February 20, 2018

Dr. Don Rucker
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

DELIVERED ELECTRONICALLY

RE: Comments on the draft, "Trusted Exchange Framework and Common Agreement" (TEFCA) published on January 5, 2018

Dear Coordinator Rucker:

I am submitting the attached comments on behalf of the American Clinical Laboratory Association (ACLA) in response to the draft, "Trusted Exchange Framework and Common Agreement" (TEFCA) published on January 5, 2018.

ACLA is a not-for-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, ESRD, hospital and nursing home laboratories. The clinical laboratory industry employs nearly 277,000 people directly and generates over 115,000 additional jobs in supplier industries. Clinical laboratories are at the forefront of personalized medicine, driving diagnostic innovation and contributing more than $100 billion to the nation's economy.

ACLA appreciates the opportunity to comment on the draft TEFCA. If there are any questions regarding the above comments, please do not hesitate to contact us by phone at (202) 637-9466 or via e-mail at tsparkman@acla.com.

Sincerely,

Thomas B Sparkman, RPh, MPP, JD
Vice President, Government Relations

ATTACHMENT: ACLA Comments

Comment Item: A User's Guide to Understanding The Draft Trusted Exchange Framework **A User's Guide to Understanding the Draft Trusted Exchange Framework**	
Slide #	**Comment**
7	**Text:** **TECHNOLOGY DEVELOPERS** Organizations that provide health IT capabilities, including but not limited to electronic health records, health information exchange (HIE) technology, analytics products, laboratory information systems, personal health records, Qualified Clinical Data Registries (QCDRs), registries, pharmacy systems, mobile technology, and other technology that provides health IT capabilities and services **Comment:** The phrase "laboratory information systems" (LIS) may create expectation that labs must become a Qualified Health Information Network (QHIN) and submit results directly to the TEFCA network. Please clarify that referencing LIS in the list of technology developers is not meant to imply that LIS must additionally report results to the TEFCA network and/or replace existing interfaces reporting to EHR Systems established under the EHR Incentive/Meaningful Use Programs, such as the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (a.k.a "ELR IG") and the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – US Realm (a.k.a "LRI IG")

Comment Item: Draft U.S. Core Data for Interoperability (USCDI) and Proposed Expansion Process **Draft U.S. Core Data for Interoperability (USCDI) and proposed expansion process**	
Page #	**Comment**
3	**Text:** The Cures Act sets an expectation that all of a patient's health information that is stored electronically will be able to be exchanged. This expectation requires that the industry collectively work towards defining the data that needs to be exchangeable, prioritizing the development of technical standards and implementation guidance to support the exchange of such data, and, ultimately, implementing those capabilities in health IT at the point of care. **Comment:** The statement that 'all of a patient's health information' will be able to be exchanged should include an additional notation to incorporate jurisdictional restrictions and patient sharing preferences. However, we do agree that Patient's should have access to all their own information. The phrase "point of care" may create expectations that laboratories must become a Qualified Health Information Network (QHIN) and submit laboratory results directly to the TEFCA network.

Comment Item: Draft U.S. Core Data for Interoperability (USCDI) and Proposed Expansion Process **Draft U.S. Core Data for Interoperability (USCDI) and proposed expansion process**	
Page #	**Comment**
	Laboratories often deal with patient specimens and not directly with the patient, but may also have facilities dealing directly with patients by collecting specimens to perform laboratory tests. The results of the test(s) are reported to the patient's provider's EHR system, ideally using the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – US Realm (a.k.a "LRI IG") cited in ONC's 2014 Edition Certification. Please clarify that referencing "point of care" is not meant to imply that laboratories must additionally report to the TEFCA network and/or replace existing reporting to EHR Systems established under the Meaningful Use Programs (for example the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (a.k.a "ELR IG") and the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – US Realm (a.k.a "LRI IG").
11	**Text:** **Data Class:** Veteran's Status/Military History **Description:** Indicates the current or former military service of the individual. This may be included with employment status and history or captured separately. **Are technical specifications available?** No. Does Not Exist **Comment:** There are definitions for Veterans Military Status and additional related attributes in the HL7 Version 2.8.2 standard, Chapters 3 and 6 that may inform ONC's technical specifications. Additionally, requirements to make military personnel anonymous in electronic data should be considered. **Excerpt below from Chapter 3, HL7 V2.8.2, PID - Patient Identification Segment:** 3.3.2.27 PID-27 Veterans Military Status (CWE) 00130 Components: <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^ <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second Alternate Value Set Version ID (DTM)> Definition: This field contains the military status assigned to a veteran. Refer to *User-defined Table 0172 - Veterans Military Status* in Chapter 2C, Code Tables, for suggested values.

Comment Item: Draft U.S. Core Data for Interoperability (USCDI) and Proposed Expansion Process **Draft U.S. Core Data for Interoperability (USCDI) and proposed expansion process**	
Page #	**Comment**
	Excerpt below from Chapter 6, HL7 V2.8.2, IN2 - Insurance Additional Information Segment: 9 XPN O Y 00480 Military Sponsor Name 10 20= ST O 00481 Military ID Number 11 CWE O 0342 00482 Dependent Of Military Recipient 12 25= ST O 00483 Military Organization 13 25= ST O 00484 Military Station 14 CWE O 0140 00485 Military Service 15 CWE O 0141 00486 Military Rank/Grade 16 CWE O 0142 00487 Military Status 17 DT O 00488 Military Retire Date 18 1..1 ID O 0136 00489 Military Non-Avail Cert On File
12	**Text:** **Data Class:** Travel Status/History **Description:** Travel history (any travel, foreign and domestic) and dates of travel. It could also include future travel. **Are technical specifications available?** No. Does not exist **Comment:** LOINC 8691-8 History of Travel is available and has been published in the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework R2, DSTU Release 2 - US Realm.

Comment Item: DRAFT TRUSTED EXCHANGE FRAMEWORK **Draft Trusted Exchange Framework**	
Page	**Comment**
2	**Text:** Table of Contents **Comment:** The adobe bookmarks are great for navigation within Adobe, but for those who might print the document, it would be helpful to display comparable level of detail, for example Part B has 10 sub-levels not included in the current table of “CONTENTS”.
Multiple	**Text:** Example Page 5: “45 C.F.R. 164.504(e)”

Comment Item: DRAFT TRUSTED EXCHANGE FRAMEWORK **Draft Trusted Exchange Framework**	
Page	**Comment**
	Comment: It appears a google search will find the referenced item on "gop.gov" per hyperlink example below, along with multiple other non-federal references (about 15,000 results for search term above). If possible, it would be helpful for ONC to add a hyperlink for all definitive sources for referenced artifacts throughout the document, or in Appendix. https://www.gpo.gov/fdsys/pkg/CFR-2011-title45-vol1/pdf/CFR-2011-title45-vol1-sec164-504.pdf Or, alternatively add generic hyperlink to GPO.gov for search: https://www.gpo.gov/fdsys/search/home.action
7	**Text:** While we applaud the progress made to date and the hard work each organization has contributed to move the industry forward, additional and faster progress must be made; this is particularly true in the case of medical specialties—such as long-term services and supports (LTSS) providing post-acute care or in lieu of institutionalization, behavioral health, and other ambulatory services. Continuing with the status quo will not be enough to ensure these stakeholders have efficient methods for engaging in health information exchange. The Trusted Exchange Framework's minimum set of policies, procedures, and technical standards are intended to advance interoperability, particularly with these stakeholders, and enable them to use HINs to support the many use cases that are important to them and their patients (clients), including the exchange of data for Treatment, Payment, Health Care Operations (TPO), Individual Access, Public Health, and Benefits Determination. We believe that the proposed Trusted Exchange Framework supports the interoperability goal of reliable information flowing to enable communication among services that make use of Electronic Health Information, ultimately providing stakeholders with greater choice. **Comment:** The phrase "Public Health" may create an expectation that labs must become a Qualified Health Information Network (QHIN) and submit laboratory results directly to the TEFCA network. Please clarify that referencing "Public Health" is not meant to imply that laboratories must additionally report to the TEFCA network and/or replace existing interfaces reporting to EHR Systems established under the EHR Incentive/Meaningful Use Programs, such as the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (a.k.a "ELR IG").
7-8	**Text:** In an effort to develop and support a trusted exchange framework for trusted policies and practices and for a common agreement for the exchange between HINs, the proposed Trusted Exchange Framework supports four important outcomes:

Comment Item: DRAFT TRUSTED EXCHANGE FRAMEWORK **Draft Trusted Exchange Framework**	
Page	**Comment**
	1) providers can access health information about their patients, regardless of where the patient received care; 2) patients can access their health information electronically without any special effort; 3) providers and payer organizations accountable for managing benefits and the health of populations can receive necessary and appropriate information on a group of individuals without having to access one record at a time (Population Level Data),[17] which would allow them to analyze population health trends, outcomes, and costs; identify at-risk populations; and track progress on quality improvement initiatives; and 4) the health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation to make health information more accessible and to improve electronic health record (EHR) usability[1]. All four of these outcomes shall be accomplished in compliance with applicable HIPAA Rules' requirements. In addition, the Trusted Exchange Framework focuses on broadly applicable use cases that are discussed further below. The use cases identified are structured to address the areas of greatest need while also allowing existing HINs and trust frameworks to vary as appropriate to meet more specialized use cases that are specific to their own Participants. We believe that this approach will significantly reduce the need for multiple point-to-point interfaces. As stakeholders noted during the public comment process, these interfaces are costly, complex to create and maintain, and an inefficient use of provider and health IT developer resources. It should be noted that while the Trusted Exchange Framework is structured to create a single "on-ramp" for the most common exchange use cases, it does not prevent organizations from creating point-to-point or one-off agreements between organizations who have a particular business need to exchange data in a manner that is different from the minimum set of policies, procedures, and technical standards outlined in the Trusted Exchange Framework, provided that such agreements do not undermine the policies of the Trusted Exchange Framework[2]. **Comment:** Since this section references "…significantly reduce the need for multiple point-to-point interfaces…" and "…most common exchange use cases…" please clarify that these statements do not impact existing laboratory results work flows already established under prior EHR

[1] [18] Under Section 4002 of the Cures Act, the Secretary is required under rulemaking to publish application programming interfaces that allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards, as provided for under Applicable Law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws.

[2] [19] The HIPAA Privacy Rule generally requires Covered Entities to take reasonable steps to limit the use or disclosure of, and requests for, protected health information to the minimum necessary to accomplish the intended purpose unless an exception applies such as for treatment purposes. In certain circumstances, the HIPAA Privacy Rule permits a Covered Entity to rely on the judgment of the party requesting the disclosure as to the minimum amount of information that is needed. Such reliance must be reasonable under the particular circumstances of the request. This reliance is permitted when the request is made by: a public official or agency who states that the information requested is the minimum necessary for a purpose permitted under 45 C.F.R. §164.512 of the Rule, such as for public health purposes (45 C.F.R. §164.512(b)), another Covered Entity or a professional who is a workforce member or Business Associate of the Covered Entity holding the information and who states that the information requested is the minimum necessary for the stated purpose. See generally, 45 C.F.R. §164.502 and 45 C.F.R. §164. 514.

Comment Item: DRAFT TRUSTED EXCHANGE FRAMEWORK **Draft Trusted Exchange Framework**	
Page	**Comment**
	Incentive/Meaningful Use programs. Laboratories are required to provide laboratory results directly to the patient's provider(s) by the Clinical Laboratory Improvement Amendments (CLIA). Additionally requiring laboratories to sending an extra copy of the lab result through a QHIN means that there are multiple copies of the patient's protected health information (PHI) being circulated through these various repositories, which obviously has a multiplier effect on potential data or security breaches. Duplicate copies of laboratory results could unintentionally skew result analysis. Also, laboratories may result interim and/or corrected results causing multiple results to the QHIN. Any network API/queries must be sophisticated enough to filter for the proper combination of results for the patient.
15-16	**Text:** **B. Implement technology in a manner that makes it easy to use and that allows others to connect to data sources, innovate, and use data to support better, more person-centered care, smarter spending, and healthier people.** Qualified HINs should use standards-based technology for exchanging Electronic Health Information with other Qualified HINs. Such technology should be implemented in accordance with standards and, as consistently as possible, follow implementation guides and authoritative best practices published by the applicable standards development organization (SDO). Minimizing variation in how standards are implemented will make it easier for others to connect to Electronic Health Information. Further, to the extent possible, Electronic Health Information stored in health IT products should be structured and coded using standardized vocabularies. Qualified HINs and their participants should provide accurate translation and adapter services to their End Users to enable them to map proprietary data to standard, user friendly vocabularies. Adapter services are designed to transform message content or, in this context, transform unstructured data to structured and coded vocabularies, so that Qualified HINs can exchange data with other Qualified HINs in a standardized format. Qualified HINs should ensure that the data exchanged within their own network and with other Qualified HINs meets minimum quality standards by using testing and onboarding programs to verify minimum quality levels. Qualified HINs may consider using open source tools, such as ONC's C-CDA scorecard tool for testing the quality of C-CDAs. They may also consider developing tools to test the quality of data exchange using Fast Healthcare Interoperability Resources (FHIR) APIs. These types of testing programs can help ensure that high quality data is exchanged both within and across HINs **Comment:** Please address considerations within the Qualified HIN (QHIN) to support non-standard vocabularies which could be pending assignment within the various terminology standard bodies. For example, LOINC currently only publishes twice a year.
25	**Text:** None, missing definition (acronym)

Comment Item: DRAFT TRUSTED EXCHANGE FRAMEWORK **Draft Trusted Exchange Framework**	
Page	**Comment**
	Comment: **A**dd **FIPS:** U.S. Federal Information Processing Standard
26	**Text:** HL7: Health Level Seven International, a standards developing organization. **Comment:** Suggest adding statement re: HL7's ANSI accreditation. HL7: Health Level Seven International, a standards developing organization accredited by the American National Standards Institute (ANSI).
27	**Text:** Participant: a person or an entity that participates in a Health Information Network that is a Qualified HIN. Without limitation of the foregoing, a health information exchange could be a Participant with respect to a Qualified HIN. **Comment:** Please clarify the second sentence, it seems overly legalistic and the meaning is not clear.
28	**Text:** Qualified HIN: a Health Information Network that meets the following criteria and has agreed to the Common Agreement including the terms and conditions set forth herein : (a) Is an entity that provides the ability to locate and transmit EHI between multiple persons and/or entities electronically, on demand or pursuant to one or more automated processes; (b) Controls and utilizes a Connectivity Broker service for all EHI exchange subject to the Common Agreement; (c) Is Participant neutral, meaning that none of the exchanges of EHI by or on behalf of the Qualified HIN include the Qualified HIN itself (whether directly or indirectly) as one of the parties except to the extent that the Qualified HIN receives and maintains such EHI as part of a repository it maintains as a Health Information Network but does not Use or Disclose it except to the extent permitted as a Business Associate under the HIPAA Regulations and other Applicable Law; (d) Has Participants that are actively exchanging EHI in the data classes included in the then Current USCDI in a live clinical environment in accordance with Section 3 and Section 6 below; and (e) Demonstrates that it has mechanisms in place, whether by contract or otherwise, (1) to impose all of the Participant Obligations on all Participants who provide or have access to any of the Health Information Network's services; and (2) whether directly or indirectly, to audit Participants' compliance with all relevant obligations and provide for appropriate remedial action (up to and including exclusion) against any Participant that fails to comply with the same.

Comment Item: DRAFT TRUSTED EXCHANGE FRAMEWORK **Draft Trusted Exchange Framework**	
Page	**Comment**
	Comment: Section 3 and Section 6 are not "below" in Part 1 Definitions, suggest adding hyperlink, or at minimum the title of the section referred to, e.g. 3. Standardization and 6. Privacy, Security, and Patient Safety in Part B, *or* 2.3 Mandatory Updating of the USCDI and 2.6 Completion of Onboarding Requirements under 2. Requirements of Qualified HINs?
29	**Text:** Record Locator Service (RLS): a service that provides the ability to identify where records are located based upon criteria such as an individual's demographic data and/or record data type, as well as providing functionality for the ongoing maintenance of this location information. **Comment:** The HL7 January 2018 HL7 Ballot of the US Core Implementation Guide[3], references StructureDefinition for Patient.gender which has a very ambiguous comment > The gender may not match the biological sex as determined by genetics, or the individual's preferred identification. Note that for both humans and particularly animals, there are other legitimate possibilities than M and F, though the vast majority of systems and contexts only support M and F. Systems providing decision support or enforcing business rules should ideally do this on the basis of Observations dealing with the specific gender aspect of interest (anatomical, chromosonal, social, etc.) However, because these observations are infrequently recorded, defaulting to the administrative gender is common practice. Where such defaulting occurs, rule enforcement should allow for the variation between administrative and biological, chromosonal and other gender aspects. For example, an alert about a hysterectomy on a male should be handled as a warning or overrideable error, not a "hard" error. The statement "….However, because these observations are infrequently recorded, defaulting to the administrative gender is common practice" implies it's acceptable to use the same field for both administrative and clinical purposes, in fact the 'Requirements' statement specifies "Gender…drives many clinical processes": > Needed for identification of the individual, in combination with (at least) name and birth date. Gender of individual drives many clinical processes. There is a LOINC code for reporting "Sex assigned at birth" (76689-9); however some states now allow patients to change their birth sex on their birth certificate as reported as a comment on the ONC Interoperability Standards Advisory (ISA 2018)[4].

[3] http://hl7.org/fhir/us/core/2018Jan/StructureDefinition-us-core-patient-definitions.html
[4] ONC 2018 ISA Representing Patient Sex at Birth

Comment Item: DRAFT TRUSTED EXCHANGE FRAMEWORK **Draft Trusted Exchange Framework**	
Page	**Comment**
	It seems that inconsistent use of administrative sex (HL7 V2, PID-8), sex assigned at birth (eDOS Implementation Guide[5] and ONC Interoperability Standards Advisory), administrative gender (HL7 V3 and FHIR), and possibly gender identity which supports male to female transsexual (MTF) and female to male transsexual (FTM) reporting (LOINC 76691-5), etc. may cause an issue matching persons/patients, if multiple values are supported in the same field. For example if "Mary Smith" has 5 historical laboratory results with administrative sex (V2) or administrative gender (V3 or FHIR) reported as "F" or "Female", but the same person also has 3 historical laboratory results with administrative gender reported as "UNK" (per ONC 2015 Edition Certification which might be used for a transgender patient), those results might not be associated in a RLS or query for "Mary Smith's" laboratory results. The American Clinical Laboratory Association (ACLA) is working on a "best practice" recommendation to present to ONC, since some laboratory results values are dependent on accurate reporting of the patient's "biological or chromosomal" sex to the laboratory. "Unknown" sex/gender could impact patient safety. For example, abnormal results would not be flagged as high, low, critical in the laboratory result; some laboratory testing is gender specific causing additional burden for the provider to interpret multiple results.

[5] HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework (eDOS), R2, STU Release 3 - US Realm ballot 2017, pending publication