



National Association for the Support of Long Term Care

June 17, 2019

Donald Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health & Human Services
Mary E. Switzer Building, M/S 7033A
330 C Street, SW
Washington, DC 20201

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

Dear Dr. Rucker:

The National Association for the Support of Long Term Care (NASL) is pleased to submit these comments in response to the *Trusted Exchange Framework & Common Agreement Draft 2 (TEFCA Draft 2)*, which was released on April 19, 2019.

NASL is a trade association representing providers of care and ancillary services and products to the long term and post-acute care (LTPAC) sector. NASL members include rehabilitation therapy companies that employ more than 300,000 physical therapists, occupational therapists and speech-language pathologists. NASL members also develop and distribute clinical electronic health records (EHRs), billing and point-of-care information technology (IT) systems and other software solutions that serve the majority of LTPAC providers. Other NASL members provide clinical laboratory and portable x-ray services as well as specialized supplies for the LTPAC sector. NASL is proud to be a founding member of the LTPAC Health IT Collaborative, which has been working to advance health IT issues by encouraging coordination among provider organizations, policymakers, vendors, payers and other stakeholders since 2005.

NASL and our membership are proud of our work with the U.S. Department of Health & Human Services' (HHS') Office of the National Coordinator for Health Information Technology (ONC), the Centers for Medicare & Medicaid Services (CMS), other federal agencies and through standards development organizations (SDOs) such as Health Level 7 (HL7) and the National Council for Prescription Drug Programs (NCPDP). NASL members have participated in Healthcare Innovation Challenge Grants from the Center for Medicare & Medicaid Innovation (CMMI) and various Health Information Exchange (HIE) initiatives. We are especially proud to note that – even though LTPAC providers are ineligible for EHR incentives under CMS' Meaningful Use/Promoting Interoperability

Program – several NASL member companies have developed software products that have been certified and listed on ONC’s Certified Health IT Product List (CHPL).

Currently, NASL and its members are actively engaged in federal health IT and interoperability initiatives such as ONC’s 360X via Direct demonstrations and CMS’ efforts around its Electronic Medical Documentation Interoperability (EMDI) Program. Our members also serve in leadership roles on Carequality’s Steering Committee and Advisory Council and with CommonWell, DirectTrust and HIMSS. NASL and several of our IT Committee members shared technical expertise with CMS, ONC and federal contractors detailed by RTI International in the April 2019 *Summary Report of the Technical Advisory Workgroup Roundtable: Use of the CMS Data Element Library to Inform Healthcare Policy & Advance Interoperability, Health Information Exchange & Quality Measurement*. Now, we are providing critical input for the PACIO Project, which is developing a post-acute care use case and Fast Healthcare Interoperability Resource (FHIR) application programming interface (API) implementation guide with the support of MITRE and the CARIN Alliance. We have shared similar input with the Centers for Disease Control & Prevention (CDC) and its efforts to develop an HL7 implementation guide for electronically reporting to CDC’s National Health Surveillance Network (NHSN). NASL also is part of NCPDP Workgroup 14, which is working to improve the Medicare Part D e-prescribing standard as it relates to meeting the unique needs and workflows in skilled nursing facilities (SNFs) and other LTPAC settings.

Steadfast advocates for health IT adoption and use, these comments reflect the recommendations of NASL and our clinical and health IT members who serve the majority of LTPAC providers of assisted living, home health, skilled nursing and other ancillary care and services.

General Comments

NASL values and appreciates ONC’s efforts to ensure that post-acute care, behavioral health, home health and other providers – deemed “ineligible” for federal incentive payments under the decade-old *Health Information Technology for Economic & Clinical Health (HITECH) Act* – now have their voices heard and concerns addressed as we work together to improve electronic exchange of health information and achieve interoperability. **Interoperable health information exchange by providers in the LTPAC sector with the rest of the care continuum is a critical and fundamental step to improving outcomes for some of our most vulnerable citizens, providing person-centered care, marshaling greater stewardship of our nation’s health care dollars and achieving interoperability.**

NASL supports the overall intent and direction proposed by ONC’s *Trusted Exchange Framework & Common Agreement Draft 2 (TEFCA Draft 2)*. We appreciate the thoughtful changes made to the January 2018 draft. The three documents that comprise *TEFCA Draft 2* – the revised drafts of the Trusted Exchange Framework (TEF) and the Minimum Required Terms & Conditions (MRTCs), along with the new Qualified Health Information Network (QHIN) Technical Framework (QTF)

Draft 1 (QTF Draft 1) – were complementary and helpful to review.

NASL supports ONC’s removal of the standards from the TEF as well as the addition of the QHIN Technical Framework (QTF). We believe that having a single point of reference – the QTF – where one may review the technical and functional components for exchange among QHINs is helpful. Further, we agree that the QTF should be incorporated by reference into the *Common Agreement*.

While the changes proposed are largely positive, we were disappointed that *TEFCA Draft 2* was not released in advance of ONC’s *21st Century Cures Act: Interoperability, Information Blocking & the ONC Health IT Certification Program Proposed Rule* or CMS’ *Interoperability & Patient Access Proposed Rule*. Better understanding ONC’s view of TEFCA as described in this latest draft certainly would have helped to inform our review of these two, complex and intertwining proposed rules. Consequently, we request clarification in key areas with regard to ONC’s expectations for implementation of TEFCA in relation to these proposed rules.

The ONC and CMS proposed rules on interoperability place tremendous emphasis on the use of FHIR standards, whereas *TEFCA Draft 2* appears to focus on leveraging existing, deployed technology infrastructure (*i.e.*, services based on IHE profiles) to support network-to-network exchange and includes references to FHIR as an “alternative, emerging Standard.” We request clarification from ONC as to whether dropping the Population Level Query from this most recent draft accounts is the reason for such a disparity. If not, should we interpret this shift in emphasis as an indication that consumer-facing applications built from FHIR APIs are not expected to impact TEFCA?

NASL also requests clarification regarding how ONC plans to reconcile TEFCA with FHIR and its proposed rule on information blocking. As noted in our June 3, 2019 comments to ONC and CMS, NASL recommended that an approval process, which meets the “gold standard” for health information exchange (and all relative laws or initiatives such as TEFCA), be put in place in advance of any CMS requirement that Medicare Advantage plans or others launch new API-based applications (“apps”). NASL reiterates that recommendation; moreover, we recommend that any such apps be vetted by the Recognized Coordinating Entity (RCE) as part of its governance of TEFCA. We envision that EHRs and others operating within TEFCA would rely on the RCE to vet such apps to ensure these apps meet the requirements of the final *Common Agreement*. Participants in TEFCA would be expected to exchange data with apps that had been vetted and found to meet those criteria. To codify this process, **NASL recommends that ONC create another information blocking exception that would exempt providers and/or health IT vendors from penalties for not exchanging data with any app that does not meet these criteria.**

LTPAC health IT companies have made significant investments in data exchange to include participation in various collaborative networks such as Carequality, CommonWell and regional Health Information Exchanges (HIEs). We remain concerned that what may be considered

“reasonable” allowable costs and fees by those who received federal health IT incentives may be viewed very differently by non-incentivized providers. Unlike acute and ambulatory care providers where the federal government is *not* the majority payer, LTPAC settings (*i.e.*, Medicare and Medicaid certified providers) struggle with tight margins and limited resources with which to offset such costs, thereby demanding careful consideration as to whether participation in TEFCA is worthwhile. Fees that are imposed on LTPAC providers and their health IT vendors will put participation out of reach and erect another barrier to interoperability.

Exchange Modalities

NASL agrees with ONC’s broadening the definition of a Qualified Health Information Network, removing the requirement to be “participant-neutral” and utilize a Connectivity Broker service. With this accommodation, ONC recognizes existing efforts where electronic health information exchange is occurring and may continue uninterrupted.

NASL believes that it is premature to expect that a new trusted exchange framework would address population-level data exchange from its inception. We appreciate the removal of population-level data exchange from *TEFCA Draft 2*.

Adjusting the timelines by granting the QHINs another six months beyond the initial 12-month timeline is another welcome change from the first draft, too. NASL agrees that allowing QHINs 18 months to update agreements and technical requirements is both reasonable and achievable.

CMS’ *Patient Access & Interoperability Proposed Rule* references a “trusted exchange framework,” but does not specify TEFCA as described by ONC as that framework. We seek affirmation from ONC that CMS is referring to TEFCA and not some other parallel framework. The infrastructure that TEFCA will provide should be sufficient to ensure that all stakeholders who wish to participate in health information exchange can participate in TEFCA.

ONC requested feedback on the exchange modalities, including QHIN Targeted Query, QHIN Broadcast Query and QHIN Message Delivery. NASL agrees with the types of queries that are outlined under the category of exchange modalities; however, we question the logic of the QHIN Targeted Query as defined. The term “targeted query” suggests that the request for information is narrowly focused on the entity that possesses the information being queried. We see the need and value of such queries (*e.g.*, a query that targets an entity such as a particular hospital where a patient had received care). As currently defined, the QHIN Targeted Query seeks information from the entire QHIN with which the hospital (and true “target” of the query) participates. We view such a query as a small scale QHIN Broadcast Query since one could retrieve the same information from conducting a QHIN Broadcast Query. **NASL recommends that ONC redefine the QHIN Targeted Query to mean a query that targets a particular entity/ participant in a QHIN.**

Exchange Purposes

NASL generally agrees with the scope of the exchange purposes detailed in *TEFCA Draft 2*, to include Treatment, Quality Assessment & Improvement, Business Planning & Development, Utilization Review, Public Health, Benefits Determination and Individual Access Services. Still, we ask for clarification with regard to benefits determination. ONC only references federal and state uses for benefit determination. For example, Carequality currently provides the ability for life insurance companies to conduct benefits determination. Would this practice be allowed to continue under TEFCA? If benefits determination were restricted to only federal and state use, what would that mean for Medicare Advantage payers and others?

We appreciate that *TEFCA Draft 2* simplifies the QHIN-to-QHIN exchange by providing guidance with regard to what charges may be levied. We remain concerned about costs associated with participation in TEFCA. As previously noted, health IT adoption and operationalizing health information exchange are costs that must be carefully considered by LTPAC and other providers that have yet to receive any federal incentive funds. LTPAC cannot absorb costs for exchange in the same manner as occurs in acute and ambulatory care settings where costs may be passed along to consumers or where costs have been offset by federal incentives.

Since it is impossible to comment yet on the Additional Required Terms & Conditions (ARTCs) that will be drafted by the RCE, **NASL recommends that any fee structure that is considered be reasonable and encourage access to TEFCA. NASL further recommends that ONC make the ARTCs available for public comment by potential users of TEFCA.**

We understand that participation in TEFCA will not be cost-free. We remind ONC that the LTPAC sector is not in a position to financially support all data exchange in terms of fees or costs imposed by this structure. NASL sees a role for the federal government in creating and maintaining (to include providing the necessary financial resources) for this essential infrastructure. **NASL recommends that ONC consider waiving any fees associated with participating in TEFCA for those excluded from *HITECH* incentives as a means to achieve some level of parity as we work toward interoperability across the spectrum of care.**

The Common Agreement's Relationship to HIPAA

No EHI Used or Disclosed Outside the United States

ONC seeks public comment on how the *Common Agreement* should handle potential requirements for EHI that may be used or disclosed outside the United States. ONC requests comment on reasonable applicability of similar limitations to preserve the security and privacy of EHI sent, stored, maintained, or used by Participants and Participant Members while also preserving the rights of each individual with respect to that EHI.

ONC notes that the *Minimum Required Terms & Conditions* as drafted currently do not permit QHINs to use or disclose EHI outside the United States, “except to the extent that an individual user requests his or her EHI to be used or disclosed outside of the United States.” NASL’s membership includes health IT developers that are based outside of the United States and provide EHRs for both US companies and international clients. Because providers treating Americans who are stationed overseas, traveling abroad or who live along our nation’s borders may need to access their patient’s health information, NASL does not believe it is reasonable to expect that EHI would not be used outside of the United States.

The healthcare industry has embraced cloud-based technology and the use of Software as a Service (“SaaS”) for creating and maintaining patient health records. Cloud-based software allows for any software updates to be applied automatically for all users of the software, eliminating the need for each clinician or facility to install updates manually. In addition, SaaS providers of EHR systems may use cloud-based storage to protect the live databases where EHI is stored and to back up data for disaster recovery purposes, thereby ensuring as little disruption as possible, to assist providers in meeting their continuity of care responsibilities. Beyond using cloud-based technology, many US companies also maintain operations outside of our nation’s borders. **NASL requests clarification from ONC as to why the MRTCs have a US-only geographic limitation on the location for storing, accessing or disclosing EHI.**

Given the focus on provider to provider exchange, NASL recommends that ONC focus on ensuring the proper encryption and other technical, physical and administrative safeguards are in place to protect the privacy and security of patients’ health data wherever it is stored, maintained or accessed, to include the cloud. Regardless of its location, EHI storage and maintenance should comply with federal and state laws.

Appendix 1: The Trusted Exchange Framework (TEF) – Draft 2

ONC outlines a common set of six principles designed to facilitate trust between health information networks. These principles serve as the “rules of the road” for nationwide electronic health information exchange.

NASL supports adherence to five of the six principles, to include: Principle 1 – Standardization; Principle 2 – Transparency; Principle 3 – Cooperation & Non-Discrimination; Principle 4 – Privacy, Security & Patient Safety; and Principle 5 – Access.

Principle 6 – Population Level Data is not a trust component, but rather a type of exchange. While we support the goal of being able to “exchange multiple records for a cohort of individuals at one time in accordance with applicable law to enable identification and trending of data to lower the cost of care and improve the health of the population,” it is not a component of trust. **NASL recommends that ONC remove Principle 6 – Population Level Data from the list of principles and include population data exchange in the discussion of exchange modalities in *TEFCA Draft 2*.**

Appendix 3: Qualified Health Information Network (QHIN) Technical Framework – Draft 1

Appendix 3 – 3 Functions & Technology to Support Exchange

...The QTF outlines the high-level technical function(s) that QHINs must support and [ONC] seeks comment on which standards the QTF should specify for implementation.

The QTF outlines a process for onboarding that identifies a cohort of QHINs that is required to work on exchanging data with each other. We expect that this process will work well in the initial stages of TEFCA when multiple health information networks (HINs) are expected to apply for QHIN status. We also anticipate that adjustments to this process may be necessary when later QHIN applications are received when no cohort is available to perform the exchange testing function. NASL recommends that ONC consider whether it will identify existing QHINs to serve that function or how the onboarding process can be adapted after initial implementation of TEFCA.

Appendix 3 – Secure Channel

ONC Request for Comment #1:

Should the QTF specify additional standards or approaches for securing QHIN Exchange Network transactions (e.g., OASIS Web Services Security)?

The QTF should consider the current standards available from Standards Development Organizations such as Health Level-7 (HL7). The QTF should specify security standards that are consistent with HL7's requirements for use of its FHIR standard. NASL recommends that ONC look at the server security and other standards required by existing exchange networks such as Carequality and CommonWell that already require the use of TLS 1.2 along with specific allowed/disallowed cipher suites, among other server security best practices.

Appendix 3 – User Authentication

ONC Request for Comment #2:

What specific elements should a SAML assertion for User Authentication include?

A SAML token includes information with regard to who is submitting a request, which is tracked for audit purposes. The process for determining the release of information to clinicians operating within a hospital or other trusted exchange partner is well understood. We would have concerns with regard to releasing information at the patient level given the current challenges with patient identification, consent and authentication. **NASL recommends that ONC focus initially on the provider-to-provider exchange.**

Appendix 3 – Query

ONC Request for Comment #4:

The Query function above describes a general workflow and set of capabilities for QHINs conducting query-based, inter-network document exchange. However, implementations may vary and result in divergence from the basic workflow. For example, a QHIN might fail to definitively resolve patient identity and consequently rely on a participant or Participant Member to determine the correct match. Likewise, Carequality's Query-Based Document Exchange Implementation Guide describes a number of alternate flows based on a "nominal flow." To inform subsequent work with the RCE to develop more specific technical guidance to address variation, comments are requested on the basic function presented and potential variations to consider.

Currently, exchange networks are conducting query-based, inter-network document exchange similar to what ONC has described the QHINs would conduct. Given the recent proposed rules, which center on payer and patient access to health information, **NASL requests clarification with regard to how ONC plans to develop and implement TEFCA over time.** Specifically, we are interested in the sequence and timelines around TEFCA as it relates to proposals from CMS and ONC on interoperability and information blocking.

NASL recommends ONC take a phased-in approach where provider to provider exchange is the first priority, followed by payer to provider exchange. Individual access and participation in TEFCA would introduce complexities due to the issues with patient identification and matching discussed in detail in our June 3, 2019 comments to ONC.

NASL requests more technical information with regard to how FHIR APIs would function within TEFCA, as well as how such APIs would meet HIPAA compliance. We also believe that individual participation in TEFCA is likely to raise provider burden as patients seek input from their providers with regard to accessing their health information.

Appendix 3 – Patient Identity Resolution

ONC Request for Comment #7:

The IHE XCPD profile only requires a minimal set of demographic information (*i.e.*, name and birth date/time). Should QHINs use a broader set of specified patient demographic elements to resolve patient identity? What elements should comprise such a set?

NASL views patient identity management as a significant challenge – both within an organization that must maintain a system for merging, purging and updating patient records, as well as externally in working with other organizations that maintain records for the same patients. Because the challenges around patient identity management are so substantial and extend well beyond resolution of patient identity within TEFCA, NASL believes that addressing patient identity management warrants a separate effort.

In the interim, NASL recommends that ONC consider best practice recommendations, review confidence level strategies and institute more granular standards for items within the US Core Data for Interoperability (USCDI). For example, demographics listing a patient’s address should reference the United States Postal Service (USPS) standards. **NASL recommends that ONC work with CMS to identify an abbreviated list of data elements that have been associated with Medicare claims rejections such as misspelling of surnames. We further recommend that ONC work with an industry workgroup to identify standards that may be used to address patient identification issues within TEFCA.**

ONC Request for Comment #9:

Different communities tolerate different degrees of risk with respect to accurately matching patient identities. Should QHINs meet a minimum performance standard (*e.g.*, a minimum acceptable matching accuracy rate) over a specified time period? Likewise, different algorithmic techniques for matching patient identities use different approaches and must be tuned to the applicable patient population and continuously refined over time. Should QHINs measure and report on the performance of the algorithm(s) they rely on (*e.g.*, by calculating precision, recall, etc.)?

NASL recommends that ONC consider the use of a patient’s Medicare, Medicaid or insurance number as a means for improving patient identification. Recent legislation in the U.S. House of Representatives has given new hope that Congress may eliminate the longstanding ban on the use of federal funding for work related to development of a National Patient Identifier. NASL appreciates the security concerns with regard having a single means for patient identification; however, we are equally concerned about the challenges of patient identification in the absence of a national public-private effort to address this issue.

Appendix 3 – Record Location

ONC Request for Comment #10:

Recognizing there are different ways to implement Record Location services, should the QTF specify a single standardized approach across QHINs?

TEFCA Draft 2 eliminated the Connectivity Broke service. NASL does not see a need to specify a standard for use across QHINs, so long as there is no delay in processing QHIN to QHIN data exchange.

Appendix 3 – Directory Services

ONC Request for Comment #11:

Should the QTF require QHINs to implement Directory Services? Recognizing there are many possible approaches for implementing Directory Services, should the QTF specify a single standardized approach? If QHINs implement Directory Services, which entities should be included in directories? Should directories be made publicly accessible?

The QTF should not require QHINs to implement Directory Services. Instead, the ONC and RCE should publish records of who is participating in TEFCA, effectively creating a single directory that TEFCA participants can reference to facilitate more targeted queries that limit the overall resources needed to process queries across TEFCA. In accordance with Section 4003 of the *21st Century Cures Act*, CMS now captures providers digital contact information in its National Plan & Provider Enumeration System (NPPEs) and that is made available through a common directory. That directory should be accessible to ONC and RCE in creation of a single TEFCA directory, which would eliminate the need for QHINs to implement duplicative directory services.

Appendix 3 – Individual Privacy Preferences

ONC Request for Comment #13:

In addition to enabling Meaningful Choice, the Common Agreement requires QHINs to collect other information about an Individual's privacy preferences such as consent, approval, or other documentation when required by Applicable Law. Should the QTF specify a function to support the exchange of such information through the QHIN Exchange Network? Which standards and/or approaches should the QTF specify for this function?

Patient consent is a major concern that has both technical and legal complications. TEFCA serves an important function in providing the infrastructure for Covered Entities and Business Associates to share patient data. In our recent comments to CMS and ONC, NASL recommended that Covered Entities and Business Associates participating in TEFCA be protected from allegations of *HIPAA* violations when they engage in such data sharing. NASL reiterates our recommendation that CMS or HHS' Office for Civil Rights (OCR) develop a standardized data sharing, patient

consent form that providers and health IT vendors can use to ensure appropriate consent for data sharing is given by the patient. We also recommend that CMS expand or clarify both the exclusions and risk assessment factors listed in 45 CFR §164.402 and the granularity required by 45 CFR §164.502's minimum necessary rule. Such standardization from HHS would further NASL members' work on existing consent to share initiatives and serve as a key resource for participants in TEFCA. NASL believes that having a specific consent form that can be used across systems, and across TEFCA, would facilitate patient-directed exchange that is supported by federal and State law.

Appendix 3 – Auditing

ONC Request for Comment #14:

QHINs may participate in a variety of activities and transactions involving First Degree Entities and/or internal operations, including receiving and processing Query and Message Delivery Solicitations, performing Patient Identity Resolution, performing Record Location, sending EHI, receiving EHI, performing queries, granting/revoking access credentials, etc. Future versions of the QTF may specify a list of events a QHIN must record involving First Degree Entities and/or internal operations. Which activities and transactions should the QTF specify as auditable events? What information should the QHIN record about each event?

The QTF should require QHIN audit logs to capture specific aspects of an auditable event: when and what information was requested, who requested the information, what information was released or made accessible and with whom the information was shared/released/accessed.

Appendix 3 – Error Handling

ONC Request for Comment #15:

Should the QTF specify a consistent set of error messages for interactions between QHINs? Which error messages should the QTF specify? Should the QTF specify a consistent format for error messages?

All standards proposed for use by QHINs already have defined error messages by IHE (QHIN to QHIN). We do not need to define additional error messages, but rather point to these standards. QHINs should be required to use and understand error messages sent from another user of TEFCA. In order to ensure consistent understanding and communication across QHINs, the RCE should resolve any potential errors that have yet to be defined. This same approach should apply to error messages between QHINs and First Degree participants. Error messages should use standards as defined. If First Degree participants are using the FHIR standard, for example, FHIR-generated error messages cannot be understood by XCA standards used by QHINs. So, error messages returned by FHIR users must be translated to the appropriate XCA error messages. Many QHINs are capable of such translation of standards/ messages; nonetheless, First Degree participants should be made aware of the dichotomies between these standards.

Conclusion

NASL appreciates the opportunity to share the views of its members on the Trusted Exchange Framework & Common Agreement. We welcome additional dialogue and stand ready to work with ONC on the integration of LTPAC into trusted exchange. Should you have any questions or need additional information, please do not hesitate to contact NASL by calling our offices at 202.803.2385 or by emailing Cynthia@NASL.org.

Sincerely,

A handwritten signature in black ink that reads "Cynthia Morton". The signature is written in a cursive style with a large initial "C".

Cynthia Morton, MPA
Executive Vice President