June 17, 2019

Donald Rucker, M.D.
National Coordinator
Office of the National Coordinator for Health IT
U.S. Department of Health and Human Services
Mary E. Switzer Building
330 C Street SW
Washington, DC 20024

Dear Dr. Rucker:

Thank you for the opportunity to provide input on the second version of the Trusted Exchange Framework and Common Agreement (TEFCA). We believe that robust exchange of health information is absolutely critical to realizing our shared vision of improving health care quality and lowering costs, and we are grateful for your leadership.

Manifest MedEx is one of the nation's largest nonprofit health information networks in the US. Manifest MedEx shares health records for 17 million people and over 400 organizations. Manifest MedEx supports physicians, nurses, hospitals, health plans, counties, public health, and other stakeholders in sharing critical health information to ensure that patients receive the safest, highest-quality care possible. Our goal is to improve the quality of patient experience, support collaboration and coordination, and improve efficiencies by making it easier for doctors, hospitals and other care providers to securely review, analyze and share health information across the care delivery system. Manifest MedEx is collaborating with its partners to transform California's healthcare system into a coordinated system that delivers higher quality and more efficient care to all Californians.

Manifest MedEx believes that nationwide interoperability is an important goal and appreciates the efforts of the Office of the National Coordinator (ONC) to further this effort through TEFCA. However, we do not believe that the near-term implementation of TEFCA is the best way to achieve this goal.

Our comments focus primarily on why we believe that postponing the implementation of TEFCA may help advance ONC's goal of nationwide interoperability. We also discuss clarifications that we think are needed when and if TEFCA moves forward.

Reasons to Postpone Implementation of TEFCA

There are three reasons we recommend a delay to TEFCA implementation.

- **National Networks**. First, national networks like eHealth Exchange, Carequality, and Commonwell have made dramatic progress in enabling the query and retrieval of a patient's health information across providers and technology platforms in the nearly three years since the 21st Century Cures Act was passed. We believe government should focus on supporting these efforts, rather than stand up a new governance structure.

- **Misalignment.** Second, discrepancies between TEFCA and other proposed interoperability rules from ONC and CMS will create confusion and administrative burden for the entire industry.
- **Too much at once.** Third, TEFCA imposes too much change too quickly, particularly in combination with other proposed regulations. Rather than accelerate and support nationwide interoperability, as ONC intends, we believe the simultaneous introduction of sweeping, complex changes in many areas will likely slow progress as stakeholders across the industry pause to make sense of the disparate rules and to understand their roles and responsibilities for implementation and compliance.

***National Networks*: Leveraging the Success of Market-Based Solutions**

Since the 21st Century Cures Act was passed into law in 2016, the market has made substantial progress toward ONC's goal of allowing participants to connect networks *for the use cases that are currently feasible*. For example, eHealth Exchange supports query-based exchange for over 120 million patients and Carequality's interoperability framework has been adopted by over 600,000 healthcare providers nationwide. These networks support targeted and broadcast queries, as described in TEFCA. In other words, the problem of network to network exchange for query-based exchange is already essentially solved and does not require new agreements, frameworks or governance.

We do not believe the other use cases—message delivery and the postponed population health data exchange—can be accomplished through network to network exchange without substantial complexity and duplication of effort. That is because they require loading and maintaining patient panels for each provider or plan, and then attributing data to patients in these panels before sending messages. It would be infeasible for every QHIN to load all of the patient panels for every provider and every health plan across the country. As an example, the patient panel for just one of our health plans has 2 million members and is updated nightly into the Manifest MedEx infrastructure.

***Misalignment* with other Proposed Regulations**

The current draft of TEFCA states that all requests to send and receive electronic health information (EHI) over the QHIN Exchange Network fall under a given set of Exchange Purposes specified in the QHIN Technical Framework (QTF). This requirement is in direct contradiction with ONC's proposed information blocking rules, which require that health information networks (HINs) exchange EHI for any purposes permitted under state or federal law. Take the simple example of chart abstraction for a health plan to conduct risk adjustment for its population, which is permitted under HIPAA but not under TEFCA. The divergent definitions will create confusion and burden for the industry, especially as the TEFCA restrictions extend to any future use of information in addition to the purpose for which information was initially requested. The persistence of the restrictions means that organizations will need to put in place costly and cumbersome mechanisms to track and restrict data use across their whole enterprise.

The narrow Exchange Purposes in the Second Draft TEFCA pose substantial business and operational concerns for Manifest MedEx. Our current policies are well aligned with HIPAA and information blocking, permitting sharing of data for purposes permitted under state and federal law. We would face significant technical and administrative burden if we are forced to re-engineer our platform, policies and

agreements with participants to ensure that data received from other QHINs are only used for the specific permitted purposes outlined, and change our participation agreements to reflect TEFCA requirements. Since our merger, we have needed to update all of our participation agreements to a consistent set of policies, services and fees. This process has taken two years and at least a thousand hours of labor for us. We would likely decline to participate in TEFCA rather than face the cost and complexity of changing our platform and agreements again.

Finally, from a business standpoint, limiting Exchange Purposes to a subset of operations and payment permitted purposes will substantially hamper participation of health plans in TEFCA. They will be forced to seek other avenues to exchange information.

***Too much at Once:* Go Slower to Move Fast**

ONC and CMS are to be congratulated for the ambitious and far-reaching policies proposed in their respective information-sharing regulations. When finalized, those rules will create substantial new requirements for every party involved in healthcare. As demonstrated during the roll-out of the EHR Incentive Program ("meaningful use"), ambitious and complex new policies require time to implement. If too many different (and conflicting) policies are introduced at once it is almost inevitable that the result will not be the desired one. This is a particular problem given that the policy and technical requirements of TEFCA are not aligned with the technical requirements in ONC and CMS's proposed rules. In addition, introducing a complex *voluntary* program at the same time providers and plans must respond to complex *required* programs, will likely mean that the voluntary program gets short shrift.

Improvements to Streamline TEFCA If and When Implemented

The Recognized Coordinating Entity and QHIN Application Process

Manifest MedEx continues to believe the governance of the Recognized Coordinating Entity (RCE) is critical to building trust and support for the TEFCA, establishing and maintaining effective operations, and ensuring equitable practices outside of the public rule making process. To support these objectives, we recommend that the Common Agreement specify a multi-stakeholder RCE governance body. The governance body should include, at minimum, providers, payers, individuals, purchasers, technology developers, and government representatives, as well as a member representative for each QHIN. To ensure a fair and transparent certification process, the RCE should also be required to specify how it determines the assignment of Provisional QHINs to cohorts and sets cohort deadlines.

Identity Proofing

Manifest MedEx continues to be concerned about requiring IAL2 identity proofing for all participants, participant members, and individual users. This requirement may serve to exclude small practices and those serving vulnerable populations and as trusted referees. In addition, it may create disparities in the level of access that different individuals have to their own health information. It is not clear to us why

the current HIPAA Security Rule requirements for a thorough assessment, and reasonable, appropriate security measures within an HIE's security framework, are insufficient.[1]

Security Labeling

We strongly recommend that ONC not require sensitive data to be electronically labeled using the HL7 Data Segmentation for Privacy (DS4P) code set. This is an immature standard that has not been widely adopted by the industry, in large part because the data considered "sensitive" vary widely by state. Its required implementation would make the exchange of data critical for patient care much more challenging and significantly burden many of the most vulnerable patient populations.

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As illustrated by the challenges associated with the Meaningful Use program, the simultaneous rollout of complex regulations is unlikely to move the industry toward a solution to this problem more quickly. We recommend instead that ONC delay TEFCA, allow the industry to absorb and adapt to the other proposed regulations, and work with industry stakeholders to leverage the most successful elements of regional HIEs and national networks like eHealth Exchange and Carequality.

Thank you again for the opportunity to provide comment. Please do not hesitate to reach out to me at Claudia.williams@manifestMedEx.org if I can be a resource to you or your team.

Sincerely,

Claudia Williams
CEO
Manifest MedEx

[1] 45 CFR §308(a)(4)(ii)(B) and 308(a)(4)(ii)(C)