GREATER NEW YORK HOSPITAL ASSOCIATION

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Don Rucker, MD National Coordinator for Health Information Technology US Department of Health and Human Services 330 C St. SW, Floor 7 Washington, DC 20201 Submitted Electronically

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

Dear Dr. Rucker:

On behalf of the 160 voluntary and public hospitals in four states that make up the acute care membership of Greater New York Hospital Association (GNYHA), we appreciate the opportunity to comment on the Office of the National Coordinator for Health Information Technology's (ONC) Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2. For more than a decade, GNYHA, its members, and strategic partners across New York State have been committed to building and implementing a Statewide Health Information Network for New York (SHIN-NY). The SHIN-NY, like the ONC-proposed approach, provides governance over the legal and operational health information networks (HINs), and various health information technology vendors in New York State. SHIN-NY stakeholders have worked toward developing policies, processes, and technical standards to improve data volume, quality, and access.

GNYHA has supported and worked alongside stakeholders to build the SHIN-NY and supports ONC's intent and direction in creating a trusted exchange framework and common agreement, which outlines a standard approach to health information exchanges nationally. TEFCA Draft 2 further clarifies and refines the plan for implementing the 21st Century Cures Act's interoperability goals and addresses many of the challenges faced by hospitals, health systems, and other health care stakeholders over the years in widely and easily exchanging health information. We believe that TEFCA's proposed governance, technical exchange standards, permitted purposes, and use cases support functional and accessible information networks that intend to offer providers a simplified, single on-ramp to a broader health information exchange than is currently possible.

However, while we support TEFCA's goals and approach, we know that alignment and standardization on the scale proposed by ONC will take time and involve an iterative process that must be pilot tested along the way. New York State and many other HINs across the country have spent most of the past decade working toward consensus on policies and technical architecture, and while there are successes in regional exchange, there are barriers to scaling up beyond local networks. Also, the recent ONC and Centers for Medicare & Medicaid Services (CMS) proposed rules on interoperability and information blocking have offered additional opportunities for advancing the TEFCA goals. However, it will also be more important than ever to ensure there is alignment across US Department of Health and Human



GNYHA is a dynamic, constantly evolving center for health care advocacy and expertise, but our core mission—helping hospitals deliver the finest patient care in the most cost-effective way—never changes.

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Services (HHS) programs and policies to avoid confusion and ensure information is shared appropriately.

Our comments on TEFCA's components are as follows.

Overall Framework and Goals

GNYHA supports ONC's proposed framework for a national network of networks. We believe such an approach could allow providers a single portal of entry into a broad and reliable health information network. Furthermore, by seeking to advance interoperability by creating a national network, defining standard policies, minimum functionality, and participant roles, and, finally, by broadly defining information-blocking, the ONC is challenging longstanding practices that have blocked progress toward widespread patient information networks, technical implementation standards, relationships, and governance for health information networks, technical implementation standards, permitted purposes for health information exchange, and use cases that will lay the foundation for a national framework will help simplify health information exchange for providers and accelerate activity toward greater interoperability.

Exchange Purposes and Modalities

We support ONC's intent to leverage existing health information network efforts, especially considering the many investments that have already been made in HINs across the country. We also support TEFCA's alignment with HIPAA, specifically ONC's plan to initially limit to a subset of purposes related to payment and health care operations. Limiting functionality to what is essential and doable and phasing in new exchange purposes will allow the network to grow while still demonstrating incremental success. We appreciate ONC's responsiveness to stakeholder comments in this regard.

ONC proposes three required modalities for TEFCA, including broadcast queries, targeted queries, and message delivery. In this draft, ONC has appropriately refined the terminology for these modalities from direct queries to targeted queries, which captures the nuanced use cases that might require this modality. Additionally, we are glad that ONC has included message delivery or alerts. While the New York State SHIN-NY has experience supporting each of these use cases, providers in New York have increasingly expressed value in data "pushes," including event notifications or alerts to providers and care coordination analytics pushed to physician practices for specific patient populations. We request ONC to clarify that message delivery does, in fact, include patient event notifications or alerts. This is particularly important due to CMS's recent proposal to require hospitals to transmit admission, discharge, and transfer notifications, an ability which would more aptly be part of TEFCA.

Lastly, we support ONC's removing the population level data exchange requirement and agree that Fast Healthcare Interoperability Resource-based (FHIR) application programming interfaces (APIs) will likely support this functionality once implemented.

TEFCA Intersection with HIPAA

As ONC acknowledges, there is a patchwork of State and Federal laws that apply to the privacy and security of health information. In addition to being misaligned with each other, these laws are often vague and unclear, having been promulgated decades ago, well before the advent of health information technology (HIT) and HIPAA. GNYHA has long called for harmonization of State law with HIPAA and agrees with the many commentators who have concluded that true interoperability cannot be achieved under the fragmented and misaligned framework currently in effect. Hospitals must routinely exercise judgment on how best to comply with these laws and often hew to the strictest standard, whether they are multi-state systems or operate within a single state. **In general**,

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ONC should be more explicit in acknowledging the complexity of the legal and regulatory framework within which hospitals and other providers operate in its development of TEFCA and other related HHS rules and programs; providers and other stakeholders should not be penalized for making efforts to comply with confusing and contradictory laws, so long as they have undertaken such efforts in good faith.

TEFCA Implementation Timeframes

We believe that TEFCA's proposed implementation timeframes are still too aggressive and fail to account for the complexity of the task of harmonizing existing HIE and HIN relationships to the TEFCA framework. Those relationships are based on years of careful work and engagement on statewide policies and practices. Over that time, in New York, for example, we have engaged in multistakeholder conversations on how to apply existing legal structures to new forms of information sharing for new purposes. Agreements with providers, vendors, and other stakeholders will take time to update and implement. Furthermore, ONC has just introduced new interoperability certification criteria that will need to be developed, tested, and implemented. It's important to ensure consideration is given to the time this will take and to align with these timeframes.

It will also take some time to re-adapt such applications to the TEFCA framework, and will require reengagement with the relevant stakeholders, and consideration of regulatory or legislative updates. It is critical that the TEFCA timeframes be appropriately timed and contain concrete milestones.

Recognized Coordinating Entity (RCE)

ONC proposes to select a RCE within the year to establish health information exchange governance, oversee Qualified HINs, and operationalize the TEFCA. In New York State, the New York eHealth Collaborative has played a similar role, convening SHIN-NY stakeholders and regional HINs to put forward policies and standards. In selecting the RCE and its governing board, GNYHA encourages ONC to ensure the RCE is independent and inclusive, particularly with end-user input into the implementation and future direction of the TEFCA.

GNYHA appreciates the opportunity to provide comment on the TEFCA and stands ready to work with its members on further guiding its development and implementation. If you have any questions regarding our comments or health information exchange in New York State, please contact me at <u>zsumer@gnyha.org</u>.

Sincerely, 3. Sm

Žeynep Sumer King Vice President, Regulatory and Professional Affairs GNYHA