NEW YORK eHEALTH COLLABORATIVE

Valerie Grey
Executive Director

June 17, 2019

Donald W. Rucker, MD
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St, SW, Floor 7
Washington, DC 20201

RE: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2

Dear Dr. Rucker:

The New York eHealth Collaborative (NYeC) is pleased to provide these comments in response to the recently released TEFCA Draft 2. NYeC is a 501(c)(3) and New York's State Designated Entity (SDE) charged with the governance, coordination, and administration of the Statewide Health Information Network for New York (SHIN-NY). In this capacity, NYeC works as a public/private partnership with the New York State Department of Health (DOH) on the development of policies and procedures that govern how electronic health information is shared via the SHIN-NY.

The SHIN-NY is a "network of networks" consisting of Qualified Entities (QEs) also known as Regional Health Information Organizations (RHIOs) and a statewide connector that facilitates secure sharing of clinical data from participating providers' electronic health records (EHRs). Participants include hospitals, clinics, labs, radiology centers, ambulatory physicians, home care agencies, nursing homes, long-term care facilities, public health departments, health plans, behavioral health providers, DOH, and Federally-Qualified Health Centers (FQHCs). SHIN-NY connects all hospitals in the state, is used by over 100,000 health care professionals, and serves millions of people who live in or receive care in New York.

NYeC's mission is to improve health care through the exchange of health information whenever and wherever needed. As such, NYeC remains very supportive of the provisions of the 21st Century Cures Act (Cures) which called upon the Office of the National Coordinator for Health Information Technology (ONC) to set forth a common set of principles for trusted exchange across networks. We continue to view the TEFCA as a tremendous opportunity to advance interoperability and health information exchange. We appreciate that ONC has been responsive to many stakeholder concerns in this second draft of TEFCA; however, some concerns remain and with the recent release of the ONC and the Centers for Medicaid & Medicare Services (CMS) proposals also implementing provisions of Cures relating to information blocking and patient access, new concerns have also come to light. Attached you will find our full comments, but below is a big picture summary of our perspective.

- NYeC views the TEFCA as an incredible opportunity to improve patient outcomes and reduce costs through the increased exchange of health information, while also spurring much needed state and national policy changes. The goal of a national system of health information exchange (HIE) is a laudable one. We agree with the concept of a single "on ramp" for HIE. Such a system would make it easier for providers, health plans, and other participants in our health care information system to access necessary data, and therefore provide better patient care throughout the country.

- While we greatly appreciate revisions in this second release of the proposal, we believe ONC should continue to explore opportunities to explicitly leverage current infrastructures to ensure TEFCA builds upon the existing infrastructure. For more than two decades, the federal government, states, non-profit organizations, providers, and health information technology organizations have helped transform a health information system that was largely reliant on paper-based exchange into one where EHRs and the electronic exchange of patient data is now commonplace. Health information networks (HINs), such as the SHIN-NY, have worked diligently to address the marketplace failures that resulted from a lack of interoperability. Clearly, more work must continue by all stakeholders to reach full interoperability and TEFCA can help positively drive this. In order to leverage the current infrastructure, we believe there are further ways ONC could streamline the transition for existing HIEs and HINs in the current requirements and also clarify the value proposition in participation.

- Success of a national network will depend on the sustainability structure, including fees, and the attainment of participation by a critical mass. Since this network would be voluntary, a clear delineation of the benefits of participation is needed to demonstrate value beyond what is provided today, especially for states with existing mature and robust HINs. In this vein, we believe it is essential that ONC provide a TEFCA participation exception and safe harbor under the recently proposed information blocking provisions. Without an appropriately specified information blocking exception, the value proposition in TEFCA participation is less apparent. Whereas, an appropriate exception and safe harbor could draw participation and help ease the burden of complying with information blocking and its complicated myriad of exceptions. To this end, we are concerned that the timeline for TEFCA and the recent ONC and CMS proposals are not aligned. With all the current moving pieces, it is difficult for the industry to see and prepare for final implementation. As such, we would encourage ONC to align these large-scale initiatives in both policy goals and timeline. Specifically, we suggest ONC phase-in certain requirements by finalizing information blocking regulations with the inclusion of a HIE/HIN exception or safe harbor which could transition to a TEFCA exception when TEFCA is fully implemented.

- Public-private partnerships should be supported as they have the potential to empower innovation while also advancing the important public mission of ensuring all providers have affordable access to information needed to improve the care of their patients and our communities. It will be important to strike the right balance between an industry-driven model and a public-utility model. Given the control the Recognized Coordinating Entity (RCE) will have over developing and updating the Common Agreement, including the

Qualified Health Information Network (QHIN) Technical Framework and any additional required terms and conditions (ARTCs), as well as the process to monitor QHINs for compliance, selection of an appropriate, experienced, unbiased RCE will be essential to the success of TEFCA. Transparency, fair process, and collaboration with stakeholders will be critical to ensure the confidence and participation of stakeholders.

- In order to achieve true nationwide interoperability, varying consent policies must be meaningfully addressed. Policy and governance, specifically regarding sensitive health information, will be crucial to the foundation of a trusted network. While ONC acknowledges this, the proposed requirements around meaningful choice fail to sufficiently address this variation and could in practice place an additional layer on top of existing state and federal requirements. While we appreciate the opt-out nature of meaningful consent, alignment or at a minimum clarification of how this will work with existing state and federal requirements will be essential to avoid confusion and minimize burden.

- Timelines and requirements should be ambitious but achievable. There are components of TEFCA, such as developing and executing new data sharing agreements, as well as future technical updates that require diligence and time to get right. While we appreciate ONC providing an additional six months for such updates, we continue to believe more time is necessary. By using a phased-in approach for certain requirements like all contractual changes, ONC could begin implementation, while also providing additional time for all agreements to be amended.

Thank you for the opportunity to provide comments. If you would like to discuss these issues further, please contact my assistant, Hope Redden at hredden@nyehealth.org or (518) 299-2321.

Sincerely,

Valerie Grey
Executive Director

NEW YORK eHEALTH COLLABORATIVE (NYeC)
DETAILED COMMENTS ON TEFCA

General Comments on Key Elements of the TEFCA

- **Goals of the TEFCA:** NYeC supports the three high level goals of: 1) providing a single on-ramp to nationwide connectivity; 2) enabling exchange of EHI to securely follow the patient when and where it is needed; and 3) to support nationwide scalability. These goals mirror much of what the SHIN-NY has accomplished and continues to work toward in New York State. From this firsthand experience, we appreciate the revised timeframe provided in this version of TEFCA, but we continue to caution ONC to be realistic in its timeline and expectations. Further, we continue to urge ONC to develop a framework that builds off the existing work of the industry and the supporting public investments that advanced HINs and HIEs across the country, something we think this draft largely embodies but could be further refined. To achieve the lofty and laudable goals of TEFCA, ONC should work with other offices within The Department for Health and Human Services (HHS) and stakeholders to clearly set forth the value in TEFCA participation.

- **QHIN Structure:** One of the most important issues for the TEFCA ecosystem is determining which organizations can serve as QHINs, the entities that will enter into the common agreement, implement the technical requirements, and be charged with ensuring participants abide by the rules of the TEFCA. While we generally agree with the requirements in the definition of a QHIN (discussed in more detail below), we encourage ONC in working with the RCE to maintain flexibility in the size and scope of QHINs approved through the application process. Some states have established SDEs like NYeC that already connect multiple HIEs using federated models. Given this structure largely mirrors that of TEFCA, SDEs and the associated network of HIEs, like the SHIN-NY, are ideal QHIN candidates.

- **Participants and stakeholders:** NYeC appreciates ONC's delineation of participants, participant members and individuals in this draft v2 as we felt the inclusion of individuals and their representatives as participants caused a great deal of confusion in the initial draft. We also appreciate ONC's flexibility in using different modalities for different use cases as may best support participants. While the requirement that participants and participant members that provide only Individual Access Services (IAS) are only required to respond to requests for IAS raises some concerns. We appreciate ONC's perceived objective to help bring more of these types of entities often not typically compliant with the Health Insurance Portability and Accountability Act (HIPAA) within some of the protections of HIPAA. It is our understanding that IAS only participants would not be eligible to be QHINs, something we urge ONC to maintain as the notion of QHIN reciprocity is essential to the success of TEFCA.

- **RCE:** ONC plans to select an RCE that will act as a governing body that will operationalize the TEFCA. We agree with this approach and we support such a model. We note that this is similar to the approach that New York State has adopted with the SHIN-NY. As the SDE in New York, NYeC oversees and collaborates with the QEs that operate in the state and has entered into contractual agreements with each to ensure that they abide by applicable laws and requirements. From our perspective, we believe that it is more efficient for a private entity to oversee the day-to-day operations of a HIN, rather than a government body. In terms of criteria for selecting an RCE, we recommend that ONC consider non-profit entities that have partnered with government agencies under public-private partnerships. The experience of having balanced the needs of public and private entities will be critical in overseeing an effort as vast as the TEFCA. The RCE will play a critical role in drafting the Common Agreement, entering and enforcing its terms and obligations on the QHINs. As such, ONC should ensure that the RCE operates in a fully transparent manner. The RCE should possess policy, governance and technical expertise and should be a neutral arbiter that consults with multiple categories of stakeholders, including patient advocates, providers, non-profits, and government agencies. From our years of experience charged with governance of the SHIN-NY, which involves the constant engagement of all stakeholders, we appreciate the RCE is required to convene public listening tours at least semiannually but feel more persistent transparency in process will be necessary to gain industry trust and support.

- **Exchange Purposes:** We continue to support TEFCA alignment with HIPAA. In this draft, ONC restricts permitted purposes to a subset of HIPAA purposes, namely, treatment, individual access, public health, benefits determination, utilization review, business planning and development, and quality assessment and improvement. Understanding that ONC made this change in an effort to be responsive to some stakeholder concerns regarding sharing for all health care operations and payment purposes, we are encouraged that ONC indicates that this is a starting point, and we remain supportive of alignment with HIPAA. We agreed with ONC's original approach, which acknowledged some HIEs currently focused on permitting information to be exchanged solely for treatment purposes may be reluctant to expand the use of data beyond such limited purpose, but acknowledged the benefit in pushing for increased exchanges. If the TEFCA is to be a "single on-ramp," then the classes of permitted purposes must be broad; otherwise organizations would still be forced to obtain data from many different sources. Furthermore, under the recently proposed information blocking regulations, absent an applicable exception, these limited purposes could be information blocking and QHINs and participants would have to find other means of making this information available. Similarly, with the recent proposal for certain payers to join trusted exchange networks, including the full HIPAA permitted purposes could ensure these payers are able to benefit from HIE to the greatest extent possible, and help draw additional, non-public payers.

- **Modalities:** ONC requires QHINs to support three modalities: Broadcast Queries under which a request is sent out to all QHINs asking for data for a particular patient; Targeted Queries under which a targeted request for a patient's information is made to a specific organization; and Message Delivery under which a QHIN delivers EHI to one or more

QHINs for delivery to one or more participants or individuals. NYeC supports this query-based approach for the TEFCA, and we note that the SHIN-NY Enterprise is a query-based exchange system. We appreciate ONC's change to more aptly refer to targeted queries, rather than directed queries. We continue to encourage ONC to factor in the possibility that 'broadcast queries' may require extra processing where the patient is not found in a given system and should consider a phase in approach to the operationalization of the use cases. We appreciate the inclusion of push messaging and encourage ONC to clarify that this modality should support patient event notifications, or alerts. In light of the recently proposed CMS requirement that all hospitals transmit admission, transfer and discharge notifications, the ability of TEFCA to share these alerts across disparate networks would further CMS' intent and could be leveraged by providers to streamline any future requirement in this regard. As ONC notes, QHINs should provide as much flexibility to their Participants and Participant Members as possible to support broad interoperability for multiple use cases, ONC should clarify that alerts of this nature could be one such use case. Lastly, we support ONC's removal of population level data exchange as premature and agree with ONC that FHIR based APIs hold great potential to achieve this functionality in the future.

The Trusted Exchange Framework (TEF)

The TEF outlines six principles that serve to engender trust between QHINs. We are supportive of these principals, many of which reflect practices that are already widely in use in New York. While we believe these principles set forth appropriate "rules of the road," as currently presented all principles are permissive in nature. As ONC proceeds it will be important to ensure these principals are embodied by all participants through Framework Agreements in a more affirmative way. While supportive of the proposed principles in general, we raise some comments or concerns with several principals.

- **Principal 2 - Transparency:** While we wholeheartedly agree with this concept and the principals that HINs should ascribe to and make public their privacy practices, we seek clarification from ONC regarding its intention of making HIN contractual agreements available. More specifically, ONC discusses the variation in allowable uses and disclosures across HINs as set forth in their data use agreements as a basis for why HINs should make legal agreements open and transparent in order to clearly communicate the minimum set of uses and disclosures they support. While it is certainly true in today's information exchange ecosystem that different HIEs and HINs provide different uses and disclosures, this portion of the principal raises questions as it seems contrary to other TEFCA requirements. Specifically, it is our understanding as currently set forth, all QHINs, participants and participant members (with the exception of IAS only participants or participant members) have a duty to respond to all requests for EHI they receive for any of the exchange purposes and this concept would be embedded as a requirement in all Framework Agreements. Based on this we seek clarification from ONC with regard to the intention of this portion of the principal.

- **Principal 4 – Privacy, Security and Safety:** We couldn't agree more that privacy and security should be a foundation for all health care stakeholders, and that the integrity of EHI is paramount to safe care. As discussed in greater detail on page 14 we urge ONC to further develop uniform guidance on patient matching. We agree HINs should consistently share a core set of demographic data every time EHI is requested, and that participants should ensure a core set of data elements are consistently captured. However, these suggestions, much of which are reliant on the acts of other participants, without more affirmative policy guidance will not solve the current variation and inadequacies with patient matching to support nationwide scalability. Furthermore, while we support the use of standard nomenclatures such has C-CDA or FHIR APIs, we appreciate the flexibility that such standards should be used where possible. We feel that flexibility is important to ensure other formats can still be exchanged with significant parts of the care continuum such as skilled nursing facilities, home health and hospice care who, based on analyses we have completed in New York, may not be able to contribute data as the traditional non-Meaningful Use providers are unable to produce a C-CDA because they do not utilize ONC-certified EHR products.

  Also, under Principle 4, ONC raises the notion of patient consent under HIPAA along with the restrictions that apply to information subject 42 C.F.R. Part 2, mental health information, HIV/AIDS information, and other sensitive health information that may have heightened consent requirements under state law. Disclosure and re-disclosure under Part 2 is also raised in the context of this principle. ONC says QHINs must have consent management capabilities that ensure consent is appropriately captured prior to the exchange of the health information. However, we are concerned that ONC has not adequately considered this issue, which has the potential to substantially interfere with information exchange if not properly addressed. We note that in addition to rules governing sensitive health information, there are state differences in general related to how consent is handled for electronic health information exchange. For example, some states have an opt-out system of consent management that basically follows HIPAA permitted uses. Other states, like New York, are opt-in and typically require affirmative written consent for access to a patient's record. This presents a significant challenge for national exchange, which we feel remains unaddressed. Presently, an out-of-state HIE seeking to obtain a patient's information from a New York State HIE would need to have that patient's consent in hand in order to access that information in the SHIN-NY, even if the out-of-state HIE properly followed its own states opt-out rules for consent. The current TEFCA does not specify any process that would allow for these differences. NYeC recommends that ONC work to streamline these requirements or at a minimum provide guidance on the interplay between these various requirements.

- **Principle 5 – Access:** We fully support the concept that the individual should be the driving force when it comes to access and sharing their health information. While we appreciate the security standards set forth, and the minimum terms ONC requires for future uses of EHI, we anticipate that one of the bigger challenges will center around establishing the appropriate identity proofing standards to ensure the necessary data protections as well as

ensuring consumers are aware of privacy policies of those non-HIPAA covered entities and are adequately informed of potential future uses of their data.

- **Principle 6 – Population-level data:** NYeC supports this concept and appreciate that this version makes clear that this is a future capability given the standards to support such exchange are not yet mature enough for widespread implementation.

Minimum Required Terms and Conditions

Appendix 2 outlines the Minimum Required Terms and Conditions (MRTCs) designed to ensure common practices of all participants. Additionally, the draft explicitly states that the RCE will have responsibility for expanding upon the MRTCs through establishment of the additional terms and conditions (ARTCs) which as we understand, may continue to grow and phase in over time. We continue to urge transparency throughout this process. We appreciate that ONC has outlined certain obligations of the RCE to convene public listening sessions, and to submit the Common Agreement including the ARTCs for a round of public comment. To maintain such trust, the RCE should carry this transparency forward for future updates and establishment of the compliance process. With regard to the currently proposed MRTCs, NYeC provides the following comments.

- **Definitions**

  - Direct Relationship: NYeC encourages ONC to further clarify the definition of a direct relationship. Given that the requirement of QHINs, participants and participant members to process IAS requests hinges on whether the QHIN, participant member or participant has a direct relationship with the requesting individual, it is important ONC be explicitly clear as to what constitutes a direct relationship. Our general understanding is that a direct relationship is intended to mean when a QHIN, participant member or participant voluntarily offers direct patient access services such as a patient portal or third-party application, and the patient consents to such services. However, the definition that direct relationship arises when a QHIN, participant member or participant "offers services to the Individual in connection with one or more of the Framework Agreements and the individual agrees to receive such," could also be interpreted to include any QHIN or HIN which has offered "meaningful choice" and responds to queries, including those for IAS, as required by TEFCA. We urge ONC to clarify this definition to avoid any ambiguity.

  - Exchange Purposes: As previously discussed, NYeC supports the inclusion of the current exchange purposes of Treatment, Utilization Review, Quality Assessment and Improvement, Business Planning and Development, Public Health, Individual Access Services, and Benefits determination. However, we believe these purposes should be expanded to include all HIPAA permitted purposes. NYeC believes HIPAA alignment is essential to achieving interoperability and ending bifurcated networks. Inclusion of all HIPAA permitted purposes would also align with ONC's information blocking provisions.

  - Health Information Networks (HINs): ONC maintains a broad definition of HIN in this draft. It is our understanding that such definition is intended to capture networks like the SHIN-NY, as well as many traditional HIEs like the QEs, and vendor networks. We are

concerned that as currently written, ONC may be unintentionally capturing entities not commonly perceived as HINs. For example, the DOH has ultimate say over the policies and procedures that govern QEs in New York State, and therefore the DOH arguably meets this definition since it "oversees policies" that define "requirements for enabling or facilitating access, exchange, or use of Electronic Health Information between or among two or more unaffiliated individuals or entities." We assume that ONC was not intending to categorize states as HINs. NYeC appreciates that in order to be eligible to apply as a QHIN, a HIN must already operate a network that provides the ability to locate and transmit EHI between multiple persons or entities on demand, and must already be exchanging EHI in a live clinical environment using the network in accordance with applicable law. However, we continue to encourage ONC to consider potential unintended consequences of a broad definition such as this. Additionally, to avoid industry confusion ONC should align the definition of HIN in TEFCA with the definition of HINs for purposes of information blocking, to the greatest extent possible.

- Individual: ONC defines an "individual" broadly to include not only patients but personal representatives, legal representatives, and executors. We agree with this approach, as it is important to allow representatives of a patient (including parents and guardians of a minor patient) to access a patient's information on that patient's behalf. We think some clarification could be provided to articulate why ONC includes both "an individual as defined by HIPAA" which would be "any person who is the subject of protected health information" and "any other person who is the subject of the electronic health information being accessed, exchange or used." Presumably, ONC makes this distinction to clarify that individuals who are the subject of EHI which is not PHI are captured under this definition, but we believe the definition could be clearer in this regard.

- Meaningful Choice: NYeC believes ONC intends meaningful choice to essentially be an opt-out form of notice for TEFCA participation. Meaningful choice is an individuals choice with respect to use of disclosure of EHI made with advance knowledge as provided by a written privacy summary containing the same content as ONC's Model Privacy Notice and additional information as required by the MRTCs which include a description and one example of each type of exchange purpose, a description of how an individual can exercise meaningful choice, and contact information to obtain further information about privacy practices. As previously discussed, NYeC is concerned that this concept of meaningful choice does not address varying consent requirements, but rather adds an additional administrative layer which ultimately adds to consumer confusion. For example, in addition to obtaining affirmative consent for Part 2 or other sensitive data, entities would also have to satisfy the requirements of meaningful choice if this information is to be shared in the TEFCA ecosystem. Also, as ONC notes, this meaningful choice notice does not supplant HIPAA Notice of Privacy Practice requirements. NYeC strongly feels alignment in requirements is needed. While we understand some of these requirements maybe be beyond ONC's control, we encourage ONC, working with other offices within HHS to align to the greatest extent possible and at a minimum, to provide guidance on the interplay and best practices for participants to adhere to all requirements while minimizing burden and patient confusion.

- Participant and Participant Members: NYeC appreciates ONC's revisions to the definition of participant and participant members in this draft. These refined definitions, including examples of the organizations that could fall under these definitions has provided clarity while also maintaining flexibility for certain entities.

- Qualified Health Information Networks (QHINs): NYeC appreciates the changes to the QHIN eligibility requirements in this draft. We share ONC's belief it is important that a HIN already operate an active network and also have demonstrated compliance with privacy and security requirements. We were concerned with the participant neutrality condition in the first draft of TEFCA. While we supported it in concept, we sought clarification that public HINs such as the SHIN-NY, who accept any individual or entity as a participant so long as the individual or entity meets required privacy and security standards was considered to meet this standard. NYeC appreciates the removal of this requirement and feels that the concern regarding network exclusivity to gain competitive advantage is adequately addressed through the reciprocity and cooperation and nondiscrimination provisions.

- **Requirements of QHINs:**

  - Initial Application, Onboarding, Designation and Operation of QHINs: As mentioned above, NYeC supports the requirements for approval as a QHIN, but we encourage ONC to clarify that a component of the written plan to achieve compliance with the Common Agreement shall provide an opportunity for QHINs to ensure they allow ample time for a amendments to all data use and participation agreements. With regard to the application process, as currently set forth, after a HIN submits an application it must make personnel and information available to the RCE, and the RCE must use commercially reasonable efforts to approve or reject an application in writing within a stated period of time. Upon written approval, the RCE shall use commercially reasonable efforts to provide the Common Agreement for signature and upon execution the QHIN becomes a provisional QHIN. A provisional QHIN becomes part of a Cohort, and it much achieve full QHIN designation by its applicable cohort deadline. NYeC encourages ONC to clarify the expectation regarding commercially reasonable efforts. Understanding the need for some flexibility, if ONC intends to reference legal terms of art they should be clear regarding such intention and more clearly articulate parameters. Furthermore, according to the notice of funding opportunity for the RCE, the RCE will begin soliciting, collecting and evaluating QHIN applications on August 31, 2020. We urge ONC working with the RCE to ensure transparency throughout every step of this process. Assuming this timeframe is subject to change, it will be important for the RCE to provide widespread notice to the industry that the application process is open and the timing for cohorts, which must at a minimum be semi-annual. The RCE should be clear regarding application requirements as well as the requirements to satisfy provisional status. It will be important for the RCE to work with stakeholders in an open, honest, transparent manner throughout the entire application and cohort process to obtain the trust of participants.

- QHIN Operations:

  - QHIN Exchange Purposes and EHI Reciprocity: NYeC supports the query reciprocity provisions. As previously mentioned, we believe this is essential to breaking down bifurcated networks and freeing the data. QHINs (and participants and participant members under their obligations) are required to respond by providing all EHI in the then applicable United States Core Data for Interoperability (USCDI). The then applicable USCDI is the newest version of USCDI 18 months after it is approved by the National Coordinator. This raises several concerns for us. First, NYeC is concerned with the 18-month timeframe to properly move updated versions of USCDI. In the expansion process, ONC indicates adequate time will be allowed for the industry to implement and upgrade their technology to support the data specified in the USCDI. As ONC is aware, in the recently proposed rulemaking, ONC provided 24 months for developers of certified products to update to this requirement. NYeC commented that HIEs, like the New York QEs, would need at least 6 months from developer upgrades to be able to exchange this standard. Under TEFCA, this 18 months begins from when the new version is approved by the National Coordinator, which will likely be insufficient time depending on how quickly developers adopt these changes. Second, while we appreciate that the requirement to exchange all EHI in the then applicable USCDI is a floor, not a ceiling, and perhaps an appropriate floor given current standards, NYeC is again concerned that without an appropriately tailored information blocking exception or safe harbor, this requirement conflicts with the recently proposed information blocking rules. As stated previously, the failure to harmonize these proposals could require HINs and participants to find other means to share EHI they may hold outside of what is included in USCDI, and decreases the value of TEFCA participation.

  - Permitted Future Uses: NYeC encourages ONC to clarify permitted future uses of EHI. As currently written the definition is circular and confusing. More specifically, the definition states that QHIN can exchange, retain, use and disclose EHI in accordance in with applicable law and only for limited purposes, one of which is "as otherwise permitted by Applicable Law." Second, any purpose would be permissible if explicitly approved by the individual after he or she has received a written privacy summary and the Minimum Information set forth by ONC, which includes statements regarding whether the information will be sold or licensed, the purpose of the use, how long and with whom the information will be shared. NYeC supports the ability to use data for research as permitted under HIPAA, as well as other uses permitted under law to advance public health. However, we are concerned with other potential data uses which individuals may unwittingly consent to if they do not read the fine print. NYeC appreciates the Minimum Information requirements set forth. Nonetheless, we remain concerned that the ability to sell individual EHI may result in a distrust of HIE that could have negative effects.

- Individual Exercise of Meaningful Choice: In addition to our previously stated concerns regarding the lack of consent alignment, we encourage ONC to further articulate the requirements for consent management. For example, under this MRTCs a QHIN must communicate a patient's exercise of meaningful choice to all other QHINs within five business days. We seek clarification from ONC on where this opt-out consent lies and encourage ONC to consider the scalability of various approaches.

- Processing of Individual Access Services Requests: As previously discussed, we encourage ONC to clarify the definition of Direct Relationship. Upon clarification that individuals may only assert their IAS right to QHINs which have voluntarily offered direct patient access through a portal or third-party application, we otherwise support the requirements that QHINs must respond to IAS queries and also provide IAS as may be required by a business association agreement. While NYeC supports what we perceive to be ONC's intention for IAS in TEFCA, this is one more example of the need to align with the recently proposed information blocking rules. Without clarification that responding to IAS queries satisfies patient access requirements for information blocking, or an appropriately tailored exception, the qualifier of a Direct Relationship seems moot. Further, ONC should work with CMS to clarify that responding to IAS queries satisfies the requirement that trusted exchange networks "support secure messaging or electronic querying by and between patients, providers and payers."

- Mandatory Updating of Technical Capacities and Agreements: As previously discussed, NYeC believe more than 18 months is needed for both technical and legal updates, particularly when the failure to incorporate the mandatory minimum obligations in an agreement is considered a material breach of the agreement.

- Data Quality: NYeC strongly agrees with the importance of data quality and the impact such can have on patient care. It seems reasonable to establish a universal approach to evaluating data quality, but we caution that the timeframe for this requirement may be difficult to achieve given the scope of exchanges and amount of data flowing through QHINs, particularly for those without record locator services established. While generally supportive of a process to evaluate data quality, this also raises questions with regard to how auditing and enforcement of such requirement would work.

- Transparency: As noted above, NYeC supports the notion of transparency as a mechanism for engendering overall trust in the framework.

- Cooperation and Non-Discrimination: NYeC supports the overall collaborative approach as put forward in the draft MRTCs. We agree with having a standard of non-discrimination to avoid any unfair treatment and/or unnecessary barriers that might impede or limit exchange or interoperability or limit Participants from joining.

  - Fees: It is important to note that the ability of QHINs to charge fees is extremely important. Becoming a QHIN will be a significant financial investment for any QHIN, and there is no government funding supporting such an endeavor. Thus, QHINs will

only be able to operate – and the TEFCA will only be able to succeed – if QHINs can charge fees that are sufficient to meet their operating costs. With this background, we have several concerns about ONC's proposed framework. Assuming ONC's concerns with these requirements is to prevent the use pricing as an excuse for blocking data, we believe this is unnecessary as such will be resolved through the information blocking requirements. NYeC is appreciative of the removal of the "Attributable Costs" limitation in this draft, as we had concerns such limiting to such fees would encourage inefficiency. Clearly, however, without an HIN, QHIN information blocking exception there is an interplay between the reasonable and nondiscriminatory fees under TEFCA and recovering costs reasonably incurred provisions under information blocking, and we continue to urge clarification that reasonable margins are permitted under these requirements. Accordingly, we urge ONC to develop further guidance or parameters with regards to what fees would be permissible and to ensure reasonable margins are permitted. Lastly, we appreciate ONC's adjustment to permit reasonable fees for respond to public health and benefits determination queries. While we have some concerns with the impact of providing responses to all IAS queries free of charge may have on QHINs, we understand the policy principals behind this fee exception.

- Privacy, Security, and Patient Safety: NYeC supports the inclusion of specific standards for privacy, security, and patient safety to maintain trust that health information is safe and secure. We support the alignment with HIPAA for individual access, disclosures of EHI, breach notification, demand for compulsory disclosures and the law enforcement exception to breach notification. We also support the requirement to make public QHIN privacy practices. With regard to the Minimum Security Requirements Standards, NYeC applauds the alignment of the HIPAA Security Rule to the NIST Cybersecurity Framework (CFS) as the overarching framework for the TEFCA to ensure the confidentiality, integrity and availability of EHI. Our cybersecurity program and the SHIN-NY Privacy and Security Policies and Procedures for QEs and their Participants reflect this alignment and industry security best practices. These requirements will help ensure that participating entities that are not covered by the HIPAA Privacy and Security Rules are following the same standards that will ensure the security of the information and support greater transparency for individuals on those entities business practices and how their data is being used. In general, NYeC supports the approach outlined specific to the requirements that govern data protection, access, authentication, and identity proofing. While supportive of these provisions, we think continued focus on these elements as well as ensuring consumers are aware of any future uses of their EHI, and the implications when their information leaves the HIPAA or TEFCA regulated sphere, will be an important continued focus. Furthermore, NYeC supports the potential of security labeling but acknowledges the lack of widespread adoption and policy implications. While we support a phased in approach such as that suggested by ONC, we encourage ONC working with subject matter experts to also take a deeper dive into technical and policy implications with security tagging in order to ensure there are no unintended consequences.

➢ **Participant and Participant Members:**

In general, the Participant and Participant member obligations outlined in the MRTCs as flow down requirements from the QHIN seem appropriate. However, NYeC would like to note that the process of amending Participation Agreements may present challenges both in terms of the cost and the lengthy process that may be involved. For example, in the SHIN-NY Enterprise, there are participation agreements between NYeC as the State Designated Entity and the QEs that would require amendment and participant agreements between the QEs and their Participants/member stakeholders. Also, in place are BA agreements and Data Use Agreements with stakeholders that are either vendors or data contributors to the SHIN-NY and that may not fall within the Participant category. Amending all of these agreements requires legal counsel, countless meetings and all at a cost to the SHIN-NY and the QEs. For example, in New York when there are amendments to QE Participation Agreements based on any regulatory or policy changes, it can take up to between 3-6 months for those policy changes to get incorporated into QE policies and procedures and then on average of up to 3-6 weeks for any Participation Agreement changes to be made. However, if the Agreements have to be renegotiated across all of the QE Participants that is very likely to add a substantial amount of time to the process. NYeC recommends that ONC consider this aspect of the process in the context of the overall timeframe that has been established and the lack of additional resources.

QHIN Technical Framework (QTF)

NYeC supports ONC's revised approach in refraining from naming specific standards and implementation mechanisms in the MRTCs, and to instead work with the RCE to develop the QTF which will be incorporated by reference in the Common Agreement. We agree with limiting the QTF to essential technical capabilities and believe the focus on QHIN to QHIN exchanges and expectations around identify proofing, authentication and connectivity services is appropriately tailored. Generally, we support the technical and functional standards set forth in this draft as they reflect those typically used in HIE today, but we have provided more detailed suggestions below as ONC and the RCE work to refine the QTF. Also, to reiterate our earlier point, we encourage transparency through the development and on-going updates to the QTF and are very appreciative of the fact that the QTF will be published for another round of public comment.

- **Query:** NYeC encourages ONC to consider the scalability and usability of the request for document standard as currently set forth. The SHIN-NY QEs currently implement this standard only for on demand document end points. The QTF should establish standardized parameters as to what should be returned for a document query.

- **Message Delivery:** NYeC encourages ONC and the RCE to consider the direct messaging standard for message delivery as this would eliminate the need to establish point to point connections.

- **Patient Identity Resolution:** The SHIN-NY and its QEs use a federated approach which we feel provides good success rates while also minimizing risk. Both the QEs and the SHIN-NY maintain a Master Patient Index (MPI) and are capable of deterministic matching. We urge the inclusion of a requirement that all QHINs have an MPI as we believe deterministic matching will be necessary given the nationwide scalability issues with probabilistic matching. NYeC is also concerned with the limited IHE XCPD profile of name and birth date, as this has the likelihood to result in unacceptable failure rates. NYeC supports expanding to a broader set of patient demographics to resolve patient identity, particularly with the implementation of USCDI and added demographic information such as phone numbers potentially becoming available for matching purposes. Given the fundamental nature of patient matching to nationwide interoperability and patient safety, we believe that a standard approach across QHINs is necessary. Given the current variation, the complexities and the essential role of matching, NYeC supports a unified coordinated effort to develop a national strategy on patient matching. We concur with sentiments of the recently released United State Government Accountability Office (GAO) report as well as the recent report from Pew Charitable Trusts on Enhanced Patient Matching is Critical to Achieving Full Promise of Digital Health Records, that we need a unified national strategy to address patient matching. We feel an ONC and CMS led effort with other public and private partners, could work to answer many of the question posed in the QTF.

- **Directory Services:** While directory services could be a phased in functionality, we do see the value in QHINs providing directory services. As the TEFCA ecosystem matures it would certainly be useful to have a directory of participants of a QHIN. This could be particularly useful with alerts, given the minimal information about the facility generating the alert that is typically included. For SHIN-NY cross QE alerts today, we add the full name, address and phone number of the generating facility. Among other use cases, a directory could help streamline this process. Further, we believe the inclusion of direct addresses in such directory would further add value.

- **Individual Privacy Preferences:** Any consent management standard set forth should classify consent based on the purpose of use. NYeC also encourages ONC to continue to explore how FHIR can be leveraged for managing consent related to Part 2 and other sensitive EHI that is subject unique legal consent requirements.

- **Auditing:** NYeC encourages ONC and RCE to further develop policies and general guidelines for audit procedures as opposed to specifying a standard. The ATNA standard currently proposed is often too specific and presents usability issues, which would result in QHINs needing to adopt additional auditing standards.

- **Error Handling:** In addition to requiring the ability to generate, send and receive error messages for QHIN to QHIN exchanges, NYeC believes it will be important for the QTF to specify a consistent set of error messages to ensure uniformity, improve functionality and minimize confusion.