a sustainable business model by which the RCE will be able to continue developing, implementing, and sustaining its obligations beyond the four year award period.
- 1.8. We support ONC's desire to ensure individuals' access to their health information without undue burden or barriers. However, we are concerned with the lack of individual protections surrounding third party applications' use of individual data. According to TEFCA 2.0, "HINs should not limit third party application from accessing individuals' EHI via an [application programming interface ("API")] when the application complies with the applicable data sharing agreement requirements and the individual has directed the entity to disclose a copy of ePHI to the application." While ONC mentions that the Common Agreement will require non-HIPAA entities participating in TEFCA to be bound by "certain provisions" aligning with safeguards of the HIPAA Rules, it is conceivable that third party applications (that are not covered under HIPAA) will collect, manipulate, and/or monetize patient health data. We recommend that ONC specify the "certain provisions" to which participating non-HIPAA entities would be bound. We also suggest that ONC establish controls upon the way information is presented to Individuals so that such information is presented in an unbiased and informative manner.
- 1.9. TEFCA 2.0's scope of Exchange Purposes is narrower than that proposed in TEFCA 1.0 in that it limits Payment purposes to Utilization Review and Operation purposes to Quality Assessment and Improvement and Business Planning and Development. In addition, we recommend that ONC include "care coordination and case management" under Operation purposes. We respectfully remind ONC that unlike providers, where care coordination and case management are considered a treatment use case, payors largely engage in care coordination and case management through Operation purposes. We are concerned that TEFCA 2.0's limited Operation purposes may discourage and/or decrease payor participation in TEFCA, thereby leaving out significant stakeholders in the healthcare industry from the TEFCA ecosystem.
- 1.10. While we are supportive of infrastructure in which participating entities can respond to EHI requests for one or more of the Exchange Purposes, we ask ONC to note that, in some cases, there may be contractual restrictions that prevent a HIN from sharing information even if

the request is for an Exchange Purpose. For instance, a covered entity may contractually limit a business associate from sharing information for non-treatment purposes. We ask ONC to clarify whether all entities participating in TEFCA, including Participants, must allow for the sharing of information for all of the Exchange Purposes. If this is not the case, we recommend that ONC specify that a QHIN shall not be in violation of TEFCA if a contractual requirement precludes the QHIN's ability to respond to a request for EHI that meets one or more of the Exchange Purposes.

- 1.11.** We are grateful to ONC for the opportunity to review, respond, and comment to TEFCA 2.0, but we urge ONC to extend review of TEFCA to the broader audience through the notice and comment rulemaking process pursuant to 5 U.S.C. § 553. This will ensure that all stakeholders that potentially can participate in TEFCA will have proper notice and have the opportunity to review and comment. We believe that broad participation in TEFCA, including its development, will allow for its more successful implementation and wider adoption.

2. Specific Comments on TEF Draft 2.

2.1. Principle 1 – Standardization.

We support ONC's efforts to require HINs to adhere to standards identified through the Interoperability Standards Advisory ("ISA"). As stated in our comment letter to TEFCA 1.0, any standards for TEFCA should provide its participants sufficient autonomy to innovate health information technology while also supporting the core principles of exchange. Therefore, we encourage ONC to take into account the ways TEFCA may impact existing and emerging interoperability standards. To that end, as discussed further in Section 4 of this letter, we do not recommend ONC specify standards in the QTF, but rather incorporate by reference standards identified by the Interoperability Standards Advisory.

2.2. Principle 2 – Transparency.

2.2.1. Part C: Publish, keep current, and make publicly available the HIN's privacy practices.

We commend ONC for its efforts to inform individuals of their privacy rights. However, ONC should clarify that HINs that do not interact with individual patients are not required to ascribe to the following:

- "HINs should not impede the ability of individuals to access their EHI and direct it to designated third parties, as required by the HIPAA Privacy Rule"; and
- "HINs should provide a method by which individuals can exercise meaningful choice regarding the exchange of EHI about them and ensure that such individual's choice is honored on a prospective basis, consistent with applicable law".

Some HINs do not provide services or products directly to individual patients, and the two privacy practices above should not be required of such HINs. While we (i) agree with ONC that HINs *that directly interact with individuals* should not impede the ability of individuals to access their EHI, and (ii) agree that HINs *that directly interact with individuals* should provide a method by which those individuals can exercise meaningful choice, we recommend that ONC limit requirements involving individuals to only those HINs that do interact with individual patients as part of their business or service offering.

2.2.2. Part D: When necessary, conduct any arbitration processes with other HINs in an equitable, transparent manner.

ONC mentions the need for HINs to ensure an arbitration process is in place to address violations of data sharing agreements among HINs. If ONC intends to outline the arbitration process by which HINs are to comply, we request that ONC propose such arbitration process through the administrative rule making process instead of delegating that responsibility to the RCE.

2.3. Principle 3 – Cooperation and Non-Discrimination.

Surescripts agrees that HINs should not implement practices that discourage or impede the exchange of health information. However, we urge ONC to note that the process of technology implementation and EHI exchange may differ based on the type of entity seeking to connect to the HIN. For instance, entities need to be adequately verified prior to the exchange of information so as to ensure compliance with federal and state privacy and security laws. Such privacy and security laws may differ based on the type of entity. We ask ONC to not consider reasonable circumstances in which a HIN may need to control the flow of EHI for privacy and security reasons an intentional attempt to impede the exchange of health information. Moreover, we ask ONC to note that implementation may differ for different types of entities and any resulting variances in connectivity may not be due to the fault of either party.

2.4. Principle 4 – Privacy, Security, and Safety.

2.4.1. Part B: Ensure providers and organizations participating in data exchange have confidence that individuals have the opportunity to exercise meaningful choice, if and when it is needed, prior to the exchange of EHI.

Similar to our comment above in section 2.2.1, not all HINs provide their services directly to individuals. Therefore, ONC should clarify that only HINs *that directly provide services to individuals as part of their business or service offering* will be required to meet the meaningful choice standards.

Additionally, as we recommended in our comment letter to TEFCA 1.0, ONC should develop a comprehensive approach to defining consent and authorization statutes and regulations.

In that letter, we noted the inconsistencies between existing state and Federal statutes and regulations that limit interoperability. Therefore, we again ask ONC to work with state governments and Federal agencies to develop clear standards and guidance so that cohesive privacy, security, and patient safety practices are established that can be understood and complied with by third parties.

2.5. Principle 5 – Access.

First, similar to our comments above in sections 2.1 and 2.4.1, not all HINs provide services directly to individuals. We are concerned that if ONC requires HINs that do not currently provide services to individuals to take on additional responsibility of providing access to EHI, the limited resources of such HINs may be unnecessarily burdened by this requirement, thereby decreasing their ability to provide efficient information exchange. This will undoubtedly discourage HINs to participate in TEFCA. Therefore, we recommend that ONC clarify that *only HINs that directly provide their service to individuals as part of their business or service offering* will be required to provide individuals with access to EHI.

Second, we disagree with ONC’s notion that EHI is accessible “at virtually no cost.” We refer ONC to the report issued by the U.S. Government Accountability Office Report (“GAO”) concerning “Fees & Challenges Associated with Patient Access,”¹ which acknowledged that patient requests for electronic medical records can be challenging as such requests (i) require the reallocation of limited staff and resources, and (ii) often create complex and challenging environments, sometimes involving multiple EHRs. The report concludes that responding to requests for electronic medical records can be costly and time consuming. As such, we direct ONC to Subsection 164.524(c)(4) of the HIPAA Privacy Rule, which allows the covered entity to “impose a reasonable, cost-based fee” based upon labor, supply, postage, or summary/explanation preparation costs. Consistent with that provision, we request that ONC replace “virtually no cost” with “reasonable cost pursuant to Part 164 of the HIPAA Privacy Rule” to avoid any confusion on fee expectations.

2.6. Principle 6 – Population-Level Data.

As mentioned in our comment letter to TEFCA 1.0, Surescripts recognizes the need for population health management and bulk data transfer, but encourages ONC to use a metered approach to create and modify standards that better support such activities prior to pushing for their adoption. Although ONC appears to acknowledge that the standards to support this use case are premature for widespread implementation, ONC also appears to be adamant in implementing population level (or “bulk transfer”) as a future use case. We are concerned that ONC’s push of HINs to support such capabilities without actual standards will create unnecessary confusion. Therefore, we urge ONC to remove the

¹ GAO, Report to Congressional Committee: Medical Records Fees and Challenges Associated with Patients’ Access (GAO-18-386) (May 2018), available at <https://www.gao.gov/products/GAO-18-386>.

Population-Level Data principle until standards are well-defined to support this particular use case.

3. Specific Comment on Minimum Required Terms & Conditions (“MRTC”).

We continue to applaud ONC’s attempts to provide groundwork on the road toward interoperability by providing core definitions, terms, and conditions; however, until the following items are included and/or clarified, we believe that there is a detrimental gap in the MRTC as is:

- Filing complaints with respect to the Common Agreement;
- Adjudicating noncompliance in accordance to the Common Agreement; and
- Limiting the additional fees in the Common Agreement.

3.1. Definitions (Section 1).

3.1.1. Direct Relationship.

We recommend that ONC revise the definition of “Direct Relationship” to read as follows:

“[A] relationship between (a) an Individual and (b) a QHIN, Participant, or Participant Member, that arises when the QHIN, Participant or Participant Member, as applicable, offers services directly to the Individual in connection with one more of the Framework Agreements and the Individual agrees to directly receive such services.” (Proposed language underlined and italicized.)

3.1.2. Electronic Health Information.

ONC’s definition of “Electronic Health Information” (“EHI”) in TEFCA 2.0 is overly broad and exceeds what was intended by Congress. Moreover, it improperly treats all identifiable information that relates to an individual’s health as EHI that is qualitatively and substantively the same. We recommend that ONC define EHI to include only observational health information² that is contained in the US Core Data for Interoperability (“USCDI”). In addition, we recommend that ONC ensure that the definition of EHI is consistent with the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program proposed rule, published in the Federal Register on March 4, 2019 at 84 FR 7424 (the “ONC Proposed Rule”) when the regulations therein are finalized.

² 84 Fed. Reg. 7424, 7516 (Mar. 4, 2019) (“...EHI that is created or maintained during the practice of medicine or the delivery of health care services to patients.”)

3.1.3. Health Information Network.

Similar to the ONC Proposed Rule,³ the definition of “Health Information Network” is broad. TEFCA 2.0 defines a Health Information Network as “an individual or entity that (1) determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities or (2) provides, manages, controls, or substantially influences any technology or services that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities”. We recommend that ONC specifically define what constitutes “substantial influence” of policies or agreements. In particular, we recommend that ONC redefine “substantial influence” as “the ability of an individual or entity to independently and unilaterally impose its view on policies or agreements that define *material* conditions or requirements that enable or facilitate the access, exchange, or use of EHI between and among two or more unaffiliated individual or entities.”

We also recommend that ONC provide clear and unambiguous definitions for terms such as “manage,” “control,” and “influence” found in clause (2) of the definition. We also recommend that ONC impose a materiality standard on all such factors, and not just on the “influence” criteria. Furthermore, there are many entities that contract or license technology or services from third parties to enable or facilitate access, use, and exchange of information (e.g., third party server service providers). We recommend that ONC clarify that third parties would not fall within the definition of HIN if such third parties license, provide, or manage technology upon terms and conditions that do not otherwise grant those third parties material control or influence over the service that enables access, exchange, or use.

Most importantly, we recommend that ONC ensure that the definition of HIN is consistent with the ONC Proposed Rule when the regulations therein are finalized.

3.1.4. Minimum Information.

We request that ONC clarify and reconcile compliance with subclauses 4, 5, and 7 in the definition of “Minimum Information” with the information blocking regulations in the ONC Proposed Rule. TEFCA 2.0 requires the disclosure of the purpose of sharing EHI. However, the information blocking regulations mandate HINs to share EHI unless an exception applies without requiring the HINs to know of the purpose.⁴ Neither TEFCA 2.0 nor the information blocking regulations identify a mechanism to obtain this information. We ask ONC to (i) specify which information blocking exception this requirement is covered under,

³ 84 Fed. Reg. 7424, 7512 (Mar. 4, 2019).

⁴ 84 Fed. Reg. 7424, 7522 (Mar. 4, 2019) (Subsection VIII(D) Proposed Exceptions to the Information Blocking Provision).

and (ii) reconcile the seemingly contradictory requirements of TEFCA and the information blocking regulations related to disclosure of the purpose of sharing EHI.

3.2. Initial Application, Onboarding, Designation and Operation of QHINs.

3.2.1. QHIN Application (Section 2.1.1).

ONC requires, if applicable, that HINs make available information relating to personnel of their vendors and persons or entities that use its network in order to address reasonable requests of the RCE. While Surescripts can require this of personnel of its own organization, we are concerned that we cannot require the same of other organizations or their personnel. We recommend that ONC clarify that (i) such vendors, persons, or entities need not be made available unless they are referenced in a QHIN application, or (ii) in the alternative, specify that a QHIN's application will not be prejudiced or rejected if it is unable to make any such vendor, person, or entity available to ONC.

3.2.2. Initial Application, Onboarding, and Designation (Sections 2.1.2 & 2.1.3).

Although ONC states that the RCE must either approve or reject each QHIN application within a stated period, it continues to state that, despite the expiration of the stated period for review, a QHIN application will not be deemed approved until the RCE issues a written notice of approval. We are concerned that without a defined "stated period" by which the RCE must either approve or reject a QHIN application, there will be a backlog of QHIN applications. Such a backlog of QHIN applications and cumbersome entry into TEFCA will certainly discourage HIN participation. Therefore, we recommend that ONC (i) define the "stated period" by which RCE must either approve or reject a QHIN application, or (ii) propose that if a RCE does not respond within the stated period, QHIN applications are deemed approved unless the RCE states otherwise.

3.2.3. Provisional QHIN Status (Section 2.1.4).

We ask ONC to clarify the purpose and reason behind implementing "provisional QHIN status". This section does not explain the purpose of "Cohorts" or "Provisional QHINs" and why this is advantageous over real-time approval to "QHIN Designation". Additionally, ONC states that "the RCE may in its reasonable discretion, assign the Provisional QHIN to another Cohort with a later Cohort Deadline". This language opens the door to arbitrary or capricious decisions. Therefore, we urge ONC to ensure accountability of the RCE by requiring the RCE to provide written explanation for any decision to either reject a QHIN application or to deny QHIN Designation assignment.

Aside from Section 2.2.7 of the MRTTC, we request ONC to provide other examples of circumstances in which the RCE will terminate a Provisional QHIN for "material breach" of the Common Agreement.

3.2.4. QHIN Operations (Section 2.2.1(ii)).

If QHINs store or maintain EHI, ONC mandates such QHINs to provide that EHI in the applicable USCDI under certain conditions. However, not all HINs store or maintain such information in an accessible manner, such as a designated record set, so as to easily obtain and send such information in response to a query. Therefore, we recommend that ONC only require QHINs to provide stored or maintained EHI if the QHIN maintains a designated record set.

We also ask ONC to clarify and provide examples of how a QHIN will demonstrate that it meets “all required conditions of Applicable Law” pursuant to Section 2.2.1(ii)(b)(3) of the MRTC.

3.2.5. Individual Exercise of Meaningful Choice (Section 2.2.3).

Surescripts acknowledges the need for individuals to access their health information. However, as mentioned above in sections 2.2.1, 2.4.1, and 2.5 of this letter, not all HINs provide services directly to individuals. Therefore, this mandate should not apply to all QHINs. Requiring such QHINs to perform these tasks will unnecessarily divert limited resources from operations in effectively and efficiently performing network information exchange operations, thereby decreasing TEFCA’s intended performance. Consistent with ONC’s proposal in Subsection 2.2.4, we recommend that ONC limit Meaningful Choice obligations to QHINs that provide direct services to or have Direct Relationships with individuals as part of their business or service offering.

Rather than requiring QHINs that do not have Direct Relationships with individuals to process each individual’s Meaningful Choice, we recommend that ONC allow such QHINs to redirect individuals to speak to their respective providers regarding Meaningful Choice. Because providers will most likely be the primary contact with individuals, it seems more reasonable for providers to notify individuals of Meaningful Choice and allow individuals to contact them should individuals decide to exercise Meaningful Choice. Providers of individuals who choose to exercise Meaningful Choice would then inform QHINs of those individuals’ Meaningful Choices.

ONC also prohibits QHINs from charging Individuals “any amount for their exercise of Meaningful Choice or for communicating it to the other QHINs”. As stated above in section 2.5 of this comment letter, we disagree with ONC’s approach to providing Individuals’ with the ability to exercise their rights concerning their health information. The HIPAA Privacy Rule, at 45 C.F.R. § 164.528(c)(2), requires covered entities to provide individuals with an accounting of their protected health information in any twelve (12) month period without charge; however, the Privacy Rule allows covered entities to charge individuals with reasonable cost-based fees (e.g., labor, supply, preparation costs) for any subsequent requests by the same individual within the twelve (12) month period. To discourage any

attempts to abuse Meaningful Choice rights, we recommend that ONC adopt the “reasonable cost-based fees” language found in the HIPAA Privacy Rule.

3.2.6. Mandatory Updating of Participant-QHIN Agreements (Section 2.2.6).

ONC mandates that QHINs incorporate all the applicable mandatory minimum obligations stated in Section 7 of the MRTC within eighteen (18) months of the publication of the Common Agreement. Incorporating the mandatory minimum obligations will require HINs to update their policies and procedures, system infrastructures, and renegotiate thousands of contracts with their customers. We do not believe that HINs, especially HINs that have been operational for several years, can perform and complete all of these tasks within eighteen (18) months. Therefore, we urge ONC to extend compliance with the updated Common Agreement to three (3) years.

3.2.7. Completion of Onboarding Requirements (Section 2.2.8).

ONC mandates that QHINs ensure that each TEFCA Participant has properly completed the onboarding process prior to allowing the Participant to exchange EHI with the QHIN. However, TEFCA 2.0 is silent on how HINs with customers that do not participate in TEFCA (or with customers have not yet completed onboarding) can become a QHIN and also continue to provide services to Participants that have not yet completed the onboarding process. We ask ONC to clarify if such a scenario is available. For example, during the transition period, would the QHIN have to establish TEFCA and non-TEFCA infrastructures to ensure continued information exchange with Participants who have and have not completed onboarding processes?

3.3. Transparency (Section 4).

3.3.1. Fee Schedule (Section 4.1.2).

As mentioned in our comment letter to TEFCA 1.0, Surescripts is supportive of an open and transparent data sharing agreement, but we are concerned about ONC’s approach to regulating fees for providing query services. Reiterating our statements from that comment letter, QHIN Broadcast Queries and certain QHIN Targeted Queries may require the industry to evaluate new business models so that they can participate in TEFCA. To encourage the private industry to support and participate in TEFCA, it must be based on a sustainable business model.

Moreover, we are concerned that HINs will not be able to have inter-related pricing models for their products and services without exposing their entire pricing structure. Also, we note that within any industry, certain fees may differ because of specific negotiations with different customers. Therefore, we ask ONC to clarify (i) whether QHINs will be required to submit a schedule of fees per industry or per customer type, and (ii) how differing fees,

negotiated per customer, will be evaluated by the RCE. Additionally, we ask ONC to clarify whether QHINs will be required to file updated disclosures for each automatic fee increase.

3.4. Cooperation and Non-Discrimination (Section 5).

3.4.1. Fees (Section 5.2).

ONC states that a QHIN must use “reasonable and non-discriminatory criteria and methods” for charging fees to another QHIN. The language is ambiguous in that such non-discriminatory criteria and methods are unspecified, leaving room for the RCE to arbitrarily determine whether fee schedules are reasonable and non-discriminatory. Therefore, we recommend that ONC adopt qualifying language, such as imposing “reasonable industry standards” to have a more definitive basis by which discriminatory or unreasonable fees are determined.

On a separate note, TEFCA 2.0 is silent on whether QHINs may charge different fees to different types of entities for its services. As different types of healthcare entities require different types and amounts of information, we recommend that ONC clarify that it is acceptable for fees to differ based on the type of participant in the exchange network.

3.5. Privacy, Security, and Patient Safety (Section 6).

3.5.1. Breach Notification Requirements and Security Incidents (Section 6.1.1).

TEFCA 2.0 mandates that each QHIN shall comply with HIPAA, regardless of whether QHINs are HIPAA regulated entities. TEFCA 2.0 also mentions that the RCE would be responsible for monitoring overall compliance and enforcement of TEFCA. However, TEFCA 2.0 appears to be silent regarding HIPAA compliance enforcement and adjudication of non-compliant entities not covered under HIPAA. Therefore, we ask ONC to clarify whether enforcement actions for non-compliance by non-HIPAA regulated entities will go beyond mere removal from TEFCA participation to investigation and/or the issuance of penalties by agencies such as the Office of Civil Rights (“OCR”).

3.5.2. Written Privacy Summary (Section 6.1.5).

Because some HINs do not provide services directly to individual patients, we ask ONC to clarify that only QHINs that have Direct Relationships with Individuals will be required to provide such Individuals with a written privacy summary.

3.5.3. Minimum EHI Security Requirements (Section 6.2).

ONC states that each QHIN shall be required to comply with HIPAA as if EHI is the same as protected health information (“PHI”) under HIPAA. This statement seems to inadvertently imply that a QHIN may be treated as a covered entity. We recommend that ONC clarify that:

(i) a QHIN would not be considered or treated as a covered entity under the TEFCA framework, and (ii) if a QHIN is a business associate under HIPAA, only the provisions applicable to business associates would apply to the QHIN. We also recommend that ONC require QHINs to demonstrate through acceptable industry means (e.g., HITRUST certification, EHNAC accreditation, etc.) that all QHINs participating in TEFCA are complying with respectable security standards.

3.5.4. Identity Proofing (Section 6.2.4).

Surescripts supports ONC's push to secure access to the exchange network by requiring identity proofing. However, we recommend that ONC revise Subsection 6.2.4(i) to read as follows:

"Prior to the issuance of access credentials, each QHIN shall identity proof any staff or users at the QHIN who may initiate a QHIN Query or QHIN Message Delivery *for the purposes of sending or receiving EHI* at a minimum of IAL2." (Proposed language italicized and underlined.)

We specifically make this recommendation because not all QHIN Queries and QHIN Message Deliveries may be for the exchange of EHI. For instance, queries without EHI may be generated for testing purposes during the staging or testing phase of establishing connectivity. Moreover, queries without EHI may be generated for the proper administration and maintenance of the network. Employees who initiate queries without the purpose of sending or receiving EHI should not be required to undergo IAL2 identity proofing.

In addition, we request that ONC clarify how the "minimum necessary" requirement in this section would work in conjunction with ONC's identity proofing requirements. We ask that ONC provide examples on how "minimum necessary" would be applied to each identity proofing category listed in subsection (i), (ii), and (iii) in this subsection (QHINs, Participants/Participant Members, and Individual Users, respectively).

3.6. Participant Minimum Obligations (Section 7).

3.6.1. Processing of Individual Access Services Request (Section 7.14).

In the context of Individual Access Services, ONC seems to create a lower regulatory and cost requirement for Participants with a non-care Direct Relationship with Individuals, such as Apple or Android mobile application developers ("Direct Access Proxies"). For example, in Section 7.14 of TEFCA 2.0, ONC appears to imply that, unlike other entities in the TEFCA framework, Direct Access Proxies are not required to obtain HIPAA authorization from Individuals and are not required to enter into Business Associate Agreements. Rather, ONC seems to imply that IAL2 identity proofing is sufficient for Direct Access Proxies' credential access. In conjunction with language found in the ONC Proposed Rule that appears to

prohibit entities from charging Direct Access Proxies,⁵ we are concerned that such Direct Access Proxies will neither bear the cost of accessing and maintaining the information exchange nor share the responsibility of meeting privacy, security, or patient safety obligations. We recommend that ONC clarify that Direct Access Proxies, such as Apple or Android mobile applications, cannot participate in TEFCA without also bearing the costs of access, use, and disclosure, and recommend that ONC reconcile TEFCA with the ONC Proposed Rule in this regard. We further recommend that ONC stipulate the privacy, security, and patient safety obligations for Direct Access Proxies looking to become a part of TEFCA and/or connect to a QHIN. Lastly, we recommend that ONC specify and provide examples of how QHINs are to interact with Direct Access Proxies (and Individuals connecting to QHINs through Direct Access Proxies) in a manner that preserves the privacy, security, and patient safety of such Individuals.

Similar to the aforementioned, the Individual Access Services provisions in TEFCA 2.0 do not address the accountability of Direct Access Proxies. We request that ONC address how it intends to keep Direct Access Proxies who may be potential bad actors accountable. Moreover, if QHINs are responsible for the identity proofing of Direct Access Proxies that access their exchange network, we request that ONC propose the infrastructure by which this is to occur, including specifying that Direct Access Proxies may bear the costs for building and maintaining this infrastructure.

4. Qualified Health Information Network (QHIN) Technical Framework (“QTF”).

4.1. General Comments.

We appreciate the opportunity to respond to the QHIN Technical Framework (“QTF”). As delineated further below, we encourage ONC to consider the specified standards and profiles in TEFCA in light of the requirements proposed in the ONC Proposed Rule. In addition, we urge ONC to note that the healthcare industry is actively working to transition to FHIR Representational State Transfer (“RESTful”) APIs for the exchange of health information. As such, we recommend that ONC structure the QTF in a manner where QHINs are not limited by the specifications in the QTF if there is general industry consensus to transition to a newer standard or profile. Specifically, in line with Principle 1 of TEFCA, we recommend that the QTF remain silent on the specified standards and profiles, and instead, incorporate by reference standards that have been identified by ONC through the Interoperability Standards Advisory. While we recognize that, as standards change, ONC and/or the RCE intend to issue an updated QTF, we are concerned that any gap in timing or any additional bureaucratic steps in specifying standards will put QHINs in violation of applicable regulations or cause QHINs to be behind on or misaligned with progress toward interoperability within the healthcare industry.

⁵ 84 Fed. Reg. 7424, 7540 (Mar. 4, 2019) (“Similarly, where an individual authorizes a consumer-facing app to retrieve EHI on the individual’s behalf, it would be impermissible for an actor to charge the app or its developer a fee to access or use APIs that enable access to the individual’s EHI. This would be true whether the actor is a supplier of the API technology or an individual or entity that has deployed the API technology, such as a health care provider.”)

4.1.1. Alignment with ONC Proposed Rule.

Among other things, the ONC Proposed Rule sets forth requirements related to APIs for Certified Health IT Technology and proposes to adopt the HL7 FHIR as a foundational standard, noting “the industry is well prepared and ready to adopt the FHIR standard.”⁶ Specifically, ONC proposes a new API certification criterion that would require FHIR API-enabled services. Moreover, ONC proposes that health IT presented for testing and certification be capable of user authentication in accordance with OpenID Connect.

On the other hand, within the QTF, ONC states that organizations involved in network-based health information exchange today generally use IHE profiles such as Cross-Community Patient Discovery (“XCPD”) and Cross-Community Access (“XCA”) to enable clinical document exchange between disparate communities. While we do not disagree with ONC and understand its intent to allow organizations seeking to become QHINs to use existing, deployed technical infrastructure, we urge ONC to note the disconnect between the QTF and the proposed infrastructure for EHRs. Further, please note that although organizations such as Commonwell Health Alliance, eHealth Exchange and Carequality may currently use IHE profiles, they are also already using or actively building infrastructure to support FHIR-based exchange of health information. For example, Carequality explicitly announced their intent to create a FHIR ecosystem in support of the aim of TEFCA to broaden the exchange of clinical data⁷. EHealth Exchange is also using FHIR to introduce new use cases, including population-level exchange, push notifications, and discrete data-level queries.⁸

4.1.2. QHIN Broadcast Queries.

In our experience developing and offering the Record Locator & Exchange service, we have found that less than 0.5% of queries send in a broadcast format yield a successful result of patient record transmission. For more precision, we use a record location tool to identify where a patient may have received care and only query those locations. Within the QTF, ONC does note that QHIN-to-QHIN exchange functions depend on accurate and comprehensive record location. However, the Example QHIN Exchange Scenarios within the QTF offer QHIN Broadcast Queries as a viable solution, obfuscating the important role of a comprehensive record locator.

We are specifically concerned about QHIN Broadcast Queries because they pose infrastructural challenges for HINs and may result in decreased participation in TEFCA. Allowing for QHIN Broadcast Queries will require HINs to expand or drastically overhaul

⁶ 84 Fed. Reg. 7424, 7478 (Mar. 4, 2019).

⁷ Carequality, Carequality FHIR Connectathon Update (June 3, 2019), <https://carequality.org/carequality-fhir-connectathon-update/>.

⁸ eHealth Exchange, Network Celebrates 10 Years of Health Information Exchange This Month; Announces New Technology Partnerships (Feb. 28, 2019), <https://ehealthexchange.org/2019/02/28/ehealth-exchange-modernizes-the-nations-longest-standing-public-private-health-information-network/>.

and rebuild their infrastructure and network capabilities to handle the vast number of queries they are to receive. Moreover, even with all of this work, a significant majority of these queries will result in “no patient found” or “no information available” responses. Without a reliable record locator, the infrastructure for most HINs to respond to such queries will be inefficient. Accordingly, we recommend that ONC require the use of a reliable record locator tool prior to sending QHIN Broadcast Queries at a large scale. In the alternative or in addition, we recommend that ONC consider imposing fees for QHIN Broadcast Queries to encourage responsible use of the interoperability infrastructure.

Moreover, we are of the opinion that without the distinction that QHIN Targeted Queries become targeted when a record locating event has occurred, there is no meaningful differentiation between QHIN Broadcast Queries and QHIN Targeted Queries, resulting in the same infrastructural challenges identified above. As such, we recommend that ONC modify the definition of QHIN Targeted Queries to include “after the location of a record” to read as follows:

“[A] QHIN’s electronic request, after the location of a record, for an Individual’s EHI (sometimes referred to as a “pull”) from specific QHINs in the context of the Common Agreement to the extent permitted by the Common Agreement and Applicable Law.” (Proposed language italicized and underlined.)

4.1.3. Public Comment Process for Changes to QTF.

We recommend that the industry have the opportunity to provide comments and responses prior to the issuance of new versions of the QTF by the RCE. Within the “Overview” of Appendix 3 to TEFCA 2.0, ONC states that it “expects the QTF to be updated, expanded, and specified completely for implementation based on public comment and through iterative revisions with the RCE and industry as the Common Agreement is developed and finalized.” However, within this section, ONC also states that “[f]uture versions of the QTF will include more detailed requirements for QHINs, as determined by the RCE.” While we understand that the RCE is ultimately tasked with developing, updating, implementing, and maintaining the Common Agreement and the QTF, the industry should be given the opportunity to provide comment and responses to proposed changes to the QTF. We believe that including all industry stakeholders in changes to the QTF will assist the RCE in understanding the then-current state of the industry and encourage sharing insights on innovative health information technology infrastructures.

4.2. Functions and Technology to Support Exchange.

4.2.1. User Authentication.

In introducing the QTF, ONC specifies that it is seeking to leverage existing, deployed technical infrastructure. However, HINs have not generally utilized the IHE XUA profile for user authentication. Additionally, the IHE XUA authorization framework is considered out-

of-date and complex relative to other user authentication methods. Instead, we recommend that ONC require the use of OpenID Connect, an OAuth 2.0 profile. OpenID Connect allows user authentication performed by an authorization server, such as a Participant Member, to be used to verify the identity of a user by a different entity, such as a QHIN. Moreover, OpenID Connect allows for organizations to obtain basic profile information about the user, allowing for “upstream” sharing of authentication information.

In addition, please note that the IHE XUA standard is not adequate for the Individual Access Services set forth in TEFCA. Rather, a modern authentication and access control framework pioneered in the web consumer space, such as OpenID Connect, is better suited. Moreover, OpenID Connect is supported in standard Java and .NET libraries and is well understood and used by application engineers.

4.2.2. Authorization & Exchange Purpose.

For the Authorization & Exchange Purpose query, we also recommend that ONC adopt OpenID Connect paired with OAuth 2.0 implementations, instead of the IHE XUA standard.

4.2.3. Query.

4.2.3.1. ONC Request for Comment #5.

ONC asks whether the QTF should specify which queries or parameters a QHIN must support. We recommend that ONC specify the following queries and parameters:

- Minimum query: “FindDocuments”
- Minimum parameters at the responding gateway: “XSDocumentEntryPatientId” and “XSDocumentEntryStatus”

ONC further asks which queries and parameters are most widely implemented and/or useful today. The most widely implemented and/or useful queries and parameters today are the following:

- Queries: “FindDocuments”.
- Parameters:
 - “XSDocumentEntryPatientId”: Required to know which patient document the system is requesting;
 - “XSDocumentEntryStatus”: Required per specification;
 - “XSDocumentEntryCreationTimeTo”: Required to narrow the scope of documents available to a relevant range for the requester; and
 - “XSDocumentEntryCreationTimeFrom”: Required to narrow the scope of documents available to a relevant range for the requester.

We note that an issue today is that certain queries may cause a responder to respond in the negative (*i.e.*, “no information”) even if the responder actually has relevant information. For example, if a requester sends a “FindFolders” query, a responder may respond that it does not have ‘folders’ for the patient of interest; however, if the requester had sent a “FindDocuments” query, the responder would have responded with clinical documents for the patient of interest. As such, standardization of this query is vital, and “FindDocuments” is the query we recommend and the query most widely adopted.

4.2.3.2. ONC Request for Comment #6.

ONC notes that the XCA profile does not necessarily support granular queries for discrete data and seeks comment on appropriate standards for implementation of such queries. In response, we recommend the use of FHIR RESTful APIs to support more granular and specific method of retrieving targeted information. FHIR allows for the content of a document to be extracted based on granular queries, while REST allows for “statelessness” where the client and server are independent of each other and all information to handle a request is housed within the request itself. This is particularly useful for query-based transactions.

4.2.3.3. Message Delivery.

We recommend that ONC replace IHE Cross-Community Document Reliable Interchange (“XCDR”) with Direct as the specified standard for Message Delivery. As ONC notes, networks currently support the Direct Protocol to securely send health information to a known Direct address. We encourage ONC to also consider the Direct Protocol when the recipient’s Direct address is unknown. We further note that the Direct Protocol has been thoroughly tested and is used pervasively in the industry for message delivery.

Additionally, requiring IHE XCDR instead of the Direct Protocol for any form of message delivery creates inconsistencies with ONC’s Health IT Certification Program, which specifically references the Direct Project as a transport method in the sending and receipt of health information.⁹ This consistency is particularly important for Health Information Service Providers (“HISPs”) certified as a Health IT Module under the ONC Health IT Certification Program as it runs the risk of putting such HISPs in violation of their certification requirements. We urge ONC to reconcile these regulations so that the industry can develop and implement standards around a single “push” mechanism.

⁹ 42 C.F.R. § 170.315(h).

4.2.4. Patient Identity Resolution.

4.2.4.1. ONC Request for Comment #7.

In response to ONC's Request for Comment #7, we recommend requiring QHINs to establish a minimum viable matching dataset that includes the following criteria:

- First name;
- Last name;
- Middle name;
- Suffix;
- Date of birth;
- Address; and
- Sex.

In addition, it would be beneficial to also include the following as optional patient demographic elements:

- Previous name(s) (e.g., maiden name);
- Previous address(s);
- Medical record number(s); and
- Other similar points of identification.

4.2.4.2. ONC Request for Comment #8.

We do not believe the QTF should specify a single standardized approach to Patient Identity Resolution because several approaches are currently being used by the industry, each with its own advantages and disadvantages. We recommend that ONC wait on specifying a single standardized approach until there is clear and strong evidence that one approach is significantly better than the others.

However, if ONC were to choose a single standardized approach, we recommend using referential matching by leveraging data from different sources to build a more complete profile of each patient over time. For Surescripts, referential matching began with a minimum viable dataset without which accurate patient matching is not possible. Beyond that minimum viable dataset, Surescripts added more information from its data suppliers to allow for referential matching. Such addition and utilization of referential matching in general requires: (i) proper tuning of the underlying algorithm; (ii) trustworthy sources of data of sufficient quality; and (iii) agreement by and capability of such sources of data to provide it in a secure structured format at acceptable business terms.

4.2.4.3. ONC Request for Comment #9.

Regarding the evaluation of patient matching algorithms, we recommend that ONC include the following metrics within any evaluation procedure or protocol it implements:

- Match rate;
- False positive rate;
- Duplicate record rate;
- Allocation of match types;
- Percentage of demographic information used by the algorithm; and
- Percentage of near matches.

In particular, we recommend that ONC include the percentage of near matches to help recognize opportunities for improving match rates and match accuracy. Additionally, measuring industry performance should take into account many different patient matching use cases and patient matching models. For example, duplicate rate is an effective indicator of matching during the hospital patient intake process, but does not work for organizations who are matching to enable real-time record location services.

Above all, it is important to remember that automated data comparison (e.g., patient matching) has inherent risks of false positives and false negatives. Any metrics would require defining the correct balance between false positive and false negative matches, which can vary by the patient matching model and the use case. For example, the consequences for incorrectly patient matching for patient's benefits information is relatively inconsequential compared to consequences for incorrectly patient matching a patient's medication history or hospital records.

Lastly, we recommend ONC adopt a grading/certification methodology where a governing body could provide an "answer key" of a set of patients they know are false positives and false negatives. This could serve as a potential unbiased testing method for grading algorithms.

4.3. Record Location.

4.3.1. ONC Request for Comment #10.

We do not recommend that ONC specify a single standardized approach across QHINs for record location services. Rather, we recommend that QHINs be allowed to have the flexibility to establish a mechanism for record location best suited for their organization.

4.4. Directory Services.

4.4.1. ONC Request for Comment #11.

We believe that directory services are vital for QHINs to facilitate the exchange of EHI and allow for the discovery of electronic endpoints and query recipients. If ONC seeks to specify a single standardized approach, we recommend that ONC the Validated Healthcare Directory (“VHDir”) based on HL7 FHIR be considered. However, beyond this, we do not recommend that ONC set forth any other specifications in the first iteration of the QTF to ensure wider participation in TEFCA by QHINs.

4.5. Auditing.

We ask ONC for clarification on how a QHIN should demonstrate that it has IHE Audit Trail and Node Authentication (“ATNA”) Integration Profile capabilities.

4.6. Error Handling.

4.6.1. ONC Request for Comment #15.

Surescripts supports clear and consistent set of error messages for interactions between QHINs.