June 14, 2019

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 Draft 2" (TEFCA) and "A User's Guide to Understanding the Trusted Exchange Framework and Common Agreement (TEFCA)Draft 2" published on April 19, 2019.

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 Draft 2" (TEFCA) and "A User's Guide to Understanding the Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2" published on April 19, 2019.

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 Draft 2 and User's Guide to Understanding the TEFCA Draft 2. 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 jkegerize@acla.com.

Sincerely,

Joan Kegerize, JD
Vice President, Reimbursement and Scientific Affairs

ATTACHMENT: ACLA Comments

Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2

Comment Item: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2	
Page	**Comment**
n/a	**Text:** N/A, general comment **Comment:** Please clarify that existing point-point interfaces, such as those developed to meet ONC Edition 2014 EHR certification for laboratory results, do not need to be replaced in order to comply with TEFCA requirements. Additionally, references to "**all** EHI" in the Qualified Health Information Network (QHIN) may create expectation that laboratories will send a copy of patient's laboratory results directly to a QHIN. We do not concur with this assumption, since, given existing ONC use cases for laboratory results, the patient's result is sent to the patient's provider's EHR system. The EHR system should forward patient data to the QHIN. The phrase "laboratory information systems" may create expectation that laboratory providers must become a Qualified Health Information Network (QHIN) and submit laboratory results directly to the TEFCA network. We believe that "laboratory information systems" used internally by laboratory providers should not be mandated to participate in QHINs, since they are reporting laboratory results directly to the provider's EHR system. Laboratory providers, and their information systems, are subject to CLIA accreditation but are not mandated to comply with ONC EHR certification. The CLIA certified laboratory result information is available from the provider's EHR system. Duplicate copies of laboratory results (received from multiple sources e.g. if received from the laboratory and the provider's EHR system) could unintentionally skew result analysis and patient safety. As a laboratory provider, we are concerned QHINs must be able to manage laboratory result status life cycle 'amalgamation' to properly support the accurate interpretation of laboratory result status terminology in order to manage, the patient's results. For example, a final result replaces a preliminary result; a corrected result replaces a final result, results can be appended or amended, etc.
2	**Text:** Table of Contents **Comment:** The adobe bookmarks are great for navigation within Adobe, but it would be helpful to have a full table of contents (TOC) in the front of the document; currently you have TOC on pages 2, 3, 24, 32, and 70.
5	**Text:** Under the MRTCs Draft 2, the Common Agreement will require strong privacy and security protections for all entities who elect to participate, including entities not covered by the Health Insurance Portability and Accountability Act (HIPAA). Establishing baseline privacy and security requirements is important for building and maintaining confidence and trust that EHI shared pursuant to the Common Agreement will be appropriately protected. **Comment:** We encourage ONC's approach to apply strong privacy and security requirements to all participants. However, since the Common Agreement is not yet published; we appreciate ONC's plan for a public comment review period currently targeted for 2020.
8	**Text:** The TEF and the Common Agreement are distinct components that aim to create a technical and legal infrastructure for broadly sharing EHI across disparate HINs to enable nationwide data exchange. ONC will maintain the TEF and will work with an industry-based Recognized Coordinating Entity (RCE) to develop, update, implement, and maintain the Common Agreement. The RCE will establish a process to continuously identify new standards and use cases to add to the Common Agreement and will convene virtual public listening sessions to allow the industry to provide objective and transparent feedback around the development of updates to the Common Agreement. ONC will have final approval of the Common Agreement and all subsequent updates. **Comment:** There should be a process to provide comments on proposed new standards and use cases in addition to (or in place of) public listening sessions. This could be fashioned after ballot process used by standards development organizations such as HL7. If listening sessions are the only alternative permitted, how will ONC insure that all facets of healthcare industry have opportunity to participate? We suggest that ONC ensure that laboratory industry is included.

Comment Item: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2	
Page	**Comment**
9	**Text:** To support the Cures Act's goal of advancing health information exchange among health information networks, the TEF creates a common set of principles that are designed to facilitate trust between HINs and by which all HINs should abide in order to enable widespread data exchange. These principles are standardization; transparency; cooperation and non-discrimination; privacy, security, and patient safety; access; and data driven accountability. These principles are non-binding, but are the foundational concepts that guide the development of the Common Agreement to support the ability of stakeholders to access, exchange, and use relevant EHI across disparate HINs and sharing arrangements. **Comment:** Why are these principles non-binding; we suggest they should be binding especially since privacy, security and patient safety require accountability.
9	**Text:** **Qualified Health Information Network (QHIN) Technical Framework (QTF):**11 Commenters, including the HITAC recommended that ONC refrain from naming particular standards or implementation mechanisms in the Common Agreement. To that end, the RCE will work with ONC to develop the QTF, which will be incorporated by reference in the Common Agreement. Where the Common Agreement will include and detail the underlying policies and expectations for exchange among QHINs, the QTF will focus on the technical components for exchange among QHINs, including, but not limited to identity proofing and authentication, and utilization of Connectivity Services. ONC developed the QTF Draft 1 and will work with the RCE and external stakeholders to modify and update Draft 1 per public comment. **Comment:** Please clarify further. The Qualified Health Information Network (QHIN) Technical Framework (QTF) **does not** include standards, how/where are standards named? Additionally, references to many different artifacts as sources can be confusing and potentially be out of synch. See page 26, Section A.
10	**Text:** **Structure of the Trusted Exchange Framework and the Common Agreement** The TEF and the Common Agreement follow a "network of networks" structure, which allows for multiple points of entry and is inclusive of many different types of health care stakeholders. Such stakeholders include, but are not limited to: • Health information networks • Health information exchanges • Individuals • Providers • Federal agencies • Public health agencies • Health plans and other payers • Health IT developers Stakeholders have the option of fulfilling the responsibilities for and participating as a QHIN, a Participant, a Participant Member, or an Individual User, each of which is explained in more detail below. **Comment:** The phrase "Public health agencies" may create an expectation that labs must become a Qualified Health Information Network (QHIN) and submit laboratory results directly to the TEFCA network. We recommend that patient laboratory results be rendered to the patient from their ordering/attending provider as their trusted primary health care provider. Please clarify that referencing "Public health agencies" is not meant to imply that commercial 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").
15	**Text:** **The Common Agreement's Relationship to HIPAA** "The Health Insurance Portability and Accountability Act of 1996 (HIPAA)[17] Privacy Rule and HIPAA Security Rule serve as the foundation for federal protection of the privacy and security of most individually identifiable health information.[18] However, the HIPAA Rules apply only to organizations defined in the Rules as Covered Entities and Business Associates." …

Comment Item: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2	
Page	**Comment**
	"In order to meet the goals of the Cures Act as well as to help address these concerns and encourage robust data exchange that will ultimately improve the health of patients, the Common Agreement requires non-HIPAA entities, who elect to participate in exchange, to be bound by certain provisions that align with safeguards of the HIPAA Rules. This will bolster data integrity, confidentiality, and security, which is necessary given the evolving cybersecurity threat landscape." **Comment:** These two statements are contradictory; The last statement is contractually obligating those entities signing the Common Agreement to comply with the same requirements that HIPAA constrains covered entities and BAs. It is up to the party signing the agreement to take on those obligations by signing. Please clarify.
16	**Text:** Participants and Participant Members that are Covered Entities or Business Associates must amend existing Business Associate Agreements (BAAs), or enter into or amend other types of data use agreements to address the mandatory minimum obligations. **Comment:** Please clarify these amendments; it is extremely burdensome to amend multiple BAAs, so sufficient time to deploy is required. Please collaborate with OCR so it is clear OCR and ONC have issued joint guidance.
17	**Text:** Breach Notification Requirements **Comment:** We suggest the HIPAA Breach Notification requirements should be clarified in agreements the Participants and Participant Members are required to sign so they are aware of their responsibility.
18	**Text:** Security Labeling **Comment:** Please clarify that TEFCA requirements do not supersede federal or state laws that may have contradictory requirements, for example 42 CFR Part II requirements.
18	**Text:** Security Labeling … (4th bullet) • At a minimum, such EHI shall be electronically labeled using the confidentiality code set as referenced in the HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 (DS4P IG), Part 1: CDA R2 and Privacy Metadata; and **Comment:** We concur with HL7 comments on ONC's 21st Century Cures proposed rule, e.g. there should be "…a refresh of the current HL7 DS4P CDA IG along with a cross paradigm specification…"
19	**Text:** Major Updates to Draft 2 of the TEF and MRTCs **Comment:** Thank you for providing this concise summary of changes
25	**Text:** HINs should adhere to federally adopted standards for EHI and interoperability. Specifically, HINs should first look to use standards adopted by HHS, then those approved by ONC through the proposed standards version advancement process as part of the ONC Health IT Certification Program (Certification Program), and finally, those identified in the ISA. **Comment:** Emerging standards in the ISA may not yet be ready for implementation. Please clarify by changing to: "those identified in the ISA which have an Implementation Maturity status of 'Production'
25	**Text:** HINs should use standards-based technology to exchange EHI with other HINs. To minimize variation in how standards are implemented, such technology should be implemented in accordance with authoritative best practices published by an applicable standards development organization (SDO). By doing so, it will make it easier for HINs to connect to each other and with their users. **Comment:** What does 'applicable' mean in this context? We recommend ANSI accredited standards SDO when possible?

Comment Item: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2	
Page	**Comment**
26	**Text:** **C. Publish, keep current, and make publicly available the HIN's privacy practices.** **(d)** HINs should provide a method by which individuals can exercise meaningful choice regarding the exchange of EHI about them and ensure that such individual's choice is honored on a prospective basis, consistent with applicable law. **Comment:** Please clarify, is this a centralized 'registry' so the patient only has to complete once, but it is also applicable for any HIN that may have access to the patient's data?
27	**Text:** Likewise, HINs should not implement technology in a manner that limits the sharing of EHI. HINs should practice data reciprocity (e.g., have a willingness to share EHI themselves as opposed to only participating in an exchange relationship only for the purpose of receiving health information from others). In addition, fees and other costs should be reasonable and should not be used to interfere with, prevent, or materially discourage the access, exchange, use, or disclosure of EHI within a HIN or between HINs. **Comment:** **Please clarify what constitutes fees and other costs as 'reasonable'.** For example, the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program proposed rule* specifically provides guidance for such fees and costs*:* Pages 7595-7596 Ensure that fees are based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests. Ensure that fees are not based in any part on whether the requestor or other person is a competitor, potential competitor, or will be using the API technology in a way that facilitates competition with the API Technology Supplier. Permitted fee—Development, deployment, and upgrades. An API Technology Supplier is permitted to charge fees to an API Data Provider to recover the costs reasonably incurred by the API Technology Supplier to develop, deploy, and upgrade API technology for the API Data Provider. (iii) Permitted fee—Supporting API uses for purposes other than patient access. An API Technology Supplier is permitted to charge fees to an API Data Provider to recover the incremental costs reasonably incurred by the API Technology Supplier to support the use of API technology deployed by or on behalf of the API Data Provider. This permitted fee does not include: (A) Any costs incurred by the API Technology Supplier to support uses of the API technology that facilitate a patient's ability to access, exchange, or use their electronic health information; (B) Costs associated with intangible assets (including depreciation or loss of value), except the actual development or acquisition costs of such assets; or (C) Opportunity costs, except for the reasonable forward-looking cost of capital.
28	**Text:** Ensuring the integrity of EHI is paramount to providing safe care. When EHI is exchanged, safe care begins with correctly matching the data to an individual so that care is provided to the right individual based on the right information. Sophisticated algorithms that use demographic data for matching are the primary method for connecting data to an individual. To support accurate matching, HINs should agree upon and consistently share a core set of demographic data each time that EHI is requested. Likewise, participants of HINs should ensure that the core set of demographic data is consistently captured for all individuals so that it can be exchanged in a standard format and used to accurately match data. **Comment:** Should this reference the "Common Clinical Data Set" as guidance of "best practice"? With the network-of-networks approach, who is the trusted source when patient demographics change?
32	**Text:** The Recognized Coordinating Entity (RCE) will combine these MRTCs, as well as Additional Required Terms and Conditions (ARTCs), developed by the RCE and approved by ONC, into a full data sharing agreement known as the Common Agreement with which QHINs may voluntarily agree to be bound. **Comment:** We recommend the Common Agreement 'Plus' including MRTCs, ARTCs should be binding to be an ONC recognized QHIN.
32	**Text:** **1. Definitions** **Comment:**

Comment Item: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2	
Page	**Comment**
	Please keep these definitions in sync with those published in the Final ONC Cures Rule, e.g. if changed in the Final Rule update here. Also add hyperlinks to the "source of truth" for each definition, whether to the ONC Final Rule or other source, especially for regulatory definitions. To improve navigation in the document, can you create each definition 'title' as a bookmarked item so the definitions are easy to find as you read the rest of the document. Bookmarks are extremely helpful in .pdfs. Please provide hyperlink to "source or truth: document; internet search often provides multiple options. Also, please include hyperlink to ONC's source documents.
34	**Text:** For the avoidance of doubt, EHI may be requested, exchanged, retained, aggregated, Used or Disclosed for an Exchange Purpose under Sections 2.2,1, 7.1, 8.1 below only for an Exchange Purpose of a Covered Entity or other health care provider that is acting in accordance with Applicable Law; provided, however, that this requirement shall not apply to Individual Access Services or Benefits Determination. For example: (a) EHI requested for Business Planning and Development may be disclosed and used only for activities conducted by or on behalf of a Covered Entity or other health care provider in accordance with Applicable Law. **Comment:** This should be 2.2.1, not 2.2,1 (change comma preceding '1' to period)
36	**Text:** For purposes of this definition, information in all capital letters shall not be used to satisfy the requirement that the Minimum Information be conspicuous. **Comment:** Instead of stating what doesn't meet your requirement (all caps) why not give examples that do meet "conspicuous format".
35 & 37	**Text:** **Pg. 35 Individual User:** an Individual who exercises his or her right to Individual Access Services using the services of a QHIN, a Participant, or a Participant Member. An Individual User is neither a Participant nor a Participant Member. **Pg. 37 Participant:** a natural person or an entity, regardless of whether the person or entity is a Covered Entity or a Business Associate, that has entered into a Participant-QHIN Agreement to participate in a QHIN. Without limitation of the foregoing, a health information exchange, health IT developer, health care system, payer, or federal agency could each be a Participant. **Pg. 37 Participant Member:** a natural person or entity, regardless of whether the person or entity is a Covered Entity or Business Associate, that has entered into a Participant Member Agreement to use the services of a Participant to send and/or receive EHI, but not an Individual exercising his or her right to Individual Access Services. **Comment:** We suggest that these alternative definitions be used: **Individual User:** A patient, who is the subject of the EHI, or their representative who exercises their right to Individual Access Services using the services of a QHIN, a Participant, or a Participant Member. **Participant:** A person or entity that has entered into a contract to participate in a QHIN. **Participant Member:** A person or entity that has entered into a Participant Member Agreement to use the services of a Participant to send and/or receive EHI.
39	**Text:** 2.1.1 QHIN Application. A HIN that wishes to become a QHIN shall begin the process by first delivering to the RCE a completed QHIN Application. The HIN shall promptly make its personnel available to respond to any reasonable questions that the RCE may have about the QHIN Application and promptly provide such further information and documentation that the RCE may reasonably request to process the QHIN Application. If applicable, the HIN shall also make available information relating to personnel of the HIN's vendors and persons or entities that currently use its network in order to address reasonable requests of the RCE. **Comment:** Suggest you offer timeframe for 'promptly', such as 5 business days? Please give examples of 'reasonable' and 'unreasonable' questions

Comment Item: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2	
Page	**Comment**
39	**Text:** 2.1.2 Timing of Review by RCE. The RCE shall use commercially reasonable efforts to approve or reject each QHIN Application in writing within a stated period after receipt of a completed QHIN Application and all responses to its questions and requests for additional information and documentation, if any, that the RCE has submitted to the HIN. Despite the expiration of the stated period for review by the RCE, a QHIN Application shall not be deemed approved by the RCE unless and until the RCE issues a written notice of approval to the HIN that submitted it. **Comment:** Please clarify "commercially reasonable" Re: "in writing" - is email permitted? Suggest adding hyperlink to 2.1.3 where you state it has to be "certified in writing" Re: "stated period" should this be 30 calendar days?
40	**Text:** 2.1.4 Provisional QHIN Status. Upon the RCE's written approval of a HIN's QHIN Application, the RCE shall use commercially reasonable efforts to promptly provide the HIN with a copy of the Common Agreement for signature by the HIN. The RCE also shall provide the HIN with a copy of the QHIN Technical Framework. The HIN must sign and return the Common Agreement within a stated period after receipt. Upon return to the RCE of the Common Agreement signed by the HIN, the RCE shall promptly sign it, return a fully executed copy to the HIN, and assign the HIN in writing to a Cohort, specifying the applicable Cohort Deadline. Upon the RCE's execution of the Common Agreement, the HIN shall automatically become a Provisional QHIN and continue in such status until it either fails to be Designated by the RCE as a QHIN by the applicable Cohort Deadline; or is terminated by the RCE for material breach of the Common Agreement or failure to be Designated by the RCE. **Comment:** Re: stated period, suggest within 15 business days Re: terminations, Will a list of these 'terminated' "material breach" entities/status be publicly available?
42	**Text:** 2.2.2 Permitted and Future Uses of EHI. Once EHI is received by a QHIN, the recipient QHIN may exchange, retain, aggregate, Use, and Disclose such EHI only in accordance with Applicable Law and only for: (i) one or more of the Exchange Purposes in accordance with the Common Agreement (subject to the restriction below with respect to Individual Access Services); (ii) the proper management and administration of its business and to carry out its legal responsibilities pursuant to the Common Agreement and the BAA, if applicable;… **Comment:** HIPAA permits this, but it is not required. This should be a permissive term, not mandatory.
43	**Text:** 2.2.3 Individual Exercise of Meaningful Choice. Each QHIN shall respect the Individual's exercise of Meaningful Choice by requesting that his or her EHI not be Used or Disclosed by a QHIN unless EHI is required by Applicable Law to be Used or Disclosed by the QHIN. … **Comment:** We believe this "opt out" function may require time to develop the process and IT functionality; please allow sufficient time to deploy before QHINs are activated. This process also has to be coordinated with multiple evolving privacy/security state laws currently under discussion. Any historical data should be purged once the individual invokes Meaningful Choice to request his/her EHI should not be used or disclosed (unless required by applicable law)
43	**Text:** 2.2.3 Individual Exercise of Meaningful Choice. …Each QHIN shall process each exercise of Meaningful Choice from any Individual, or from Participants or Participant Members on behalf of any Individual, and communicate the choice to all other QHINs within five (5) business days after receipt in accordance with the requirements of the QHIN Technical Framework. … **Comment:** We agree that the communication of the individual's Meaningful Choice should be communicated within five (5) business days. However, we suggest this also includes the implementation for all QHINs to exercise

Comment Item: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2	
Page	**Comment**
	the Meaningful Choice from the individual and consider a longer timeline as this requirement could be burdensome to implement.
44	**Text:** (iv) A QHIN is prohibited from requiring the submission of a HIPAA authorization (see 45 CFR 164.508), or a Business Associate Agreement (see 45 CFR 164.504(e)), in order to process a request for Individual Access Services from a Participant who provides Individual Access Services that has been selected by the Individual User who is requesting EHI for Individual Access Services. **Comment:** Please clarify the scenario if a patient is requesting access on behalf of 3rd party, e.g. Apple Health or other health app. If OCR has provided guidance for this scenario please add a hyperlink to the OCR guidance and provide standard 'permission/consent guidance' language for this scenario.
44	**Text:** 2.2.5 Mandatory Updating of Technical Capacity. If the National Coordinator approves a new version of the USCDI; and it is identified in ONC's Interoperability Standards Advisory, after a QHIN has signed the Common Agreement, the QHIN shall technically support the exchange of such new data not more than eighteen (18) months after the date that the new version of the USCDI was approved by the National Coordinator **Comment** Does this mean that USCDI will always be backward and forward compatible? Otherwise how does the QHIN deal with historical data if a subsequent version of the USCDI revises (for example) the data format?
53	**Text:** 7.1 Exchange Purposes and EHI Reciprocity. The following applies in the context of the Participant-QHIN Agreement to which the Participant is a party. All action permitted or required hereunder shall be taken only in accordance with the requirements of the Participant-QHIN Agreement to which the Participant is a party and Applicable Law. For the avoidance of doubt, a new version of the USCDI shall be the "then applicable" USCDI eighteen (18) months after it is approved by the National Coordinator. **Comment** Does this mean that USCDI will always be backward and forward compatible? Otherwise how does the QHIN deal with historical data if a subsequent version of the USCDI revises (for example) the data format?
55	**Text:** 7.3 Individual Exercise of Meaningful Choice. Each Participant shall respect the Individual's exercise of Meaningful Choice by requesting that his or her EHI not be Used or Disclosed by a Participant unless Applicable Law requires the Participant to Use or Disclose the EHI. However, any Individual's EHI that has been Used or Disclosed prior to the Individual's exercise of Meaningful Choice may continue to be Used or Disclosed for an Exchange Purpose. **Comment:** Any historical data should be purged once the individual invokes Meaningful Choice to request his/her EHI should not be used or disclosed (unless required by applicable law)
85	**Text:** 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? **Comment:** We suggest a broader set of data elements should be used for matching. Birth sex is not reliable due to recent changes in state laws permits their residents to change their birth sex. Since these vary regionally additional data elements should be considered for matching.
85	**Text:** 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.)? **Comment:** There must be additional data points for an effective patient matching algorithm; this could vary by region.

Request to add Hyperlinks:

Request to add Hyperlinks:

Comment Item: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2	
Page	**Comment**
Multiple	**Text:** Example footnote page 15: "[16] See 45 CFR 164.501 Definitions **Comment:** A google search will find the referenced item on "gop.gov" per hyperlink example below, along with multiple other non-federal references (about 37,600 results for search term above). Please add a hyperlink for all referenced artifacts throughout the document, https://www.govinfo.gov/content/pkg/CFR-2011-title45-vol1/pdf/CFR-2011-title45-vol1-sec164-501.pdf Or, alternatively add generic hyperlink to GPO.gov for search: https://www.gpo.gov/fdsys/search/home.action
6	**Text:** Footnote 7: Pub. L. 114–255 (Dec 13, 2016). **Comment:** Please provide hyperlink to the Cures Act in final publication https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf
17	**Text:** In addition, as part of its ongoing security risk analysis and risk management program, QHINs shall review the most recently published version of the HIPAA Security Rule Crosswalk to the NIST Cybersecurity Framework. **Comment:** Please add hyperlink to HIPAA Security Rule Crosswalk to NIST Cybersecurity Framework
17	**Text:** This notice should mirror ONC's Model Privacy Notice and include information an explanation of how an Individual can exercise their Meaningful Choice and who they may contact for more information about the entity's privacy practices. **Comment:** Please add hyperlink to ONC's Model Privacy Notice - you provide on page 28 but this is first occurrence in the document: https://www.healthit.gov/sites/default/files/2018modelprivacynotice.pdf
29	**Text:** Footnote 28: See 45 CFR 164.524 **Comment:** Provide hyperlink: https://www.govregs.com/regulations/expand/title45_chapterA_part164_subpartE_section164.524#title45_chapterA_part164_subpartE_section164.524
32	**Text:** 45 CFR § 164.508 45 CFR § 164.402 **Comment:** Please provide hyperlinks
33	**Text:** 45 CFR § 160.103 45 CFR § 164.504(e) **Comment:** Please provide hyperlinks
34	**Text:** 45 CFR § 160.103 45 CFR § 164.404(a)(2) 16 CFR Part 318 **Comment:** Please provide hyperlinks
35	**Text:** 42 U.S.C. § 300gg, 29 U.S.C. § 1181 *et seq.* 42 U.S.C. §1320d *et seq*. 42 U.S.C. § 17921 et seq.

Comment Item: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2	
Page	**Comment**
	45 CFR Parts 160, 162, and 164 45 CFR § 160.103 45 CFR 164.502(g); 45 CFR §164.524(a) 45 CFR §164.524(c)(2) 45 CFR §164.524(c)(3)(ii) 45 CFR Part 171 **Comment:** Please provide hyperlinks
36	**Text:** 45 CFR §164.502(b) and §164.514(d) NIST Special Publication 800-63 NIST Special Publication 800-171 Model Privacy Notice (MPN): **Comment:** Please provide hyperlinks
37	**Text:** ONC's Interoperability Standards Advisory (ISA): **Comment:** Add hyperlink: https://www.healthit.gov/isa/
37	**Text:** Patient Demographic Data Quality (PDDQ) Framework: **Comment:** Add hyperlink: https://www.healthit.gov/playbook/pddq-framework/
37	**Text:** 45 CFR § 160.103 **Comment:** Please provide hyperlink
38	**Text:** 45 CFR §164.512(b) 45 CFR §164.514(e) 45 CFR § 164.501 **Comment:** Please provide hyperlinks
39	**Text:** 45 CFR § 160.103 (2)(v) of the definition of payment at 45 CFR § 164.501 **Comment:** Please provide hyperlinks
43-44	**Text:** 45 CFR § 164.524(c)(3)(ii) 45 CFR 164.508 45 CFR 164.504(e) **Comment:** Please provide hyperlink
46	**Text:** 45 CFR § 164.514(d) 45 CFR § 164.508; or (iv) 45 CFR § 164.512(a) **Comment:** Please provide hyperlinks
48	**Text:** 45 CFR Part 164 Subpart D 45 CFR §164.304 45 CFR 164.412(b)

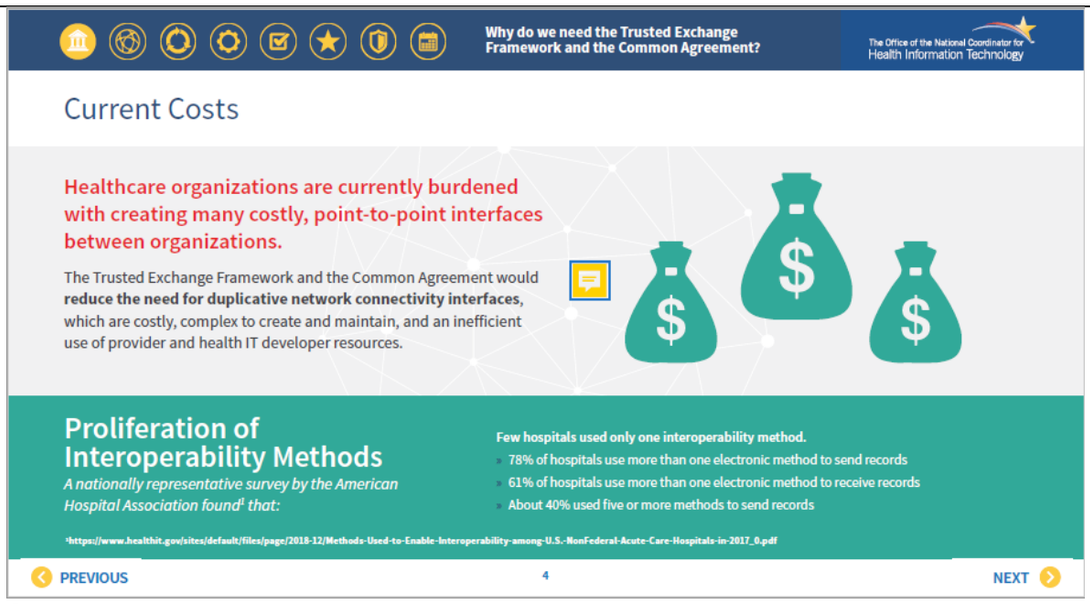
Comment Item: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2	
Page	**Comment**
	Comment: Please provide hyperlinks
49	**Text:** 45 CFR 164.520 **Comment:** Please provide hyperlink
50	**Text:** HIPAA Security Rule Crosswalk NIST Cybersecurity Framework and ONC/OCR HIPAA Security Risk Assessment Tool NIST Special Publication 800-171. **Comment:** Please provide hyperlinks
51	**Text:** IAL2 AAL2 FAL2 **Comment:** Please provide hyperlink to NIST SP 800-63A Digital Identity Guidelines, which identifies IAL2 identity assurance levels: https://pages.nist.gov/800-63-3/sp800-63a.html
67	**Text:** 45 CFR 164.508 **Comment:** Please provide hyperlink

2019 Comments – TEFCA Draft2 User's Guide

Comment Item: A User's Guide to Understanding The Draft Trusted Exchange Framework https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf	
Slide #	**Comment**
N/A	**Text:** N/A, general comment **Comment:** Please clarify that existing point-point interfaces, such as those developed to meet ONC Edition 2014 EHR certification for laboratory results, do not need to be replaced to meet requirements of the Cures Act or TEFCA. Additionally, references to all Electronic Health Information (EHI) existing in the Qualified Health Information Network (QHIN) may create expectation that laboratories will send a copy of patient's laboratory results directly to a QHIN. We do not concur with this assumption, since, given existing ONC use cases for laboratory results, the patient's result is sent to the patient's provider's EHR system. We recommend that patient laboratory results only be rendered to the QHIN from their ordering/attending provider as their primary health care provider. We believe that Laboratory Information Systems (LIS) (e.g. a class of "certain health IT developer") should not be mandated to participate in QHINs, if they are reporting laboratory results to the provider's EHR system. LIS systems, especially those developed by commercial laboratories but not sold commercially, are subject to CLIA accreditation, but are not mandated to comply with ONC EHR certification. We do not view this as "Information Blocking", as the laboratory result information is available from the provider's EHR system. Laboratories may result interim and/or corrected results causing multiple results to the QHIN or other health information exchange. This laboratory result reporting workflow must be supported by QHIN other health information exchange, e.g. they must be sophisticated enough to filter for the proper combination of results for the patient. Additionally, having multiple deliveries of the same data carries with it the additional risk of data breach. The more deliveries of data that you have … the greater the risk of some sort of security incident.

Comment Item: A User's Guide to Understanding The Draft Trusted Exchange Framework https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf	
Slide #	**Comment**
3-4	**Text:** Pg 3 - **Current Proliferation of Agreements** Many organizations have to join multiple Health Information Networks (HINs), and most HINs do not share data with each other. Trusted exchange must be simplified in order to scale. Pg 4 - **Healthcare organizations are currently burdened with creating many costly, point-to-point interfaces between organizations.** The Trusted Exchange Framework and the Common Agreement would reduce the need for duplicative network connectivity interfaces, which are costly, complex to create and maintain, and an inefficient use of provider and health IT developer resources. **Comment:** Existing point-to-point (P2P) interfaces can remain in place instead of switching to network interfaces. P2P interfaces are not equivalent to network interfaces. Laboratories are mandated by CLIA regulations to certify interfaces to provider, therefore we do not see that laboratory to provider interfaces could be replaced by TEFCA/QHINs unless the CLIA regulations are modified.

Comment Item: A User's Guide to Understanding The Draft Trusted Exchange Framework https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf	
Slide #	**Comment**
4	**Text:**

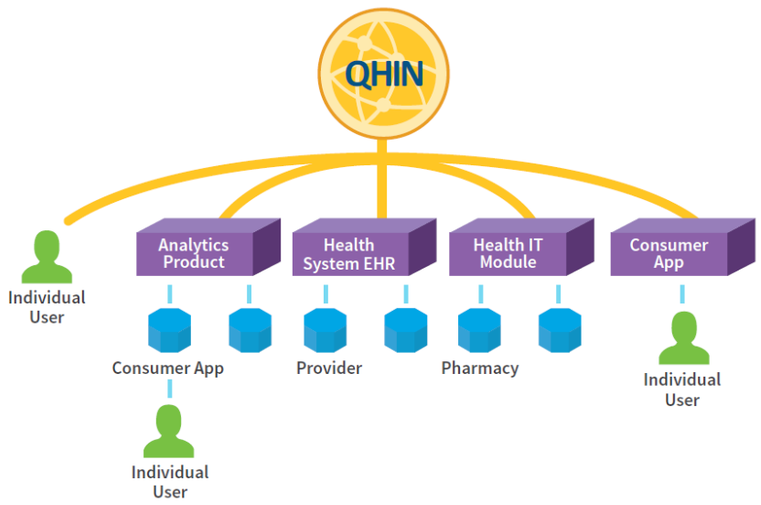


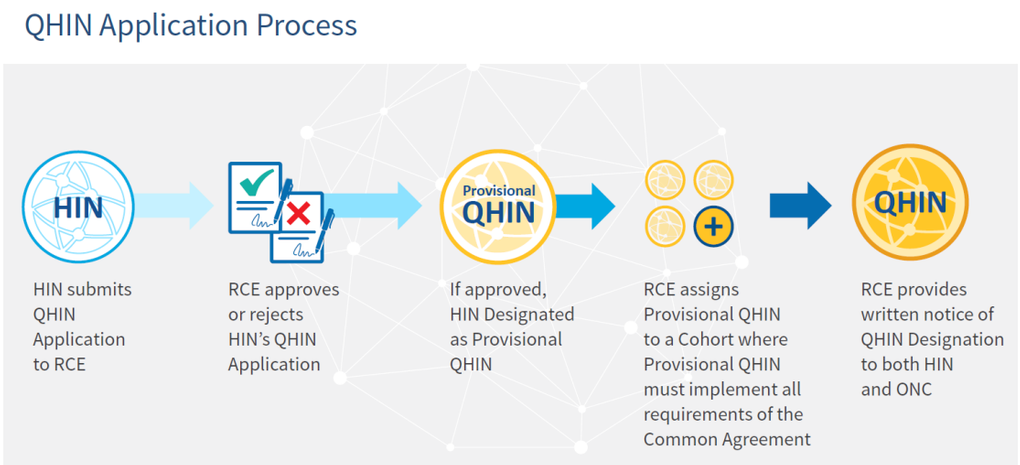
Comment:
Laboratories are mandated by CLIA regulations to certify interfaces to provider, therefore we do not see that laboratory to provider interfaces could be replaced by TEFCA/QHINs unless the CLIA regulations are modified.

Comment Item: A User's Guide to Understanding The Draft Trusted Exchange Framework https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf	
Slide #	**Comment**
13	**Text:**

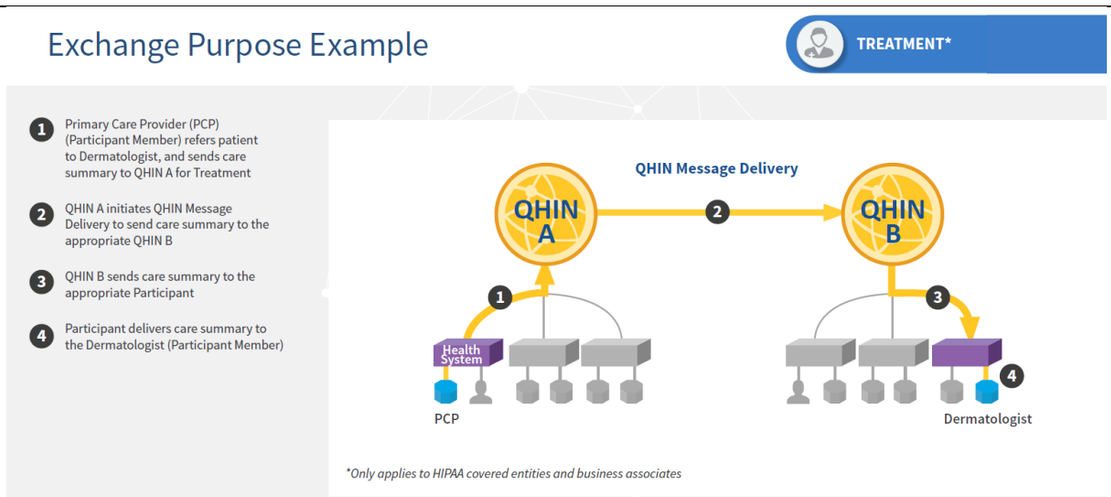
Comment:
Since this is definition of a term, suggest adding a footnote that any terms not defined in this User Guide or TEFCA document default to definitions in ONC's 21st Century Cures proposed rule.

Comment Item: A User's Guide to Understanding The Draft Trusted Exchange Framework https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf	
Slide #	**Comment**
16-17	**Text:** **Pg. 16 - Structure of a Qualified Health Information Network** **Participant** A natural person or entity that has entered into a Participant-QHIN Agreement to participate in a QHIN. **Participant Member** A natural person or entity that has entered into a Participant Member Agreement to use the services of a Participant to send and/or receive EHI. **Individual User** An Individual who exercises their right to Individual Access Services using the services of a QHIN, a Participant, or a Participant Member.

	Pg. 17 - QHIN Example: Network of Health IT Developers In this example, the QHIN supports a broad range of different health IT developer Participants. The users of the health IT developers' products are Participant Members. Individual Users connect directly to the QHIN, Participants, and Participant Members.  **Comment:** We suggest that these alternative definitions be used that are more in line with the definitions in the TEF. **Participant** A person or entity that has entered into a contract to participate in a QHIN. **Participant Member** A person or entity that has entered into a Participant Member Agreement to use the services of a Participant to send and/or receive EHI. **Individual User** A patient, who is the subject of the EHI, or their representative who exercises their right to Individual Access Services using the services of a QHIN, a Participant, or a Participant Member.

Comment Item: A User's Guide to Understanding The Draft Trusted Exchange Framework **https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf**	
Slide #	**Comment**
21	**Text:**  **Comment:** Suggest there should be a public listing of approved QHINs on the ONC website, similar to the Certified Health IT Product List (CHPL): https://chpl.healthit.gov/unsupported-browser.html

Comment Item: A User's Guide to Understanding The Draft Trusted Exchange Framework **https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf**	
Slide #	**Comment**
28	**Text:**



Comment:

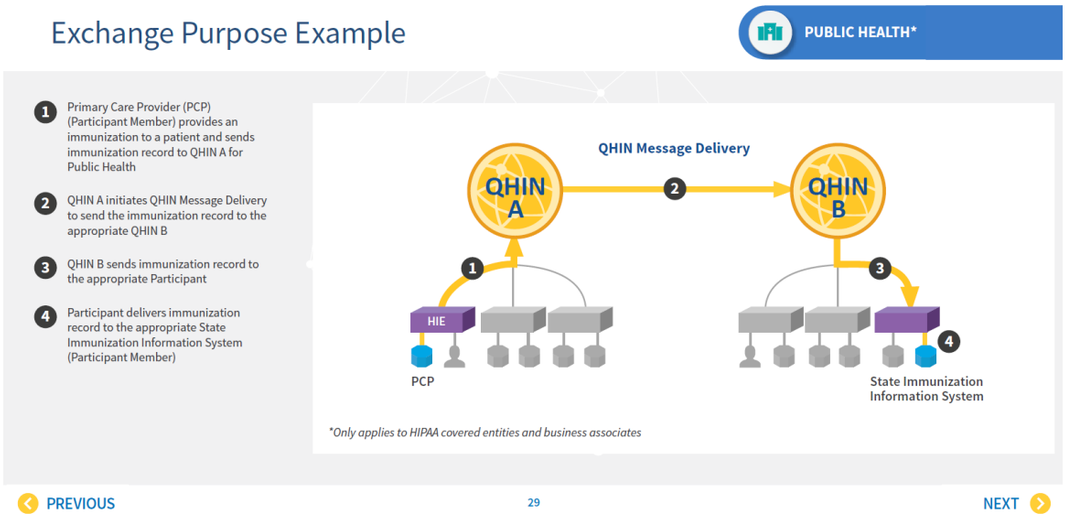
(Step 1) Please clarify that EHR systems with exiting functionality don't have to "rip and replace" to participate in a QHIN, e.g. they can still send care summary direct from PCP to Dermatologist (in this example) bypassing the QHIN (1 step instead of 4).

How does the PCP in QHIN A (step 1) know that the dermatologist (step 4) determine the dermatologist is a enrolled in QHIN B? Doesn't this add an additional provider burden for the provider to do a directory lookup, or otherwise confirm if the dermatologist is participating in a QHIN? Please clarify.

PCP could additionally send to QHIN so the record is available for query, but don't have to initiate a new multiple step workflow to achieve the same purpose.

The QHIN would be more acceptable for new development, vs. installing point to point interfaces, but should not replace existing, functional interfaces.

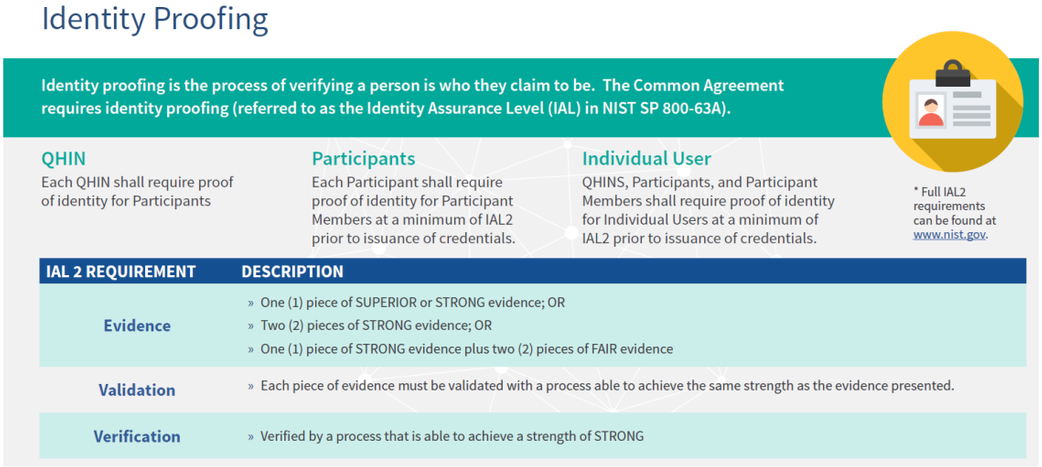
Comment Item: A User's Guide to Understanding The Draft Trusted Exchange Framework https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf	
Slide #	**Comment**
29	**Text:**



Comment:

Please see our comments on slide #28.

Comment Item: A User's Guide to Understanding The Draft Trusted Exchange Framework https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf	
Slide #	**Comment**
34	**Text:**



Comment:
Why does it take two 'Strong' in 2 but only one 'Strong' in 1? Please clarify the evidence requirements.

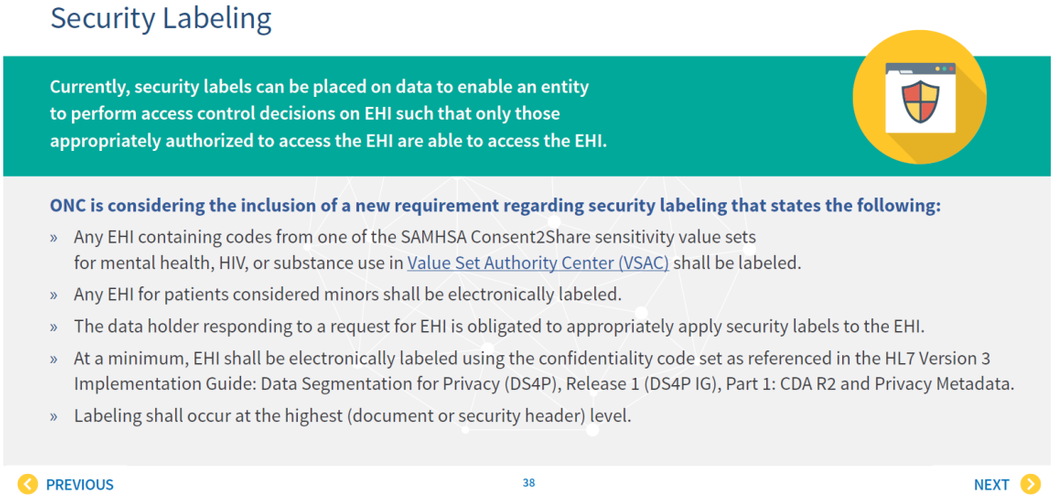
We suggest you change the first bullet to conform with NIST 800-63A Evidence Collection Requirements, it is confusing as is since the '**if**' statement is omitted, please change to:

"One piece of SUPERIOR or STRONG evidence **if** the evidence's issuing source, during its identity proofing event, confirmed the claimed identity by collecting two or more forms of SUPERIOR or STRONG evidence **and** the CSP validates the evidence directly with the issuing source; **OR"**

Comment Item: A User's Guide to Understanding The Draft Trusted Exchange Framework https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf	
Slide #	**Comment**
37	**Text:** 

Comment:
Please add a hyperlink to ONC's Model Privacy Notice you reference in the Written Privacy Summary section.

Comment Item: A User's Guide to Understanding The Draft Trusted Exchange Framework https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf	
Slide #	**Comment**
38	**Text:**

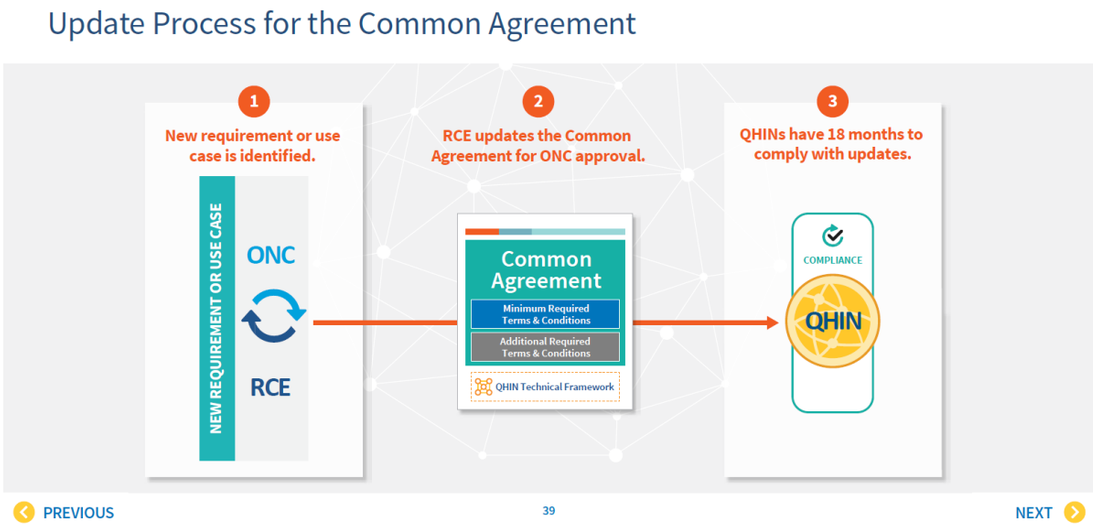


Comment:

Re: EHI for patients considered to be minors, it seems that protecting a minor's EHI could potentially obscure significant clinically relevant portions of patients medical records, especially if the labeling is at the document level; please clarify. Why is all "minors" EHI restricted?

We concur with HL7 comments on ONC's 21st Century Cures, e.g. there should be "...a refresh of the current HL7 DS4P CDA IG along with a cross paradigm specification..."

Please add additional information on how security labels should be used.

Comment Item: A User's Guide to Understanding The Draft Trusted Exchange Framework **https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf**	
Slide #	**Comment**
39	**Text:**  **Comment:** Please clarify the process for stakeholders to comment on new requirement or use case. RE: QHINs 18 month compliance for updates, we suggest adding an exception process so the RCE may grant an extension to the QHIN, if circumstances are justified.