



May 30, 2019

Don Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services (HHS)
Mary E. Switzer Building, Mailstop: 7033A
300 C Street SW
Washington, DC 20201

Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule (NPRM) RIN 0955-AA01

Submitted electronically to: <https://www.regulations.gov/>

Dear Dr. Rucker:

Health Level Seven (HL7®) International welcomes the opportunity to submit comments on the proposed rule *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*.

HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related interoperability standards, including the rapidly evolving Fast Healthcare Interoperability Resources (HL7® FHIR®), the Consolidated Clinical Document Architecture (C-CDA®), and the widely used V2 messaging standards. We have more than 1,600 members from over 50 countries. HL7 greatly values its on-going collaboration with ONC and other federal government agencies to ensure that the products of our organization positively impact the lives of many Americans, providing the underpinnings for connected, patient-centered health care and an information highway for precision medicine.

HL7 appreciates the role of the proposed rule in moving healthcare forward and the increased emphasis on the linchpins of:

- Improving the interoperability of electronic health information;
- Enhancing care coordination; and
- Fostering innovation that promotes patient access to and control over their health information.

We are delighted that ONC proposes adoption of the HL7® Fast Healthcare Interoperability Resources (FHIR®) standard as a foundational standard for application programming interfaces (APIs) within the proposed rule. HL7 FHIR® is well positioned to support the proposed deployment of APIs and to help ensure that a patient's electronic health information (EHI) is accessible to a patient and the patient's designees, in a manner that facilitates communication with the patient, health care providers and other individuals. Given the centrality of HL7 and its standards in this proposed rule – we provide our detailed comments in the appendix to this letter about the use of our organization's standards and resources, as well as the proposed rule's constructs, implementation, timelines and other issues.

Key themes and highlights of our comments include:

- **FHIR Release 4 (R4)** - HL7 strongly supports and recommends FHIR R4 being the explicitly named standard in the final rule.
- **Implementation Specifications and Sub-regulatory Guidance** - HL7 believes that implementation specifications, particularly related to the proposed API standards, should not be included in the regulation but rather in sub-regulatory ONC guidance.
- **Timeframes and Synchronization** - HL7 emphasizes the importance of synchronizing the CMS regulations (which reference FHIR) and this ONC regulation. Currently, the CMS propose rule's initial API implementation date is January 1, 2020, at least 18 months (or more) before the effective date of the ONC regulations. This aggressive timing creates an undesirable issue regarding which FHIR and implementation specification versions would be appropriate for use under the CMS rules on January 1, 2020. We made timing recommendations to CMS with the need for synchronization in mind.
- **Accredited Standards** - HL7 believes that the API Resource Collection in Health (ARCH) and other relevant ONC standards-referencing works should be limited to accredited standards or unaccredited standards that meet all ANSI essential requirements within the voluntary consensus standards process.
- **ARCH** - ARCH is acceptable as a concept, in the short term, with a clearer explicit definition and constraints on its content to ONC's stated intent. However, HL7 believes that ARCH should be limited to the FHIR resources developed by HL7, constrained by the final USCDI, and as quickly as possible, should be transitioned to a private sector/SDO implementation specification that maps to the USCDI, as do the current Argonaut/US Core implementation guides.
- **Revised and New 2015 Edition Criteria (CQL)** - HL7 recommends including its Clinical Quality Language (CQL) in the "Emerging Standards" section of the rule. More information can be found at:
<https://ecqi.healthit.gov/hqmf-health-quality-measure-format/content/clinical-quality-language-cql>.
- **Electronic Health Information (EHI) Export Criterion** - HL7 registers its concern that the lack of a consistent data format will limit the benefit of this data export. Because such standardization is not feasible at this time, we suggest the data export proposal should be reconsidered.
- **USCDI Standard (General – Data Classes Included)** - HL7 applauds the advancement of the USCDI in this proposed rule. USCDI should be used to guide the selection of additional standards, when accredited standards are available, in several areas:
 - Standards related to payer-provider data exchange and payer-payer data exchange. The Da Vinci Project is developing exciting new standards and methods for these exchange use cases.
 - Data standards related to the social determinants of health. The HL7 Gravity Project has promising early stage work underway in this area.
 - Additional clinical data and clinical device data;
 - Consumer data and patient-generated health data;
 - Registry data and public health reporting data; and
 - Privacy, security, and trust concepts.

It should be noted that not all requirements for the use of USCDI data are appropriate for all parties and use case scenarios. For example, some data in the USCDI are not relevant to, or appropriate for, electronic case reporting and cannot be received by State Public Health Agencies in accordance with State laws. As a result, we believe that ONC and CMS provisions that require use of the USCDI should take a modular approach, only requiring applicable USCDI elements.

- **USCDI Standard (Clinical Notes)** - HL7 agrees with the option chosen by ONC to consider a minimum standard of eight note types derived by those identified by the Argonaut Project participants for adoption in the USCDI v1. We agree that the clinical note types identified are useful to providers for clinical care and believe they represent a good starter set for the USCDI. HL7 recommends these clinical notes should be equally included in summary documents; CCD, Hospital Summaries, etc. as indicated in the C-CDA Companion Guide, and, they also should be able to be shared as separate C-CDA document types when using Direct or Exchange transport, analogous to the capabilities proposed for FHIR using the DocumentReference resource. HL7 does not agree with ONC's proposal to require, as it proposes to do, that clinical notes for exchange must be in the original source format. Such formats may vary by system.
- **USCDI Standard (Clinical Notes C-CDA Implementation Specification)** - HL7 agrees with ONC's proposed recommendation to adopt this C-CDA Companion Guide to support best practice implementation of USCDI v1 data classes and 2015 Edition certification criteria that reference C-CDA Release 2.1. HL7 agrees that best practices and guidance should be separate from, and not intended to be used for certification criteria moving forward. In addition, HL7 encourages ONC to reference in the final rule the latest version available of the C-CDA and C-CDA companion guide.
- **USCDI Standard (Provenance)** - HL7 welcomes the inclusion of a Provenance data class in the proposed rule, recognizing that there is much needed standards development underway to ensure that such provenance data can be interoperably exchanged with and transformable among key HL7 product families. Our organization supports a consistent definition of provenance in the final rule.
- **Data Segmentation for Privacy (DS4P)** - Implementation of DS4P in an interoperable and policy specific manner requires much more groundwork than the proposed rule outlines. HL7 generally supports moving the industry toward "sharing with protections" by implementing security labeling to enable data segmentation for privacy [DS4P], API attribute based authorization, and computable consent directives. The standard for DS4P should be HL7 standards for CDA, Version 2, and FHIR security labeling and not be the SAMSHA Consent 2 Share (C2S). Practical issues of implementation with DS4P are substantial. As a result, pilot projects should be integral to ONC roll-out of this concept, evaluated, and such results of these pilots should be incorporated in future regulatory and sub-regulatory actions. HL7 strongly recommends that ONC support HL7 in expediting a refresh of the current HL7 DS4P CDA IG along with a cross paradigm specification to address the proposed rule's intent in the § 170.315(b)(12) Data segmentation for privacy – send and § 170.315(b)(13) Data segmentation for privacy – receive.
- **Standardized API for Patient and Population Services** - HL7 welcomes ONC support for its collaboration with SMART on FHIR to augment Authorization Server capabilities by incorporating support for more complex scopes, for example as proposed in [Using JSON to Model Complex OAuth Scopes](#). As discussed in HL7 comments on data segmentation for privacy, the need to develop default security labels for privacy policies and consent directives to which an exchange partners must comply, must also apply to specifying interoperable use of security labels as clearances in Smart on FHIR scopes and access tokens.

- **CDS Hooks** - HL7 applauds ONC's interest in the use of CDS Hooks as a standard able to bring consistent and current opioid prescribing guidelines to the point of care. HL7 has experience in how this approach can be used to ensure patient safety while preserving patient privacy.
- **Conditions and Maintenance of Certification (Communications and Public Health)** - HL7 requests that the final rule explicitly clarify that the protected communication guidelines also apply to Public Health authorities who interact with both Health IT developers (vendors) and users (healthcare organizations).
- **Conditions and Maintenance of Certification (APIs)** - Many of the references to APIs focus exclusively on the technology of RESTful query and ignore the “push” elements of the FHIR API such as “POST,” “PUT,” and FHIR Messaging. In a number of respects the query focus represents technology driving programs and does not focus on the many public health and clinical program use cases, like reporting, that need “push” transactions from EHRs and other data sources. Regarding public health specifically, access into EHRs has been limited to date. ONC should therefore examine the suitability of APIs for reporting requirements relative to “push” models of data exchange.
- **Standards Version Advancement Process (SVAP)** - The Standards Version Advancement Process needs to be clarified to describe a more collaborative process for determination of when standards are ready for implementation across organizational boundaries in scenarios where there are two or more partners involved in the exchange. Systems that adopt new versions must retain support for previous versions so as not to disrupt existing interoperability. Managing backwards compatibility must be addressed with respect to addition of updated standards and implementation specification, and as the SVAP is implemented.
- **Registries Request for Information** - HL7 notes that a lack of standardization across electronic infrastructure on the data element, definition, and value set level has made implementation of health information technology within registries difficult. More work needs to be done to encourage the originators of data to adhere to standards to promote bidirectional data exchange. Supporting a widely used, consensus-based standard like FHIR reduces burden, including on health IT implementers. HL7 supports an effort by ONC to help harmonize the EHR reporting infrastructure and standards involved in reporting to registries and getting information from registries back to clinical care. It is critical that in considering EHR connection to registries, that the existing work public health has done in immunizations, electronic case reporting, cancer case reporting, newborn screening, the FHIR Common Reporting Framework (Public Health Work Group) and other HL7 work in Common Clinical Registries, be considered and that HL7 be involved in any process going forward.

Our organization will reach out to you to request a meeting to discuss how HL7 can best meet the needs of ONC in alignment with the HL7-related provisions in this proposed rule. Issues for this meeting agenda should include expected resource requirements, work priorities, and timelines.

There is much work to be done and HL7 stands ready -- as an active, innovative partner -- to support ONC in HL7's recognized work with the federal government to “move forward to a truly collaborative, interoperable health system that supports patients in seeking low cost, high quality care.” HL7 Work Groups have put forth a dedicated effort to submit specific and substantive feedback on relevant questions posed by ONC in the proposed rule. HL7 Work Groups contributing to these comments include:

- Clinical Interoperability Council
- Clinical Quality Information
- Community-Based Care and Privacy

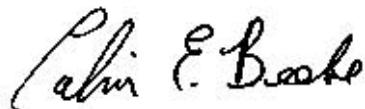
- Public Health
- Security
- Structured Documents

Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion and offer our assistance to HHS and ONC.

Sincerely,



Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International



Calvin Beebe
Board of Directors, Chair
Health Level Seven International

Appendix: HL7 Detailed Responses to ONC Proposed Rule

Below are HL7's detailed responses to the proposed rule *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*.

Section IV. Updates to the 2015 Edition Certification Criteria

ARCH (API Resource Collection in Health)

Comments:

- ARCH is acceptable as a concept, in the short term, with clearer explicit definition and constraints on its content to ONC's stated intent. However, HL7 believes that ARCH should be limited to the FHIR resources developed by HL7, constrained by the final USCDI, and as quickly as possible, should be transitioned to a private sector/SDO implementation specification that maps to the USCDI, as the current Argonaut/US Core do.
- HL7 believes the ARCH and other ONC standards-referencing works, should be limited to accredited standards or unaccredited standards that meet all ANSI essential requirements within the voluntary consensus standards process. The scope and limits to the ARCH, as well as its update process and path, should be more clearly defined.

FHIR Release 4 (R4) – Proposed API Standards, Implementation Specifications and Certification Criterion

ONC proposes four options for FHIR standards in this area: 1) FHIR Release 2 (as proposed); 2) FHIR Release 2 and Release 3 (either for certification option); 3) FHIR Release 2 and Release 4; or 4) Just FHIR Release 4.

Comments:

- HL7 strongly supports and recommends Option 4, FHIR R4 being the explicitly named standard in the final rule.
- HL7 believes that implementation specifications related to these provisions should not be included in the regulation but rather in sub-regulatory ONC guidance.
- Implementation specification guidance could be promulgated in any of the multiple mechanisms employed by HHS agencies and could be updated more flexibly than regulatory text. In addition to the mechanism proposed by ONC for managing changes in named standards, ONC could allow the use of updated standards versions using the discretion of compliance enforcement, coupled with guidance, just as CMS is doing with the HIPAA named standards.
- HL7 emphasizes the importance of synchronizing the CMS regulations (which reference FHIR) and this ONC regulation. Currently, the CMS proposed rule's initial API implementation date is January 1, 2020, at least 18 months (or more) before the effective date of the ONC regulations. This aggressive timing creates an undesirable issue regarding which FHIR and implementation specification versions would be appropriate for use under the CMS rules on January 1, 2020. We made timing recommendations to CMS with the need for synchronization in mind.
- Managing backwards compatibility must be addressed with respect to addition of updated standards and implementation specifications, and as the Standards Version Advancement Process (SVAP) is implemented.

Revised and New 2015 Edition Criteria

Comments:

- HL7 recommends including its Clinical Quality Language (CQL) in the "Emerging Standards" section of the rule. CQL is an HL7 standard for trial use and it supports efforts to harmonize standards between electronic

clinical quality measures and clinical decision support. More information can be found at: <https://ecqi.healthit.gov/hqmf-health-quality-measure-format/content/clinical-quality-language-cql>.

USCDI Standard (General – Data Classes Included)

ONC proposes to replace the current Common Clinical Data (CCDS) set with the United States Core Data for Interoperability (USCDI). The USCDI is defined at the level of data classes. ONC intends to evolve the USCDI through its Standards Version Advancement Process.

Comments:

- USCDI should be used to guide the selection of additional standards, when accredited standards are available, in several areas:
 - Standards related to payer-provider data exchange and payer-payer data exchange—The Da Vinci Project is developing exciting new standards and methods for these exchange use cases.
 - Data standards related to the social determinants of health—The HL7 Gravity Project has promising early stage work underway in this area.
 - Additional clinical data and clinical device data;
 - Consumer data and patient-generated health data;
 - Registry data and public health reporting data; and
 - Privacy, security, and trust concepts.
- We applaud the advancement of the USCDI in this proposed rule and support ONC's recommendation to include 'transmission to public health agencies - electronic case reporting' (§ 170.315(f)(5))" in the USCDI and Certification Criteria that reference the USCDI, but only if specific language and context is added to properly identify the USCDI role. HL7 would welcome an opportunity to discuss the complexities and specifics of case reporting issues with ONC.

As background, the HL7 CDA eICR and FHIR eCR transactions have referenced and mapped to both the C-CDA and the Common Clinical Data Set (CCDS)/US Core FHIR Profiles in order to align with other health IT programs, to promote interoperability, to maximize the use of existing EHR data, and to minimize provider burden. As suggested in the proposed regulation, these implementation guides can be updated to replace the CCDS references and mappings with USCDI references and mappings moving forward. But language needs to be added in the final rule to address points relative to the "use" of the USCDI for public health electronic case reporting and perhaps elsewhere.

- Not all requirements for the use of USCDI data are appropriate for all parties and use case scenarios. For example, some data in the USCDI are not relevant to, or appropriate for, electronic case reporting and cannot be received by State Public Health Agencies in accordance with State laws. As a result, we believe that ONC and CMS provisions that require use of the USCDI should take a modular approach, only requiring applicable USCDI elements.

USCDI Standard (Clinical Notes)

With respect to the note types "... ONC proposes to include the following clinical note types for both inpatient and outpatient (primary care, emergency department, etc.) settings in USCDI v1 as a minimum standard: (1) Discharge Summary note; (2) History & Physical; (3) Progress Note; (4) Consultation Note; (5) Imaging Narrative; (6) Laboratory Report Narrative; (7) Pathology Report Narrative; and (8) Procedures Note. "

Comments:

- HL7 agrees with the option chosen by ONC to consider a minimum standard of eight note types derived by those identified by the Argonaut Project participants for adoption in the USCDI v1. We agree that the clinical note types identified are useful to providers for clinical care and believe they represent a good starter set for the USCDI.
- The scope and nature of the document type and what must be contained (or not) in the note (e.g., free text narrative relevant to a specific note type) would be optimally defined in the regulation.
- HL7 recommends these clinical notes should be equally included in summary documents; CCD, Hospital Summaries, etc. as indicated in the C-CDA Companion Guide. They also should be able to be shared as separate C-CDA document types when using Direct or Exchange transport, analogous to the capabilities proposed for FHIR using the DocumentReference resource.
- HL7 does not agree with ONC's proposal to require that clinical notes for exchange must be in the original source format. Such formats may vary by system.

USCDI Standard (Clinical Notes C-CDA Implementation Specification)

Comments:

- HL7 agrees with ONC's proposed recommendation to adopt this C-CDA Companion Guide to support best practice implementation of USCDI v1 data classes and 2015 Edition certification criteria that reference C-CDA Release 2.1.
- HL7 agrees that best practices and guidance should be separate from and not intended to be used for certification criteria moving forward. In addition, HL7 would encourage ONC to reference in the final rule in the latest version available of the C-CDA and C-CDA companion guide.

USCDI Standard (Provenance)

Comments:

- HL7 welcomes the inclusion of a Provenance data class in the proposed rule, recognizing that there is much needed standards development underway to ensure that such provenance data can be interoperably exchanged with and transformable among key HL7 product families: HL7 Version 2, CDA, and FHIR.
- HL7 believes there should be a consistent definition of "provenance" provided in the rules.
- It would also be helpful for clinical quality management (CQM) purposes to have provenance of the data elements being used in clinical quality measures.
- HL7 emphasizes that data provenance elements named in this section of the proposed rule could be helpful to registries in validating the origination of data they receive.
- With respect to the initial three data elements called out by ONC (author, author's timestamp, author's organization) for Basic Provenance: HL7 supports the refined [U.S. Core Data for Interoperability Task Force Meeting Slides April 15, 2019](#) recommendations on slide 11 to (1) Use "Agent/Entity" in place of "Author", "Agent/Entity" Time Stamp, and "Agent/Entity" Organization to include name and location.
- Precursor data, like author information, must be present in underlying artifacts such as source C-CDA documents in order for provenance, e.g. reports derived from FHIR provenance resources, to be effective.
- HL7 recommends that ONC further consider, as it expands the USCDI over time, additional provenance data elements for capture in "extrinsic" Provenance records (i.e. those that can be put into a Provenance report or Provenance Resource). Examples of such data elements include:
 - The FHIR Provenance Resource or the inline "relevant history" element in Resources with workflow, which are viewed as "high value" in HL7 Provenance related projects.
 - Identity of the individual or entity the data was obtained from or sent by, sometimes discussed in standards working groups as the provenance of the data's last hop.

- Identifiers or references to algorithms, policies, or rule sets used by or controlling the provenance activity, and digital signatures for non-reputable accountability for the provenance target (resulting artefact). HL7 and its Basic Provenance Project can share additional information about emerging and approved concepts/products that relate to potential additional ONC provenance data elements.
- Regarding “Coverage and Identifier” of the subject of the information, the HL7® FHIR® “Coverage Resource” carries that information and should be made part of the USCDI. There is also the need to use Payer Identifier to identify the payer that will receive the data.
- As useful background for ONC, a list of current HL7 provenance projects include:
 - [Provenance Domain Analysis Model \(DAM\)](#) –The proposed Privacy and Security Architecture Framework (PSAF) Provenance Domain Analysis Model (DAM) specifies the information and behavioural models needed in order for a policy domain to federate provenance, i.e., how to stipulate the provenance information required by workflow areas to exchange interoperable provenance records. The PSAF Provenance DAM is built on W3C PROV, the HL7 and ISO standards on Healthcare Lifecycle Events, and provenance work from the research community.
 - [FHIR Provenance Resource](#) - The FHIR Provenance Resource, which is at FHIR Maturity Level 3, and is intended to provide a platform specific model, based on the same core as the PSAF Provenance DAM that is built on, W3C PROV.
 - [Basic Provenance](#) - Basic Provenance is an ONC/HL7 project to develop specifications that satisfy the USCDI requirements for CCDA and FHIR.
 - [CrossDomain Provenance](#)
 - [DaVinci PDex IG](#) - The DaVinci PDex IG provides data provenance, which is developing the platform specific provenance content needed to capture the PDex use case requirements.

Clinical Quality Measures—Report Criterion

ONC proposes to eliminate HL7 QRDA Release 1 from one of the ONC CQM certification criteria 170.315(c)(3) Clinical quality measures (CQMs) — and report and only certify to the CMS QRDA Implementation Guide. Specifically, ONC proposes certification testing for 170.315(c)(3) Clinical quality measures (CQMs) — and a report should be based only on the CMS IG, rather than the HL7 version. HL7 QRDA is an Implementation Guide (IG) of the CDA that re-uses some C-CDA templates where applicable and the CMS QRDA IG is an implementation guide based on HL7 QRDA that reflects CMS-specific policies.

Comments:

- The HL7 QRDA should remain in certification criteria, as an optional criterion, since other organizations (e.g. The Joint Commission) use the HL7 IG (QRDA) and implementers report a need to assure the same style for submission across programs. HL7 recommends that the HL7 QRDA implementation guide persist as a continuing option in the certification program to enhance alignment with other standards and C-CDA, and to encourage a base standard alignment across implementers (e.g., CMS, The Joint Commission).
- We further suggest that CMS continue to only publish specific constraints on the HL7 QRDA standards as the CMS IG, rather than a complete re-write of the standard.

Electronic Health Information (EHI) Export Criterion

The scope of the EHI export in the ONC proposed rule includes: clinical, administrative, and claims/billing data. The proposed rule does not specify a standard or data format that must be used for EHI export. The data exporter would be required to make their data format publicly available.

Comments:

- HL7 is concerned that the lack of a consistent data format will limit the benefit of this data export. Because such standardization is not feasible at this time, we suggest the data export proposal should be reconsidered.

Data Segmentation for Privacy and Consent Management Criteria (Implementation With the Consolidated CDA Release 2.1)

and

Data Segmentation for Privacy and Consent Management Criteria (Implementation With FHIR Standard)

Comments:

- HL7 generally supports moving the industry toward “sharing with protections” by implementing security labeling to enable Data Segmentation for Privacy (DS4P), API attribute based authorization, and computable consent directives.
- HL7 recommends that DS4P implementation in this rule should not exceed what is already implemented. The standard for DS4P should be HL7 standards for CDA, Version 2, and FHIR security labeling, not the SAMSHA Consent 2 Share (C2S). The language in the proposed rule mixes CDA and FHIR-based concepts particularly with security labeling. We urge a review by ONC for proper context and labelling. There is a need for cross-paradigm regulatory alignment on the use of the same security terminology for HL7 product families. HL7 has already undertaken early work toward evolving DS4P/security labeling implementer guidance via the HL7 V2 to FHIR mapping project sponsored by the HL7 Orders and Orders WG. We would be happy to share our emerging activities and applicable learnings with ONC.
- Practical issues of implementation with DS4P are substantial. As a result, pilot projects should be integral to ONC rollout of this concept, evaluated, and such results of these pilots should be incorporated in future regulatory and sub-regulatory actions.
- ONC asks “given the extensive coding enabled via the privacy and consent management criteria, and the limited real world implementation experience in the healthcare industry, what are the best practices or regulatory guide lines to be followed when coming across specific tags?” HL7 recommends that a companion guide be developed to assist implementers, if this proposal is to be enacted. Evaluation of future pilot projects using this process could shed light on issues such what to do when a document with redacted content is received.
- HL7 observes that CDS and Clinical Quality Measurement data segmentation at the data element level (both current and historical data coming into a system) could create issues, biases, and other problems related to the completeness and reliability of the information being reported, including issues with numerator/denominator and CDS ‘false’ alerts. We recommend ONC clarify how to address segmentation of data in CDS and Quality Measurement.
- As we argue below, implementation of DS4P in an interoperable and policy specific manner requires much more groundwork than the proposed rule outlines. The use of security labels for privacy tagging requires a consensus around which codes or “privacy tags” in a security label codify a shared policy in a policy domain. Otherwise, receivers may not recognize or enforce the privacy policy or consent directive that security labels on imported content represents; they may have very different ideas on how to represent and enforce a specific privacy policy/consent directive; or may not have implemented this optional criterion.
- While “[c]ertification to this criterion would be at a health IT developer’s discretion and would indicate that a system is capable of responding to requests through an API for patient consent directives that include standards-based security labeling”, without the required consensus on how to encode privacy policies with security labels, we are concerned that new security labelling requirements ONC is considering under Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA) and the proposed rule’s information blocking requirements could drive non-interoperable adoption.

Specific Data Segmentation Comments:

Issue 1: DS4P IG

HL7 Recommendation:

- HL7 strongly recommends that ONC support HL7 in expediting a refresh of the current HL7 DS4P CDA IG along with a Cross Paradigm specification to address the proposed rule's intent in the § 170.315(b)(12) Data segmentation for privacy – send and § 170.315(b)(13) Data segmentation for privacy – receive.

Background and Rationale:

Regarding the C2S specification, it does not map well to other platform specific standards nor does it support other privacy policies, including HIPAA Authorizations for Disclosure to non-HIPAA entities such as SSA or for HIPAA Self-Pay, Psychotherapy Notes, to Title 38 Section 7332, and the myriad of state specific privacy consents that preempt HIPAA. If ONC wishes to certify compliance with a HL7 DS4P CDA, FHIR, or V2 security labeling specification that only tags content with a confidentiality code of restricted rather than supporting HL7 CDA, FHIR or V2 granular tagging, then ONC should support HL7 development of standard implementation guidance on how that limitation of application should be achieved. And rather than reference a product line-specific DS4P approach, ONC should reference the HL7 Privacy and Security Healthcare Classification System [HCS]. The HCS is foundational to HL7 security labeling and supports the current work being done in Cross-Paradigm projects to encode the rules for generating and transforming security labels across HL7 product lines and possibly for other standard's syntaxes such as X12N, NCPDP, and NIEM.

Globally, the HL7 Security Work Group approved a resolution to update the recently reaffirmed DS4P CDA Implementation Guide to accommodate all types of consent directives in the international realm, i.e., beyond 42 CFR Part 2. This includes the EU General Data Protection Regulation consent directives.

Issue 2: Encoding Consent Directives

HL7 Recommendation:

- ONC should encourage and resource the development of a Cross Paradigm approach to encoding consent directives able to meet the proposed rule's intended goals.

Background and Rationale:

The following text on page 107 of the proposed rule is an overstatement: "SAMHSA created a FHIR implementation guide (the Consent2Share Consent Profile Design, hereafter referred to as "Consent Implementation Guide") that describes how the Consent2Share(C2S) application and associated access control solution uses the FHIR Consent resource to represent and persist patient consent for treatment, research, or disclosure." While FHIR R4 is at maturity level 3, there is on-going development to prepare it to support the full set of scoped consent types. Where legally required, such as encoding the underlying privacy policy provisions, linking the patient viewed consent form to the computable consent, and inclusion of signatures, there is on-going work to delineate which consent use cases are appropriate to the FHIR Consent Resource and which are appropriate to the FHIR Contract Resource. This work was initially conducted under the ONC Patient Granular and Research Choice Projects and needs to be completed as FHIR implementation guidance in order to provide those accountable for implementing legally compliant consent directives with the needed tools.

Issue 3: Developing Consensus Default Security Label Specification for US Priority Privacy Policies

HL7 Recommendation:

- HL7 stands ready to develop consensus default security label specification for the US priority privacy policies needed to enable sharing of sensitive information with protections required by the *21st Century Cures Act*. HL7 is expert in mapping between privacy policies and consent directives to security labels, which are being developed as part of the HL7 Cross Paradigm Model Transformation Service project, and stands ready to work with ONC on developing those specifications and to advance a refined set of labels for priority privacy policy profiles.

Background and Rationale:

HL7 supports the proposed requirement to “preserve privacy markings to ensure fidelity to the tagging based on consent and with respect to sharing and re-disclosure restrictions” with the caveat that “privacy mark” tagging must be based on consensus about how tagging is done for each privacy law or policy that governs the disclosed information. HL7 security label rules and vocabulary are specified in the HL7 Privacy and Security Classification System. That is a conceptual model for which there are platform specific standards in HL7 Version 2.9 (which may be pre-adopted by implementers of earlier versions), CDA, and FHIR.

The HL7 Security Work Group has approved a FHIR DS4P IG project, which will provide FHIR security labeling guidance for applying policy specific labels with privacy tags representing either the policy, such as required for marking CUI, or the consent directive governing the collection, access, use, and disclosure of the target FHIR Resource(s). The IG will provide guidance on how to select a security label based on the HL7 Privacy and Security Healthcare Classification System (HCS) label adjudication algorithms, the value in establishing consensus on a default security label for representing policies or consent directives within an exchange ecosystem, and how an Access Control System, such as an OAuth Authorization Server, can use the security labels to filter responses to person or population based queries and pushed disclosures.

Consent Management for APIs

General Comments:

HL7 supports Consent management for APIs where required by policy but notes several issues with the proposed §170.315(g)(11) Consent management for APIs:

- With respect to the implementation specification adopted in § 170.215(c)(2), HL7 supports establishment of a FHIR based consent directive, but does not support the adoption of Consent2Share, which, as indicated, has not been balloted as an HL7 standard.
- We also note that Consent2Share does not support a consenter’s signature or specification to protect information content data requirements, e.g., the appropriate LOINC code to indicate information is an Opioid Treatment Agreement, which are required elements of a 42 CFR Part 2 compliant consent. Nor does it include the policy under which the information is governed. For example, HIV tagged information governed by HIPAA can be disclosed without authorization (consent). Such an ability to disclose may not be the case in where HIV privacy laws govern, for example if HIV is a comorbidity of substance use disorder diagnosed or treated in a Part 2 facility. With respect to Opioid Treatment Agreement (OTA), we encourage ONC to consult with HL7 and other relevant parties about the appropriate LOINC code to identify documents specifically as Opioid Treatment Agreements when sending/receiving so that these can be correctly processed. LOINC 89424-6 seems ideal, but a standard should be specified.
- In addition, the other security labels in FHIR Consent related to purpose of use, refrain policies, and obligations to which a recipient must comply, differ according to the applicable laws. FHIR Consent supports this as does the FHIR Contract R4. Note that neither C2S or FHIR Consent support an inline

signature, but FHIR Contract does, and this is required by some consent directive policies. FHIR Consent may be referenced by a FHIR Provenance Resource, but that is merely a recording of the “signing ceremony”, not a signature on the consent directive itself. Until that happens, ONC should not reference this work for the [§170.315\(g\)\(11\) Consent management for APIs](#) Testing Procedures.

- HL7 welcomes collaboration with ONC on furthering development of these capabilities as standards, e.g. complete development and balloting of a FHIR Privacy Consent Directive implementation guide.

Specific Comments (Standardized API for Patient and Population Services):

- HL7 welcomes ONC support for its collaboration with SMART on FHIR to augment Authorization Server capabilities by incorporating support for more complex scopes, for example as proposed in [Using JSON to Model Complex OAuth Scopes](#).
- The API specification based on Smart on FHIR does not at this time enable the application of consent directives or privacy policies to a requester’ scopes and the access tokens received from the Authorization Server. ONC should clarify what the certification expectations are for how an API responds to requests for data in accordance with the retrieved consent.
- In addition, Smart on FHIR scopes and access tokens are not able to handle inclusion of security labels, which are the means by which the API’s Authorization Server is able to control the permissions granted that the Client may request of the FHIR Server via an access token. While there are efforts underway to augment the approach used by Smart on FHIR for authorizing patient and population level queries, that specification is not currently able to meet the requirements of this provision.
- As discussed in HL7 comments on data segmentation for privacy, the need to develop default security labels for privacy policies and consent directives to which exchange partners must comply, must also apply to specifying interoperable use of security labels as clearances in Smart on FHIR scopes and access tokens.

ONC notes on page 146 of the proposed rule that “Clinical Decision Support (CDS) Hooks is a health IT specification that has the potential to positively affect prescriber adoption of evidence-based prescribing guidelines by invoking patient-specific clinical support from within the clinician’s EHR workflow” and has requested public comment on other health IT solutions and effective approaches to improve opioid prescription practices and clinical decision support for Opioid Use Disorder (OUD).

Comments:

- HL7 applauds ONC’s interest in the use of CDS Hooks as a standard able to bring consistent and current opioid prescribing guidelines to the point of care. HL7 has experience in how this approach can be used to ensure patient safety while preserving patient privacy.

Section VI. Health IT for the Care Continuum

Recommendations for the Voluntary Certification of Health IT in Pediatric Care

Comments:

- Many of the recommendations in this section may affect children’s health (and therefore public health). With respect to recommendation 5,
 - The reference should be to § 170.315(b)(1) rather than VDT for recommendation 5.
 - The requirement for clinical information reconciliation and incorporation (§ 170.315(b)(2)) should be augmented to include immunization to support Recommendation 5.

Section VII. Conditions and Maintenance of Certification

Communications

Comments:

- HL7 requests that the final rule explicitly clarify that the protected communication guidelines also apply to Public Health authorities that interact with both Health IT developers (vendors) and users (healthcare organizations).

Application Programming Interfaces

Comments:

- Many of the references to APIs focus exclusively on the technology of RESTful query and ignore the “push” elements of the FHIR API such as “POST,” “PUT,” and FHIR Messaging. In many respects, the query focus represents technology-driving program and does not focus on the many public health and clinical program use cases, like reporting, that need “push” transactions from EHRs and other data sources. Regarding public health specifically, access into EHRs has been limited to date. ONC should therefore examine the suitability of APIs for reporting requirements relative to “push” models of data exchange.

Real World Testing - Standards Version Advancement Process

Comments:

- The Standards Version Advancement Process needs to be clarified to describe a more collaborative process for determination of when standards are ready for implementation across organizational boundaries in cases where there are two or more partners involved in the exchange. Systems that adopt new versions must retain support for previous versions, so as not to disrupt existing interoperability. As we mentioned in our introductory comments, managing backwards compatibility must be addressed with respect to addition of updated standards and implementation specification, and as the Standards Version Advancement Process (SVAP) is implemented.

IX. Registries Request for Information

Data, Standardization and Programs

ONC’s proposed rule includes a Request for Information (RFI) on how a standards-based API might support improved information exchange between a health care provider and a registry in support of public health reporting, quality reporting, and care quality improvement. Comment is sought on use cases where an API using FHIR Release 4 might support improved exchange between a provider and a registry.

Comments:

- HL7 notes that a lack of standardization across electronic infrastructure -- on the data element, definition, and value set level -- has made implementation of health information technology within registries difficult.
- More work needs to be done to encourage the originators of data to adhere to standards in order to promote bidirectional data exchange. Supporting a widely used, consensus-based standard like FHIR reduces burden, including on health IT implementers.
- HL7 applauds an effort by ONC to help harmonize the EHR reporting infrastructure and standards involved in reporting to registries and getting information from registries back to clinical care. Siloed programs and the lack of a common EHR reporting framework are directly related to real and perceived provider burden. It is critical that in considering EHR connection to registries, that the existing work public health has done in immunizations, electronic case reporting, cancer case reporting, newborn screening, the FHIR Common

Reporting Framework (Public Health Work Group) and other HL7 work in Common Clinical Registries be considered and that HL7 be involved in any process going forward.

- It is important that there be a focus on more than the data “what” of reporting so that standards and clinical infrastructure to automate the “when, where, and how” of registry population reporting and reduce provider burden are also available. Also critical is that data authorities, considerations for chronic diseases, reportable conditions, and other public health programs are all thoughtfully considered. It is critical that public health be adequately represented in these activities and that other reporting functions including quality reporting, pay for performance, and other payer driven activities use and support common EHR reporting infrastructure as well.

