February 20, 2018

Don Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health & Human Services (HHS)
330 C Street, SW – 7th Floor
Washington, DC 20201

Re: Draft Trusted Exchange Framework & Draft U.S. Core Data for Interoperability

Dear Dr. Rucker:

We thank the Office of the National Coordinator (ONC) for sharing its vision for the Trusted Exchange Framework and Common Agreement (TEFCA) in response to the 21st Century Cures Act, and embracing stakeholder input and ideas as a key part of the ONC's approach. Netsmart provides electronic health records (EHRs) and HIE Solutions for behavioral health, addictions, child welfare, developmental disabilities, home care, hospice, palliatiative care, skilled nursing, assisted living and independent living. Our platform provides clinical and social determinants information to care team members when they need it. We make the complex simple and personalized so our clients nationwide can concentrate on what they do best: provide services and treatment that support whole-person care to some of the most vulnerable populations in the United States.

At its core, we support the ONC's goal to bridge the gap between providers, patients and information systems to enable interoperability across disparate health information networks. However, we urge the ONC to implement a solution that builds on the successful work that has already been demonstrated in the healthcare industry for sharing electronic health information. We also ask that the ONC take into account the lessons learned from unsuccessful projects or initiatives that have been attempted in the past.

Industry Interoperability Challenges

At their inception, Health Information Exchanges (HIEs) were very well funded by the American Reinvestment and Recovery Act (ARRA). This drove accelerated adoption in the short-term. However, because information repositories are expensive to maintain, the cost has outlived the funding. In addition, patient information shared to an HIE was bound to that geographic region, but information owners, the patients, are not bound to geographies, so the sharing of data was limited. Furthermore, data sharing was often not an option for health and human services providers served by Netsmart because the HIEs did not have the data governance required to accept, house and share data for people with a history of substance use subject to the regulations of 42 CFR Part 2.

www.ntst.com
4950 College Boulevard
Overland Park, KS 66211
800.842.1973

To solve the challenge of sensitive data shared from behavioral health providers, several initiatives were launched to create some access to patient information across disparate networks. DS4P and Consent2Share were developed in an attempt to standardize the information that could be shared and to give patients a voice in who their information would be shared with. However, the cost and complexity of implementing DS4P led to low adoption and little use. The implementation of Consent2Share was unsuccessful because it required changes to consent policy, imposed a workflow burden on patients and required a significant amount of training of both providers and patients to implement.

Finally, the largest impediment to successful interoperability initiatives has been the lack of funding in the health and human services and post-acute sectors. For any form of interoperability in healthcare to be successful, it must span all communities. Unfortunately, the focus of interoperability in the past has primarily focused on the acute care and primary care market.

However, as the industry continues its shift from volume to value and Accountable Care Organizations (ACOs), bundled payments, and whole-person care initiatives become increasingly common, it is becoming especially important to share as much information as possible with the providers responsible for reducing readmissions. These providers and organizations are already operating on thin margins, so without specific funding sources and incentives, it will be difficult for organizations to afford to it. We ask on behalf of the clients and sectors served by Netsmart that this be considered when writing TEFCA implementation timelines.

Successful Solutions for Interoperability Challenges

Netsmart responded to the industry's interoperability challenges by successfully connecting providers in the sectors we serve with each other and with acute-care health systems. First, utilizing industry standards, we developed a network that connects our clients. This standards-based approach uses a uniform method of connectivity across our client base, which in turn ensures more efficient implementation and lower costs. In addition, we control our own consent model for those with the most sensitive data in healthcare, including the ability to record electronic consent and embed it in our transactions.

Netsmart and our clients learned a lot from these efforts. It became clear that a push based process, while powerful, could be improved by allowing our clients to query the health systems they partnered with, and vice versa. We partnered with Epic and other vendors to create the Carequality network. Netsmart is a founding member and live implementer of the Carequality Interoperability Framework which contains more than half of all healthcare providers in the country. Carequality has allowed Netsmart clients to share authorized health data on a nationwide scale with providers across the country. The ability to gain a longitudinal view of where a person has presented in the past, along with their clinical history, has supplemented the traditional single Continuity of Care Document (CCD) received from one provider as part of the electronic push referral process. In addition, the common rules of the road amongst implementers has created efficiencies by reducing the

number of data sharing agreements that need be signed. This incentivizes providers and vendors to join the initiative, creating a well-adopted network.

We strongly encourage the ONC to leverage the success of initiatives like Carequality and Commonwell. We urge the ONC to work with these successful private-sector initiatives to implement a framework *in tandem with* and not *instead of* those efforts. Significant work has been done in these models to connect disparate systems and networks; the implementation of TEFCA should not hinder that good work, but only expand on it.

Positive Items in the Current TEFCA Draft

1. **We support the foundation of the Common Agreement.**

Netsmart has found success working with other framework initiatives like Carequality and Commonwell in part because of their use of a common agreement. A common agreement adhered to by all participating entities is essential to interoperability adoption and buy-in across the healthcare landscape. It would also eliminate the burden of disparate data sharing agreements and provide clarity for the rules of the road to which all parties in TEFCA must abide. This ensures that the permitted purposes for each entity are clear, and fosters good stewardship of the network. We urge the ONC to take into account existing common agreements that are already successfully enabling the sharing of data.

2. **We support the use of the existing Common Clinical Data Set.**

Utilizing the existing CCDs will be vital to quickly gaining lift in the sharing of data via the TEFCA. We agree that using what has already been adopted by a large number of healthcare providers and vendors as part of ONC certification can serve as a floor for the data that can be shared across the continuum.

3. **We support the expansion of the list of permitted purposes.**

We appreciate the ONC incorporating new permitted purposes in addition to the traditional purposes of treatment, payment and operations that are widely used today. By expanding the purposes, there will be greater inclusion of vendors, providers, market segments, etc., and this will provide lift to the data that can and will be shared. However, we urge the ONC to provide relief and/or protection regarding patient-directed queries. We ask that language be included to diminish the liability of QHINs/HINs because if a query is patient-directed, the individual should be able to consent to share if initiated outside of an EHR.

4. **We support the idea of a single on-ramp.**

We fully support the idea of a single on-ramp that is proposed by the ONC. A single on-ramp to connectivity will ensure that providers will have a low cost, efficient way of connecting so that data can be shared via a common highway.

Netsmart Suggested Changes to TEFCA

1. **We recommend the Common Agreement be at the top tier and filter down.**

Although we are supportive of the idea of a common agreement by which to implement the TEF, we urge the ONC to implement the common agreement across QHINs. This would then filter down to the HINs and Participants connecting through them. We have found this model to be successful in our implementation of Carequality in which we consent to the agreement language and pass those terms through to the providers we serve. That model has been very successful from both a private and public sector perspective.

2. **What is proposed may not be a single on-ramp.**

Although we are supportive of the idea of a single on-ramp for connectivity, we are concerned that the proposed model in the draft TEF will not achieve this goal. By allowing the formation of multiple QHINs, the ONC may be effectively creating several different on-ramps. Because each QHIN will be its own separate entity with its own business model and infrastructure, we are concerned that the financial capital, human capital and technology stack may vary significantly across QHINs, thereby creating an uneven playing field. We appreciate the language within the Common Agreement that prohibits the throttling of the transactions of data. However, variance in the levels of infrastructure between QHINS could create an inadvertent unfair difference in the speeds with which data is sent, or disparities in the ability of HINs and Participants to connect due to resource constraints. We recommend that the ONC select the RCE and work with that entity to outline a more stable and specific definition of QHIN that addresses the above concerns.

3. **Concern around the connectivity brokers.**

We urge the ONC to reconsider the proposed connectivity broker requirements. We question the language within the draft TEFCA that alludes to the role of a connectivity broker as a separate entity that handles all transactions on behalf of the QHIN. For example, if there is a requirement such as the need for a Record Locator Services (RLS) that cannot be fulfilled by the QHIN, they will have to go through a connectivity broker. However, there are only a few companies that can realistically serve the functions of an RLS, and these companies may not provide one-to-one services. The fact that these services may be dissimilar from QHIN to QHIN may also provide an uneven playing field. In addition, there is concern that as QHINs find the need to employ additional connectivity brokers, the cost could be passed onto the HINs and Participants that need to connect. If these costs are different from broker to broker, that means costs will be different from QHIN to QHIN, again creating an uneven, not collaborative, situation.

4. **Concern around 42 CFR Part 2 and sensitive data.**

As mentioned above, one of the impediments to the adoption of data sharing initiatives in healthcare has been the ability to accept sensitive personal health information (PHI). We know a desired outcome of the 21st Century Cures Act is to enable the full sharing of data

across the continuum. To that end, we urge the ONC to create alignment with SAMHSA and other regulatory bodies on 42 CFR Part 2 requirements to enable the real-time sharing of data across providers and venues, at the discretion of the individual. With the growing opioid epidemic, it is more important than ever to give providers access to data that could aid in a person's recovery and ensure care is provisioned in a fully-informed, safe, responsible way.

5. **We recommend that the RCE not be a technology vendor.**

In the ONC's selection of an RCE under the draft language in TEFCA, we urge the ONC to select a non-profit organization to serve as the RCE. This organization should have a proven track record of working across vendors and HINs in an agnostic way. The neutrality of the RCE is vital to the success of the implementation of TEFCA, and it should operate without prejudice in its governance of this initiative across QHINs, HINs and Participants.

6. **We are concerned about the scope of HINs.**

While we agree that the QHINs should be responsible for adhering to the standards necessary to transact data among every permitted purpose, we believe that under the draft TEFCA, HINs would not need to adhere to all the permitted purposes/requirements. We propose that HINs enter into a single contract with a QHIN for the permitted purposes they will fulfill on behalf of their Participants, as opposed to an all-encompassing agreement for every permitted purpose of connectivity. Then, as part of implementation, use case-specific requirements should be delivered that are reflective of the permitted purpose one would claim. These can be called out in separate implementation guides passed down to the HINs by the QHINs.

7. **We recommend PDMPs be mandated to connect through the QHIN to share data seamlessly across HINs and Participants.**

To combat the growing opioid epidemic in this country, we recommend that state PDMPs also be required to share their data through the TEF to QHINs. This will ensure that prescription data can be accessed anywhere and at any time to seamlessly provide data to care team members, who can then responsibly prescribe appropriate medications. For patients who have a history of substance use and live on state lines, this is especially important as there is still no centralized repository of prescription drugs.

8. **We recommend that payers be required to send prescription claims data to supplement the provider data of prescriptions issued.**

While provider-level data of prescriptions is important, claims data can help supplement that data and provide crucial insight to providers. As the industry continues to move from volume to value, this insight can help care team members identify outliers and mitigate risk. For example, a person may have asthma and have a controller medication prescription. However, if a provider can identify that there was no controller medication filled through claims data, then the provider can do outreach to the individual and prevent a readmission.

We urge the ONC to take metrics like this into account to improve patient outcomes through the sharing of data.

9. **We recommend the ONC align the rollout timeline for TEFCA with regulatory updates with CMS.**

Because providers in the health and human services and post-acute communities are already under-funded and susceptible to sweeping regulations, we urge the ONC to collaborate with CMS and others to mitigate the risk to these organizations and reduce the burden of a potential implementation that could occur in tandem with a large regulatory release.

Sincerely,

Kevin Scalia
Executive Vice President
Netsmart