surescripts

February 20, 2018

Via E-Mail - exchangeframework@hhs.gov

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:

Surescripts is pleased to respond to the Draft Trusted Exchange Framework issued on January 5, 2018, for comment. Our experience represents what we believe is the nation's greatest success story in healthcare interoperability, and we draw upon our 17 year history of creating and operating the Surescripts network to provide comments for this important ONC initiative. Our comments are outlined in three specific areas: (1) Background on the Surescripts network experience; (2) comments regarding ONC's development of a "trusted framework"; (3) General Comments to the TEFCA; (4) Comments to Part A – Principles of Trusted Exchange; and (5) Comments to Part B – Minimum Required Terms and Conditions.

EXECUTIVE SUMMARY

- The government has a role to play to identify and enforce consistent and expected standards of network-to-network exchange in areas that lend themselves to commonality in order to create trust among health information exchanges and to remove factors that discourage participation of the healthcare community. We believe those areas that lend themselves to commonality in our view are:

    a. identity proofing of participants
    b. authentication of participants onto a system once properly ID proofed
    c. matching of individuals
    d. security standards
    e. obligations of privacy
    f. consistency and enforcement of trust obligations throughout the movement of information from point A to point B over multiple networks

- ONC should ensure that the framework and the "common agreement" do not disrupt current frameworks, and that the framework and "common agreement" allow market participants to continue to (i) innovate (both in business and technological advances), (ii) compete, (iii) encourage new entrants (whether commercial, governance frameworks, or otherwise) into the market, (iii) advance in product development, and (iv) develop new business models that achieve the goals of the parties and create financial sustainability for networks and their participants.

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

SURESCRIPTS.COM

- ONC should consider the downstream effect of a trust framework or a "common agreement" on entities beyond the networks themselves. A "common agreement" among networks may include provisions that need to be imposed on entities downstream from the network, which could affect hundreds, if not thousands, of agreements.

1) Background on the Surescripts network experience

As background, today Surescripts operates the nation's largest clinical health information network, delivering 13.7 Billion transactions in 2017, or more than 700,000 health transactions every hour, transacted both within our network and across networks with which we connect. Founded in 2001 by pharmacies and pharmacy benefit managers to establish a technology infrastructure to connect disparate technology systems across the nation to enable e-prescribing, we now connect over 99 percent of all retail pharmacies and most mail order pharmacies in the country, more than 250 EHRs and health technology vendors, representing more than 1,300,000 prescribers and hundreds of health systems. The underlying infrastructure facilitating these transactions includes a provider directory (containing the previously mentioned 1,300,000+ prescribers) and our Master Patient Index covering 230 million insured patients.

Over the past several years, Surescripts has made significant investments in leveraging the strength and unique assets of the network to deploy new services that extend beyond e-prescribing in order to enable providers to deliver the high-value care envisioned in ONC's Shared Nationwide Interoperability Roadmap. As just one example, we are using the Surescripts network to create and operate a Record Locator & Exchange Service (RLE) that offers providers a fast and easy way to obtain historical patient visit locations and retrieve clinical records, regardless of geography or EHR systems. RLE already includes 230 million patients and more than 4 billion potential patient visits by referencing historical Surescripts network activity. NRLS is now live nationwide across 43 health systems and operates within the Carequality Interoperability Framework.

Our National Progress Report, which can be found at www.surescripts.com/report, provides more information about the scope of the network.

The vast majority of the health information that flows through the Surescripts network does so under the auspices of Surescripts' governance framework for our own network. In addition, we are founding members of DirectTrust, which offers a governance and trust framework related to Direct messages. We also are founding members of Carequality, a national-level, interoperability framework for trusted exchange between and among health information networks, programs, and services. A growing number of our health information transactions are exchanged under the auspices of those frameworks.

2) Comments regarding ONC's development of a "trusted framework"

The 21st Century Cures Act requires ONC to "build consensus and develop *or support* [emphasis added] a trusted exchange framework, including a common agreement, *among health information networks nationally* [emphasis added]." The Act expressly states that participation in any such trusted exchange framework and common agreement is voluntary. The Act also states that the trusted exchange framework and common agreement "shall take into account existing trusted exchange frameworks and agreements used by health information networks to *avoid the disruption of existing exchanges between participants of health information networks* [emphasis added]."

Interoperability occurs only when data moves – moves by and among providers (including pharmacies), payers, patients (as well as their authorized family or other caregivers), public health, and/or researchers. Our experience is that trust is essential in any movement of health information – trust, among other things, (i) that the person with whom you are communicating with is who they claim to be, (ii) that the data will be secure, (iii) that the data will be used only in accordance with law, for the agreed upon purposes, and in adherence to patients' privacy rights, and (iv) that everyone in the chain of trust is abiding by the same rules. And, this trust must exist not only between contracted parties, or between networks, but also along a sometimes long continuum of parties who touch the data as it moves from one point to its final destination.

ONC's leadership to drive a trusted framework is to be applauded. We believe government has a role to play in establishing or supporting a framework and a common agreement that will guide, and can be used by, networks that desire to connect with one another. The 21st Century Cures Act provides the roadmap for that role by stating that the common agreement *may* [emphasis added] include: (1) a common method for authenticating trusted health information network participants, (2) a common set for rules for trusted exchange, (3) organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur, and (4) a process for filing and adjudicating non-compliance with the terms of the common agreement.

We believe that the language of 21st Century Cures gives ONC the authority and flexibility as indicated in the emphasized language above to use its discretion to ensure that the approach is just the right approach to build trust in network-to-network exchange by supporting existing frameworks and providing guidance for the creation of new frameworks in the market as needed, all without disrupting existing exchanges between participants of health information networks. Congress also was not prescriptive in what the common agreement must address – Congress stated what the common agreement may address, but makes no explicit requirements. To that end, we believe that the government has a role to play to identify and enforce consistent and expected standards of network-to-network exchange in areas that lend themselves to commonality in order to create trust among health information exchanges and to remove factors that discourage participation of the healthcare community. At the same time, it will be extremely important to ensure that the framework and the execution under the framework allow market participants to continue to (i) innovate (both in business and technological advances), (ii) compete, (iii) encourage new entrants (whether commercial, governance frameworks, or otherwise) into the market, (iii) advance in product development, and (iv) develop new business models that achieve the goals of the parties and create financial sustainability for networks and their participants.

3) General Comments to TEFCA

Our summary comments are below, followed by our more detailed comments:

1. The vision and goal articulated by TEFCA is both laudable and ambitious. We are concerned, however, that as drafted there is no network or other organization that could meet all of the requirements of a QHIN without substantial cost and effort, and that even in the best of circumstances it would take a long period of time for any entity to meet all of the requirements of TEFCA. TEFCA will have a greater chance of success if multiple entities elect to become QHINs, creating both competition in the marketplace as well as the system contemplated by ONC for ubiquitous exchange among all providers. If no entity is, or if few entities are, able to meet the requirements of a QHIN or choose to become a QHIN, then we are concerned that this effort will not succeed. We suggest a more iterative approach, seeking consensus on areas that can be achieved quickly, and

building on that progress on a step by step basis. Accordingly, we suggest that ONC allow a phased and modular implementation of TEFCA. To help ensure non-disruptive implementation, we suggest that ONC work with the RCE and the marketplace to explicitly phase-in the TEFCA in a modular and predictable fashion, likely by use case, permitted purpose, and technology approach. The RCE, once established, should manage this phase-in using its processes of broad and transparent stakeholder engagement, in alignment with its work on use-case-specific implementation guides.

2. We support ONC's intention to build on existing private-sector models and to leverage existing standards rather than undertaking the long and expensive process of creating new standards. Building on existing models and standards will help minimize disruption to existing initiatives that are effectively advancing interoperability, which is consistent with congressional intent. Such an approach will lower the costs for all involved, which is particularly important since significant investment is required to create the strategic, operational and administrative infrastructure required for a viable information exchange ecosystem. Implementation of TEFCA, including the RCE, must occur under long-term sustainable business models. These models should not be overly reliant on federal funding, which, over time, is subject to the constraints of the budget process and competing priorities.

3. We suggest that ONC focus on refining and articulating policy goals and principles, rather than on detailed agreement terms and technical requirements. Networks in existence today have a plethora of arrangements, including downstream arrangements. We encourage ONC to work with the RCE and the marketplace within a defined time period to implement these policy goals in an operationally manageable set of terms, drawing on comments on this draft and ongoing public and implementation community input. In addition, it will be essential to build in a responsive change management process and the ability to iterate and incorporate learnings using an "agile" approach.

4. We suggest that many of the provisions in the trusted exchange framework, as well as those envisioned for the Common Agreement, especially in Part B (Minimum Required Terms and Conditions), should be moved from the Common Agreement into use case-specific implementation guides. The rapidly evolving market and need to support innovation underscores the need for technology requirements to be maintained in implementation guides rather than the Common Agreement. It can be very challenging to build all use case-specific terms into one legal agreement. Doing so runs the risk that elements that work well for one use case are applied to others for which they are less appropriate. Implementation guides can be incorporated by reference into the final Common Agreement, so that they are just as legally binding as the terms in the Common Agreement itself. They can also be updated more flexibly and frequently to reflect changes in technology and standards than would be desirable for an underlying legal agreement. We would suggest that ONC clarify that only the Common Agreement is legally binding and that the trusted exchange framework, including Parts A and B, is intended to provide guidance to development of the Common Agreement.

5. We would note that the process to amend all of the current agreements and all of the downstream agreements to comply with the Common Agreement likely would take substantial time and expense, both financially and resource wise. Hundreds, if not thousands, of agreements have been negotiated, with the parties allocating rights and responsibilities, as well as liability among them. Changing all of these agreements, and reallocating obligations as well as risk allocation, will be a substantial undertaking. Accordingly, we strongly urge that ONC focus on principles rather than specific legal language.

6. While we understand the intent of one "on-ramp" for all providers, we are concerned that the focus on one on-ramp for all use cases could hinder innovation. It is feasible that a QHIN could be devoted to a use case that would make multiple on-ramps for efficient.

7. Overall, we suggest that ONC focus on fee transparency rather than introducing detailed requirements that dictate what commercial entities charge. There must be room for innovation in the market and a return on investment to spur innovation. Being prescriptive on the economic relationships will, in our view, deter participation in TEFCA and could result in less innovation instead of more innovation.

8. Given the scope of TEFCA, we suggest that ONC must publish a second draft of the TEFCA for public comment before finalizing the Framework later this year. This type of iterative feedback is a common form of design, and additional input will ensure that the necessary revisions to the Framework do not themselves introduce unintended consequences.

9. You asked for specific comment on PDMPs as they relate to the opioid crisis. In your question you state that important data included within a PDMP may reside outside of EHR/pharmacy systems. That is not our experience. PDMPs obtain data from pharmacy systems to populate the PDMPs data bases, and often those PDMP systems only have controlled substances. Surescripts, in fact, provides a national medication history solution available to providers across the country that has data sourced not only from pharmacies, but from PBMs as well. Moreover, Surescripts medication history service is not limited to controlled substances, but in fact contains non-controlled prescriptions as well – important data for providers to have in the fight against the opioid crisis. And our system is nation-wide. This more fulsome data set is an important tool in the fight against the opioid crisis. Today, Surescripts is in fact the single on ramp to medication history for providers. Last year alone we provided over 1 billion medication histories to providers for purposes of providing care to their patients. Moreover, our medication history service is integrated into the workflow of EHRs. Surescripts is positioned to support opioid use cases, and is actively pursuing the development of solutions that will meet the needs of providers as they address the opioid crisis.

The following are specific comments that we would offer.

PART A – PRINCIPLES

- **Principle 1 – Standardization**
    - 1.A – Surescripts supports ONC's efforts to continue to define standards through the Interoperability Standards Advisory. Defining the core setup of standards for exchange is integral to creating a cohesive network that is truly interoperable, but we'd like to caution ONC away from defining a single endpoint or edge implementation. The standards must allow for the innovation of health technology while supporting the core principles of exchange. For example, the expansion of the Direct XDR Edge Implementation into the 2015 Certification Program has limited the level of innovation that can occur on other endpoints and has required significant resources to adopt XDM for health technology who have adopted other Direct Edge implementations.

- **Principle 2 – Transparency**

  - 2.A & 2.C – Surescripts supports the concept of transparency and agrees that success will be dependent on transparency. The RCE should define the important aspects that must be publically available, while preserving the ability to maintain confidentiality of sensitive information.

  - 2.B – Surescripts supports defining a minimum set of permitted purposes, but recommends against mandating that all must be supported by each Qualified HIN, especially at the outset. ONC should pursue a more iterative approach to the use cases.

- **Principle 3 – Cooperation and Non-Discrimination**

  - 3.A – While Surescripts agrees with the goals of Principle 3, the TEFCA must recognize that there are legitimate privacy and security concerns in the exchange of health information, and that standards that protect privacy and security must be maintained and adhered to. Whether a requirement that imposes privacy and security standards is appropriate is often in the eyes of the beholder, and while entities should not refuse to share data for purely competitive purposes, nor should entities be able to claim that proper and legitimate requirements relating to privacy and security are merely a pretext for not exchanging data. There are many threats to the privacy and security of health information, and there must be a high standard throughout the chain of trust for ubiquitous exchange to be successful. Safety and security of the health information is paramount to the success of data exchange. In addition, creating a health data network with complete data reciprocity is a laudable goal that should be strived for, but for that network to be successful it needs to be supported by a successful business model.

- **Principle 4 – Privacy, Security, and Patient Safety**

  - 4.A – Surescripts supports defining a minimum set of patient demographics that must be captured and exchanged through a standardized format for patient mapping.

  - 4.B – Surescripts recommends a comprehensive approach to defining consent and authorization laws/regulations. The inconsistencies under existing State and Federal laws/regulations often limit interoperability and it must be addressed in a comprehensive format for the TEFCA to be successful. The Federal and State Governments must have a cohesive list of requirements for privacy, security, and patient safety practices. Clear standards and guidance must be provided regarding how the appropriate consent or authorization is captured, maintained, and relied upon by third parties.

- **Principle 5 – Access**

  - Surescripts recommends that ONC provide additional clarification around revoking participation in QHIN activities.

  - ONC or the RCE should provide guidance and consistent as to the proper means by which a QHIN or its participants allow a patient to revoke his/her participation in the QHIN.

- **Principle 6 – Data-Driven Accountability**

    - Surescripts recognizes the need for population health management and bulk data transfer, but the existing standards outlined for QHIN activities don't appropriately address the concerns about large file data transfer. Surescripts encourages a metered approach in this area to create/modify standards to better support these activities before pushing for this adoption.

PART B – TERMS AND CONDITIONS

1. **Standardization**

    - Surescripts is concerned about network traffic if all requests must receive a response. Surescripts recommends appropriate standards to be defined to identify appropriate non-response for certain data classes as the lack of data. Requiring a response in every scenario creates unnecessary network traffic which could limit the success of the network.

    - Surescripts supports population level data exchange. We recommend a more metered approach to adopting the Population Level Query/Pull standards that may be defined. Expanding the window for adoption will allow for appropriate implementation and testing of large data file transfers to ensure that the network isn't put at risk. Surescripts recommends extending the implementation of such standard to 24 months.

    - Surescripts would like clarification on the appropriate Audit Log capabilities as it is related to the Query/Pull functionality. Existing laws address access to health information in terms of an Electronic Health Record, but fall short when addressing network level message audits. Through our experience with 2015 Certification related to HISP activities, we believe this needs to be better defined than through the existing regulations and laws.

    - 3.1.8 & 3.1.9 - Surescripts is concerned about the traffic volume involved in the broadcast query approach described in these sections.

2. **Transparency**

    - 4.1.2 – Surescripts is supportive of an open and transparent data sharing agreement, but is concerned about the approach the ONC is taking to regulate fees for these services. Several requirements, like the population and broadcast queries, are pushing the industry into uncharted territory where new business models need to be properly evaluated. This requirement adds a high level of risk that could limit participation. To rely on private industry to support these activities they must be based on a sustainable business model.

3. **Cooperation and Non-Discrimination**

    - 5.1 – Surescripts is seeking further definition of the term "…to the extent the EHI is available."

    - 5.2 - QHINs, Participants, and End Users must retain the ability and responsibility to protect their systems and networks with tools such as data throttling. As drafted, ONC indicates that a

QHIN must permit another system to perpetuate a denial-of-service attack and it would be a violation of the agreement for the QHIN to restrict or limit the access of another system even if the other system's resource overuse threatened to degrade performance and system responsive for the QHIN. Connecting to the Trusted Exchange Framework must not infringe of the system performance of the QHIN. If the QHIN's system is so taxed by another participant that they cannot load patient information in a timely fashion, then patient care is negatively affected.

- 5.2.4 – Please provide clarification of what reasonable prior written notice constitutes?

- 5.3 - HIT developers invest significant time and effort in constructing their systems to be responsive and to use hardware investments effectively. If other network participants are able to make system demands that they do not have to pay for, it perpetuates the current cost-shifting problem of healthcare. Instead, all Trusted Exchange Framework participants should pay fairly for the system resources they use and be incentivized equally to use those resources wisely.

- 5.4 – Section 5.4 should be clarified to ensure it does not infringe on the ability of QHINs and their Participants to always be innovating with new types of arrangements and corresponding agreements. If QHINs are limited in their ability to form other agreements (besides the Common Agreement) then they are less able to experiment with new and innovative models, or to do work that extends beyond currently available industry standards.

4. Privacy, Security, and Patient Safety

- 6.1.1 – Surescripts supports patients having full access to their health information. Surescripts recommends that the ONC provide clarifications on the expectations of a Qualified HIN to support this patient right. Surescripts recommends that the ONC provide clarification that ensures a qualified HIN cannot limit access to patient facing application requests, but that a qualified HIN does not need to create or maintain a patient facing application or tool to support the right to the information. The responsibility to obtain patient consent or authorization should remain with the organizations that are the sources or consumers of ePHI, and which have the relationship with the patient to make that consent management feasible.

- 6.1.6 AND 6.1.7 – Surescripts recommends a comprehensive approach to defining consent and authorization laws/regulations. The inconsistencies under existing State and Federal laws/regulations limit interoperability and it must be addressed in a comprehensive format for the TEFCA to be successful. The responsibility

- 6.2.4 – Surescripts supports the efforts of ONC to move identity proofing down the local level. It creates an undue burden to manage individual identity proofing at a network level. In addition, we suggest ONC examine barriers that stringent identity proofing and authentication have erected to other interoperability initiatives, such as e-prescribing of controlled substances. We are concerned that the barriers have slowed adoption of that technology and will have a similar effect on adoption of the Trusted Exchange Framework.

5. **Access**

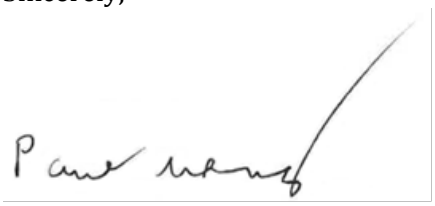
    - 7.2 – We believe this requirement institutes and undue burden to require all QHINs support No Data Exchange requirements. Surescripts recommends that appropriate controls are put in place by the requesting party to ensure data is only exchanged when appropriate.

6. **Data-drive Choice**

    - 8.1.1 – Surescripts supports population level data exchange. We recommend a more metered approach to adopting the Population Level Query/Pull standards that may be defined. Expanding the window for adoption will allow for appropriate implementation and testing of large data file transfers to ensure that the network isn't put at risk. Surescripts recommends extending the implementation of such standard to 24 months.

We thank you for the opportunity to provide comment on this important matter.

Sincerely,



Paul Uhrig
Chief Administrative, Legal, & Privacy Officer