



Health Level Seven® International
Unlocking the Power of Health Information

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Submitted electronically to: <http://www.healthit.gov>

Dear Dr. Rucker:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on ONC's 2017 Interoperability Standards Advisory (Advisory) with considerations for the release of 2018 "Reference Edition". HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related interoperability standards, including the rapidly emerging Fast Healthcare Interoperability Resources (FHIR), the Consolidated Clinical Document Architecture (C-CDA), and the widely used V2 messaging standards. HL7 is comprised of more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

As the global authority on interoperability in healthcare, HL7 is a critical leader and driver in the standards arena. The products of our organization – including the rapidly evolving FHIR standards - provide the underpinnings for connected, patient-centered health care and an information highway for precision medicine.

We appreciate ONC's continued progress forward with each subsequent ISA edition and the forum to provide input to the Interoperability Standards Advisory in preparation of the 2018 ISA "Reference Edition". Based on input from HL7's diverse Work Groups we offer: general considerations, responses to the questions ONC specifically raised, as well as detailed suggestions on both a number of already documented interoperability needs and additional interoperability needs.

Key high-level comments include the following:

- **ISA Introduction** – HL7 recommends further clarification in the ISA Introduction about how use cases and interoperability needs are selected for ISA inclusion, including a short paragraph describing scope and focus in this area. Providing transparency on criteria and sourcing would also be helpful.
- **Use Case Context and Variance** – ISA use cases that include specifications should indicate adoption level within specific settings (i.e. ambulatory vs. inpatient, work-based vs. mobile). Having knowledge of these variances can help put adoption levels and standards maturity ratings into context.
- **2018 Reference Edition Lock –In Date** – HL7 appreciates the efforts to continuously update the ISA as new information becomes available. In reviewing the current ISA, questions remain as to when a "Reference Edition" would be locked in to maintain a steady point of reference. HL7 suggests a lock-in of the 2018 ISA Reference Edition

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when the PDF publication becomes available, accompanied by an on-going ability to generate a PDF of the most current state for off-line use.

HL7 Work Groups have put forth a dedicated effort to submit specific and substantive feedback on relevant ISA questions posed by ONC. HL7 Work Groups contributing to these comments include those on:

- Clinical Decision Support
- Clinical Quality Information
- Community-Based Care and Privacy
- Electronic Health Records
- FHIR Infrastructure
- Orders and Observations
- Patient Care
- Public Health
- Security

Related to this, you will find in this submission detailed comments on ISA topics such as:

- Patient Clinical “Problems” (i.e., conditions)
- Admission, Discharge, and Transfer
- Clinical Decision Support
- Public Health Reporting
- Security
- Research
- Clinical Trials

In addition, we suggest specific new use research and public health cases to be added to the 2018 ISA and that a separate use case/interoperability need be created to address a Secure Application Infrastructure and address SMART, OAuth 2.0, and OpenID as implementation guidance and standards. Lastly, we offer the library of HL7 functional models, functional profiles, and domain analysis models to provide context to the interoperability needs documented in the ISA.

Attached we provide further detailed comments. Please do not hesitate to contact us to discuss our suggestions in more detail. 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 ONC.

Sincerely,



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



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General Considerations

- We suggest that ONC provide further clarification in the Introduction about how use cases and interoperability needs are selected for inclusion into the ISA, e.g., the criteria to accept/reject proposed suggestions. Providing such transparency on criteria and sourcing would be helpful.
- We suggest that use cases reflect interoperability needs that include specifications that may have wide adoption in either an ambulatory or inpatient setting. In some instances, the specifications may be widely adopted using workstation based technology, but not in a mobile setting. Having some indication and discussion of these variances can help put adoption levels and standards maturity ratings into context.
- Considering the above and the need for general clarity on the scope of a use case and interoperability need, we suggest that a short paragraph be provided to describe the scope and focus of the ISA.
- Considering the increased focus on security and privacy as health data is shared across providers, we have included various comments on the inclusion of security labels in Section I Vocabulary, and across a variety of interoperability needs in Section II. This includes:
 - The SAMHSA stewarded NIH VSAC sensitive clinical code value sets¹, which enable the computable assignment of security labels;
 - The HL7 vocabulary referenced by the HL7 Privacy and Security Healthcare Classification System (HCS), which are used for security labeling across HL7 Product Families; and

This vocabulary is used or required by HL7 Version 2 CON and ARV segments, CDA Consent Directive, Data Segmentation for Privacy, and Data Provenance Implementation Guides; and the FHIR AuditEvent, Provenance, and Consent and Contract (typed as a privacy consent directive) Resources to convey computable privacy, consent, security, provenance, and trust policies.

¹ <https://vsac.nlm.nih.gov/valuesets> - need a UMLS Account. Search on SAMHSA to locate the SAMHSA Sensitive Clinical Code Value Sets.

Responses to Questions Raised

17-1. In what ways has the ISA been useful for you/your organization as a resource? ONC seeks to better understand how the ISA is being used, by whom, and the type of support it may be providing for implementers and policy-makers.

- We suggest based on feedback from our membership that there is mixed use of the ISA. To some, it provides a helpful overview of the interoperability standards/implementation guides/profiles landscape including adoption and maturity. The ISA is also used to help identify an appropriate standard to consider for new interoperability needs they need to support. In some scenarios, the ISA is hardly used where a high level of familiarity exists.
- We appreciate the elimination of the label “best available” as this term would not clarify how good it is, which is more appropriately expressed through the adoption and maturity ratings.
- We are concerned with the limited value the ISA has for use in roadmap activities and planning that enables implementers to better decide when to adopt certain standards. It would be helpful for ONC to indicate what the minimum thresholds are for new or revised certification editions and to consider a standard/implementation guide/profile suitable for national adoption.
- We very much appreciate the increased focus on implementation guides and profiles rather than base standards. We indicated in specific areas where such a focus is absent and where more specific guidance is already available. When referencing an implementation guide or profile, there is no need to also reference the base standard as such usage may be interpreted as an alternative, thus opening up all the ambiguities, flexibilities or variances that the implementation guide or profile was intended to remedy for that use case. We therefore urge ONC to not reference a base standard when referencing an implementation guide or profile.

17-2. Over the course of 2017, various new functionalities have been added to the ISA to make it a more interactive and useful resource (e.g., print-friendly pages, change notifications, advanced search functionality, etc.). Are there additional features or functionalities that would enhance the overall experience?

- We appreciate the web-published version in general as it provides capabilities that are otherwise hard to achieve in a PDF. We also appreciate the ability to submit individual comments that therefore yield better visibility into not only what was included, but also why something may not be included. However, we are concerned that the web published version of the ISA remains a challenge to use, particularly regarding the navigation. We offer the following suggestions to make further improvements:
 - Provide navigation at the top of the form, not just at the bottom, to save clicks and scrolling.
 - Fix the forward/backward navigation when within a sub-section. Effectively, navigation is backwards as within a section it starts with the last interoperability need in the list and goes up, rather than starting at the top of the list and going down.
 - Provide searches on “modified” or “added since a certain date”. Since the initial publication of the 2017 ISA, a number of updates have been made. Continuous updates are helpful, but they must be easy to recognize and find.
 - We suggest that each row in the interoperability needs main table have an identifier for easy reference.
 - We note that on this page (<https://www.healthit.gov/isa/iii-a-push-exchange>), the list in the main form is not the same as in the navigation pane on the left.
- As we reviewed the latest version of the Interoperability Standards Advisory (ISA), we appreciate the efforts to continuously update the ISA as new information becomes available. The updates summary helps to understand what changed. We also appreciate that most recently the PDF version of the 2017 ISA was locked into its original publication. For further ease of revision control, tracking, and transparency, we offer the following suggestions:
 - Provide an ability to generate the most current content in PDF format. The “View ISA as a Single Page” is close, but does not seem to include everything, e.g., Introduction.
 - Include updates on a regular scheduled basis rather than as they become available, e.g., monthly or quarterly, that include an announcement and summary of changes and a trigger for interested parties to review the details of the change. This could point to the “Recent ISA Updates” page.

- We note a typo in the left-hand navigation pane that states for Section II-K Healthy Weight (typo highlighted in red) “Sending Health Weight Information”.

17-3. An [Appendix II](#) has been added that includes educational and informational resources as recommended by the Health IT Standards Committee/2017 ISA Task Force. Are there other topics and/or existing resources which would be helpful to include in this area to increase stakeholder understanding of health IT interoperability issues?

- We appreciate the addition of this appendix. We suggest adding a link to the HL7 CDS Standards wiki page that summarizes related standards: http://wiki.hl7.org/index.php?title=HL7_CDS_Standards.

Section I: Vocabulary/Code Set/Terminology Standards

17-4. Are there additional Interoperability Needs (with corresponding standards) that represent specific [sociodemographic, psychological, behavioral or environmental domains](#) that should be included in the ISA?

- No comments.

Section II: Content / Structure Standard and Implementation Specifications

17-5. A new interoperability need, [Reporting Birth Defects to Public Health Agencies](#) was added to Section II-R: Public Health Reporting. Please review and provide comment about the accuracy of the attributes.

- No comments.

Section III: Standards and Implementation Specifications for Services

17-6. A new subsection, III-J: [Consumer Access/Exchange of Health Information](#) has been added, with four interoperability needs. Please review and provide comment about the accuracy of the attributes. ONC also seeks suggestions for additional consumer access related interoperability needs for inclusion, as well as other known standards or Open APIs that should be listed for existing consumer access interoperability needs.

- We support the inclusion of the interoperability need for [Remote Patient Authorization and Submission of EHR Data for Research](#).
- We suggest that ONC add both the HL7 Personal Advance Care Plan Document (PACPD) and Questionnaire/Response Document implementation guides to this section.
- We note that there are a number of research related FHIR Resources, and the work underway under the ONC Patient Choice for Research Technical Project with the REACHnet Pilot to exercise a FHIR Informed Consent Bundle using FHIR Contract, Consent, Research Subject, Research Study, Plan Definition, and a pick list of clinical intervention FHIR Resources with which to describe a specific healthcare research protocol.
- With respect to additional consumer access related interoperability needs, ONC should consider the Consumer Centered Data Exchange (CCDE) use cases developed for an exercise in the September 2017 FHIR Connectathon, and likely to be further explored in upcoming FHIR Connectathons. The focus of the CCDE use cases are various approaches to using SMART on FHIR or UMA to enable a consumer to control App access to their health information whether stored in a EHR or other resource server.

A key CCDE challenge is developing an approach to using OAuth 2.0 or UMA 2.0 that complies with HHS guidance on [Individuals’ Right under HIPAA to Access their Health Information 45 CFR § 164.524](#) that states the individual’s Right of Access request must “be in writing, signed by the individual, and clearly identify the designated person and where to send the PHI”, and elsewhere refers to designated third-parties. HHS also stated that with respect to “Do individuals have a right under HIPAA to have a covered entity establish a direct connection between the covered entity’s system and the individual’s app or device in order to provide the individuals with access to their PHI, [...]that starting in 2018, under Stage 3 of the EHR Incentive Program, eligible professionals, eligible hospitals, and critical access hospitals (CAHs) using Certified EHR Technology must enable application programming interface (API) functionality that would allow patients to use the application of their choice to access their data.

Various CCDE Connectathon track participants explored using SMART on FHIR, UMA 2.0, and Cascading OAuth protocols with OAuth Access Tokens as the means to convey such a Right of Access Request, which is captured using either a FHIR Consent Resource with a referencing FHIR Provenance the memorializes the signature ceremony and a FHIR Contract typed as a Right of Access request that contains the individual's signature inline. An alternative approach considered is retrospectively recording an individual's authorization of an App to access health information using either a FHIR Consent or FHIR Contract Resource. A concern with these different approaches is the extent to which the Right of Access request captured is legally binding.

Section IV: Models and Profiles

17-7. Is the existing ISA format used for listing standards and implementation specifications applicable for listing Models and Profiles? Are there additional or different attributes that should be collected for them? Are there additional models and/or profiles that should be listed?

- We support the inclusion of the various functional profiles and models as they provide very helpful context, overviews, and definitions of terms for a number of use cases. These models inform the scope of implementation guides and profiles in particular. They also can serve as an introduction to individuals new to interoperability issues and be an aid in understanding the requirements to be addressed, and perhaps potential gaps to be considered for future updates.
- We suggest that functional profiles are more clearly shown as derivations of functional models as systems would claim conformance to functional profiles, not functional models.

Section V: Administrative Standards and Implementation Specifications

- We do not have specific feedback on the questions raised, but do offer various suggestions for new use cases/interoperability needs in Section V of the Detailed Response.

17-8. Please review the contents of the new [Section V: Administrative Standards and Implementation Specifications](#) and provide comments about the accuracy of any of the listed standards/specifications and attributes.

17-9. Are there additional administrative-related interoperability needs that should be listed in this section?

17-10. For Interoperability Need: [Health Care Claims or Equivalent Encounter Information for Institutional Claims](#), feedback is requested on the update process for X12 standards, and how a more streamlined process can be implemented with greater industry engagement. Other improvement ideas are also encouraged to enhance the benefit of the transaction.

17-11. For Interoperability Need: [Health Care Claims or Equivalent Encounter Information for Dental Claims](#), feedback is requested from the dental community on enhancements to the transaction to increase uptake on electronic transactions.

17-12. For Interoperability Need: [Enrollment and Disenrollment in a Health Plan](#), feedback is requested on the use of the adopted enrollment transaction, its value to the industry, and any enhancements that could be made to increase utilization.

17-13. For Interoperability Need: [Electronic Funds Transfer for Payments to Health Care Providers – Professionals and Institutions](#), are there known barriers to the use of the EFT transaction based on contract concerns, excessive fees, enrollment constraints or other non-EDI issues?

17-14. For Interoperability Need: [Health Care Payment and Remittance Advice](#), feedback is requested on how the transaction or use by the submitter and/or receiver can be improved to enhance its use and increase the value of the transaction.

17-15. For Interoperability Need: [Referral Certification and Authorization Request and Response for Dental, Professional and Institutional Services](#), feedback is requested to better understand the workflows that will increase adoption of this transaction.

17-16. For Interoperability Need: [Operating Rules to Support Eligibility and Claim Status Transactions \(Phase II\)](#), feedback is requested on: a) the process for creating the operating rules; b) current adoption of the batch vs. real time rules for both providers and health plans; c) need for other operating rules that will improve adoption of the transactions.

17-17. For Interoperability Need: [Operating Rules for Electronic Funds Transfer \(EFT\) and Electronic Remittance Advice \(ERA\) for Payments and Reconciliation \(Phase III\)](#), feedback is requested on other operating rules that will increase adoption

and/or use of the standards for EFT and ERA.

Detailed Response

Introduction

We suggest that ONC clarify in the Introduction – ISA Structure that Section I represents general vocabulary references for defined use cases and interoperability needs, but that the implementation guides / profiles referenced in Section II will provide any specific use of such vocabulary in the context of that implementation guide / profile and the ISA Section I does not override that guidance.

Section I

A – Allergies

- No comments

B – Encounter Diagnosis

- No comments

C – Family Health History

- No comments

D - Functional Status/Disability

- Interoperability Need: Representing Patient Functional Status and/or Disability
 - We recommend considering PROMIS, acknowledging it is not an official standard and comes with the associated risk, as well as that its implementation has many challenges. We suggest this be used as a platform to urge further work, as no other viable standard is available.

Additionally, standards not maintained by an SDO or similar organization increases risks for implementers. While appropriate experts have developed many standards with the best of intentions, failure to move such standards into formal SDO organizations and processes leaves the standards without a clear plan for ongoing maintenance, update, and support. However, we still suggest including these types of standard where ONC can clearly identify they are not under active maintenance by a formal SDO, and the risks to implementers are clearly stated.

E – Health Care Provider

- No comments.

F - Imaging (Diagnostics, interventions and procedures)

- No comments

G – Immunizations

- No comments

H – Industry and Occupation

- We note that the links got to the wrong site and that Industry and Occupation should be reflected through two different sets as suggested below:

Type	Standard Implementation/ Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
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Type	Standard Implementation/ Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	Occupation CDC Census 2010	Final Draft	Production Pilot	Feedback Requested	No	Free	N/A
Standard	Industry CDC Census 2010	Final Draft	Production Pilot	Feedback Requested	No	Free	N/A

The observations they're related to are Past or Present Occupation, Past or Present Industry, Usual Occupation and Usual Industry. The observation LOINC codes:

- LOINC code for Past or Present Industry: 86188-0 'Occupation Industry'
- LOINC Code for Past or Present Occupation: 11341-5 'History of Occupation'
- LOINC code for Usual Industry: 21844-6 'Usual Industry'
- LOINC code for Usual Occupation: 21843-8 'Usual Occupation'

I – Lab Tests

- We suggest that ONC remove the second bullet in the Limitations section as the third bullet provides a more accurate definition. E.g., the third bullet indicates that a single lab test with a single result “will” have the same LOINC term, while the third bullet states this more appropriately as a “may”.
- We suggest that ONC add a reference for LOINC codes, which are also used for Ask-At-Order Entry questions when ordering tests. The suggested value set is those LOINC codes that can be found using "aocobservation:notnull".

J – Medications

- No comments

K – Units of Measure

- No comments

L – Nursing

- No comments

M: Patient Clinical “Problems” (i.e., conditions)

- Interoperability Need: Representing Patient Clinical “Problems” (i.e., Conditions)
 - We note that the hyperlink to LOINC projects in the Limitations section actually goes to the full list of projects, not just LOINC projects. We suggest that ONC provide a more specific link, or another means to identify projects related to problems related projects.

N – Preferred Language

- No comments

O – Procedures

- No comments

P – Race and Ethnicity

- No comments

Q - Research

- No comments

R – Sex at Birth, Sexual Orientation and Gender Identity

- No comments

S – Social Determinants

- No comments

T – Tobacco Use

- No comments

U: Unique Device Identification

- Interoperability Need: Representing Unique Implantable Device Identifiers
 - We suggest that ONC replace the link on the HL7 Harmonization Pattern for Unique Device Identifiers with the following more current link:
http://www.hl7.org/documentcenter/public/wg/orders/Harmonization_Pattern_for_Unique_Device_Identifier_R3_20160314.docx. We note that this document is expected to go through ballot in January 2018 and shortly thereafter will be published with various updates.
- Interoperability Need: Representing Unique Implantable Device Identifiers
 - We note that the FDA’s UDI regulation is actually not an interoperability standard and should not be listed as such. Rather it defines what a UDI is and prescribes the need for capturing and presenting such data. The actual UDI standard is “UDI System for Medical Devices (Version 2.0)” by IMDRF, while the FDA provided further guidance in “Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI) - Draft Guidance for Industry and Food and Drug Administration Staff”. We suggest to list these instead.

We suggest that ONC adds the following additional Vocabulary use cases and standards:

- Interoperable security labels with standard privacy tag vocabulary
 - [HL7 Privacy and Security Healthcare Classification System Release 1](#) [HCS] for use across HL7 V2, V3, CDA, and FHIR as well as in IHE transport protocols, and in FHIR.
 - We appreciate that a number of security patterns reference the need for security labels. We suggest that ONC references the HCS in all those instances as “standard metadata”.
- Sensitive Clinical Information
 - SAMHSA stewarded Sensitive Code Value sets from the [National Library of Medicine Value Set Authority Center](#) (VSAC).

Section II

A - Admission, Discharge, and Transfer

- Interoperability Need: Sending a Notification of a Patient’s Admission, Discharge and/or Transfer Status to Other Providers
 - We recognize that HL7 ADT messages are commonly used to notify interested stakeholders outside the organization of key events going through an HIE or increasingly using Direct. We suggest that ONC clarify this interoperability need in the Limitations section, specifying the potential of using Direct (which is then further defined in Section III) to encourage further adoption of such messages where health information exchange networks are not in place or not used by a user for this purpose.
 - We also reiterate our view, expressed above, that referencing a base standard is not very helpful, even when only a small data set is in play. It can lead to highly variant implementations. We suggest in this scenario that, for specific use case interoperability needs, ONC more strongly highlights this issue and invites active stakeholders to work with SDOs, taking their experiences and turning them into an implementation guide / profile for wider, more consistent industry adoption. We also note that having implementation guidance in this space will be critical to further interoperability through the Trusted Exchange Framework and Common Agreement (TEFCA) as identified in the *21st Century Cures Act*. This approach for implementation guidance may include specifications using FHIR profiles as well.

- We ask ONC to help encourage the industry to address security labeling in V2 messages/segmentation to comply with laws, policies, and consent directives governing HIPAA PHI and specially protected information (SPI). HL7 has projects in place to create the necessary V2 implementation guidance. We also note that Use of HL7 Healthcare Privacy and Security Classification (HCS) security label syntax and vocabulary in HL7 Version 2 ADT is being planned for implementation by the Michigan Health Information Network (MiHIN). MiHIN has piloted this use for the Basic Choice phase of the ONC Patient Choice Technical Project. MiHIN demonstrated this capability at HIMSS 2017 Interoperability Showcase.

B – Care Plan

- No comment

C – Clinical Decision Support

- Interoperability Need: Sharable Clinical Decision Support
 - We suggest that CQL should reference R1.2.
 - We suggest to include in the Applicable Security Patterns Considerations the use of FHIR security labels as described at <http://www.hl7.org/fhir/security-labels.html> to support compliance with laws, policies, and consent directives governing HIPAA PHI and specially protected information (SPI). Using security labels would enable a Clinical Decision Support (CDS) system to aware of sensitive information to which a treating provider may not be authorized to access except in the case of potential patient safety issues. A security label aware CDS could alert an otherwise unauthorized provider to “Break the Glass” in order to avert harm to the patient, while ensuring that the provider’s access is auditable.
- Interoperability Need: Provide Access to Appropriate Use Criteria
 - We are unclear what this use case represents when it is not the knowledge artifact, and it is not the service. This is an example where a short description of the interoperability need would be helpful to provide context and clarify that this addresses the interaction between the user and the appropriate use criteria knowledge base.
 - We note that the FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR) in STU 3 was incorporated into FHIR as a core implementation guide, FHIR Clinical Reasoning. We thus suggest removing CQF on FHIR Release 1, which was an older version of ClinicalReasoning.
 - While it is still reasonable to reference the IHE GAO profile, since within HL7, GAO is inactive and possibly withdrawn. However, parts of it are likely to resurface as part of CDS Hooks. We therefore suggest to clarify that the emerging CDS Hooks standards are targeted to replace this.
 - We are concerned that calling out CDS interoperability needs at this level of granularity may lead to having to highlight many other CDS interoperability needs as well, although we recognize that emerging implementation guides may be at that level of granularity. As standards and implementation guidance are expected to be CDS Hooks based, it is possible to have one general interoperability need in Section III that focuses on the basic capabilities and to enumerate in this section under one interoperability need, the emerging variety of profiles and implementation guides, or use a reasonable grouping.
 - We suggest to include in the Applicable Security Patterns Considerations the use of FHIR security labels as described at <http://www.hl7.org/fhir/security-labels.html> to support compliance with laws, policies, and consent directives governing HIPAA PHI and specially protected information (SPI).

D – Clinical Quality Measurement – CQI

- Interoperability Need: Sharing Quality Measure Artifacts for Quality Reporting Initiatives
 - We suggest to reference FHIRPath as an emerging standard (previously called FluentPath and now renamed). http://www.hl7.org/implement/standards/product_brief.cfm?product_id=460
 - We suggest that ONC add a roadmap consideration under Limitations, Dependencies, and Preconditions for FHIR Clinical Reasoning
 - We suggest that ONC replace HQMF STU 2.1 with HQMF Normative (R1). http://www.hl7.org/implement/standards/product_brief.cfm?product_id=97
 - We suggest to include in the Applicable Security Patterns Considerations the use of FHIR security labels as described at <http://www.hl7.org/fhir/security-labels.html> to support compliance with laws, policies, and consent directives governing HIPAA PHI and specially protected information (SPI).

E – Clinical Quality Reporting

- Interoperability Need: Reporting Aggregate Quality Data to Federal Quality Reporting Initiatives
 - We suggest that ONC update QRDA Category III to STU 2.1 for aggregate reporting in 2018 and 2019.
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=405
- Interoperability Need: Reporting Patient-level Quality Data to Federal Quality Reporting Initiatives
 - We suggest that ONC update QRDA Category I to STU 4 for implementation of eCQMs in 2018 and QRDA Category I STU 5 for implementation of eCQMs in 2019.
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35
- Reporting Patient-level and Aggregate Quality Data for Quality Reporting and Evaluation
 - We noticed that this interoperability need reflects the combination of the prior two interoperability needs combined and just lists FHIR. We suggest that this should not be a separate interoperability need, rather that the suggested standards are listed under each of the prior two interoperability needs.
 - We suggest to include in the Applicable Security Patterns Considerations the use of FHIR security labels as described at <http://www.hl7.org/fhir/security-labels.html> to support compliance with laws, policies, and consent directives governing HIPAA PHI and specially protected information (SPI).

F - Data Provenance

- Interoperability Need: Establishing the Authenticity, Reliability, and Trustworthiness of Content Between Trading Partners.
 - We suggest that the standards and commentary are not limited to CDA R2. Provenance data is available in many implementation guides/profiles, integral to those specifications rather than externally defined. (E.g., FHIR has a Provenance resource, while in V2 this information is integrated into the various messages/segments). We acknowledge that there is not necessarily clarity for those other specifications about what data is specifically supporting provenance and thus has to be maintained with the essential data being communicated, e.g., results. An example of this would be the EHR-S Functional Requirements for laboratory results that identify data that must be persisted, which includes provenance data, although not separately highlighted. Perhaps this is another example where the ISA can be used to call out a gap for SDOs to document what data -- regardless of transport and format (document/message/service) -- establishes core provenance that implementation guides/profiles should always include as well as encourage systems to hold on to and pass along, accompanied by specific guidance on how such data is included in the various formats, e.g., a V2 Data Provenance IG or a FHIR Provenance IG comparable to the CDA Data Provenance IG.
 - We suggest that ONC add a reference to the FHIR Provenance resource as an emerging standard, recognizing that profiles and implementation guides are not yet available, thus implementation maturity should be a “pilot” and adoption level --at most-- one bullet.

G - Diet and Nutrition

- No comments

H - Drug Formulary and Benefits

- No comments

I - Electronic Prescribing

- Interoperability Need: A Prescriber’s Ability to Create a New Prescription to Electronically Send to a Pharmacy
 - This may be an example where clarifying that the use case/interoperability need encompasses various settings such as mobile devices or office/clinic/hospital setting that the interoperability need title would not convey.

J - Family Health History

- No comments

K - Healthy Weight

- No comments

L - Images

- No comments

M - Laboratory

- Interoperability Need: Receive Electronic Laboratory Test Results
 - We strongly urge inclusion of the HL7 Lab EHR-S IG, which clarifies sender/receiver responsibilities to achieve end-to-end interoperability. If it is included in Section IV with other functional profiles, we suggest that the Limitations section references the Section IV entry as a dependency.
 - We ask ONC to help encourage the industry to address security labeling in V2 messages/segmentation to comply with laws, policies, and consent directives governing HIPAA PHI and specially protected information (SPI). HL7 has projects in place to create the necessary V2 implementation guidance.
- Interoperability Need: Ordering Labs for a Patient
 - We ask ONC to help encourage the industry to address security labeling in V2 messages/segmentation to comply with laws, policies, and consent directives governing HIPAA PHI and specially protected information (SPI). HL7 has projects in place to create the necessary V2 implementation guidance.

N - Medical Device Communication to Other Information Systems/Technologies

- No comments

O - Patient Education Materials

- No comments

P - Patient Identification Management

- No comments

Q - Patient Preference/Consent

- Interoperability Need: Recording Patient Preferences for Electronic Consent to Access and/or Share their Health Information with Other Care Providers
 - We suggest ONC clarify that this interoperability need focuses on computable consent directives that support security labels.
 - We suggest that ONC add the FHIR Consent Resource and FHIR Contract Resource typed for different types of consent directives including privacy, medical, advanced directives and informed consent for research as emerging standards, recognizing that further profiles and implementation guides are in progress. These are necessary condition for *21st Century Cures Act* trusted exchange.

R - Public Health Reporting

- Interoperability Need: Reporting Cancer Cases to Public Health Agencies
 - HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 - US Realm
 - We suggest that ONC replace the implementation specification with: [Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, August 2012](#). This is the standard named in the 2014 final rule and is in use for Stage 2 MU.
 - We suggest that ONC replace “balloted draft” with “final”. It was never balloted. The HL7 CDA R2 replaces this standard in the 2015 final rule.
 - HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm
 - We suggest to remove “Emerging”. This standard is being used.
 - We suggest to replace pilot with production.
 - We suggest to replace the current testing validation tool with: <http://cda-validation.nist.gov/cda-validation/muCRV.html>
 - HL7 FHIR Implementation Guide: Structured Data Capture (SDC) Release 1
 - We suggest to remove this implementation guide. This standard defines the framework and structure for SDC and it does not contain cancer case reporting library of questionnaires.

- We suggest to include the standard for Pathology Laboratory reporting to Cancer Registries. It has never been HL7 balloted, but it uses the HL7 2.5.1 standard. This standard can be found at the following links:
 - IHE Anatomic Pathology Reporting to Public Health (ARPH): https://www.ihe.net/Technical_Framework/upload/IHE_PAT_Suppl_ARPH_Rev2-0_TI_2010-07-23.pdf
 - North American Association of Central Cancer Registries (NAACCR) Volume V Pathology Laboratory Electronic Reporting Standard: <https://20tqtx36s1la18rvn82wcmprn-wpengine.netdna-ssl.com/wp-content/uploads/2016/11/Pathology-Laboratory-Electronic-Reporting-Version-4.0-April-2011.pdf>. The IHE Profile was developed based on the NAACCR Volume V specification.
- Interoperability Need: Case Reporting to Public Health Agencies
 - We suggest that FHIR DSTU 2 and STU 3 are not yet appropriate standards to reference as there is no profiling/implementation guidance available yet. However, as soon as available we will inform ONC of its publication. Conversely, the SDC implementation guide is not adequate to be a case reporting specific implementation guide, thus should be removed as it is not applicable.
 - HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2 - US Realm - the Electronic Initial Case Report (eICR)
 - We suggest to correct the implementation guide name to name of the implementation guide: HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2, STU Release 1.1 – US Realm, the Electronic Initial Case Report (eICR)
 - We suggest to add the testing tool: <https://validator.sandbox.aimsplatform.com/hitspValidation2/>
 - We suggest to replace the bullet “Electronic case reporting is not wide spread and is determined at the state or local jurisdiction” with “Electronic case reporting involves reporting to State and/or Local jurisdictions and is not yet widespread”
 - We suggest to add the following implementation specification:

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption level	Federally Required	Cost	Testing Tool Availability
Implementation Specification	HL7 CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.0 US Realm	Balloted Draft	Pilot	One dot	No	Free	No

- We suggest to include in the Applicable Security Patterns Considerations the use of FHIR security labels as described at <http://www.hl7.org/fhir/security-labels.html> to support compliance with laws, policies, and consent directives governing HIPAA PHI and specially protected information (SPI).
- Interoperability Need: Reporting Birth Defects to Public Health Agencies
 - We note the suggestion by HIMSS to update the interoperability need to reflect “Reporting Newborn Birth, Health and Death to Public Health Agencies”. We suggest that Newborn Birth and Birth Defects should be maintained as two separate interoperability needs as birth defects may be diagnosed years after birth, thus needing to consider additional/other data to be exchanged. Instead we suggest to add the following standards under a Newborn Screening interoperability need:

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption level	Federally Required	Cost	Testing Tool Availability
Implementation Specification	HL7 Version 2.6 Implementation Guide: Critical Congenital Heart Defects (CCHD) pulse oximetry screening results, Release 1	Balloted Draft	Pilot	One dot	No	Free	No
Implementation Specification	HL7 Version 2.6 Implementation Guide: Early Hearing, Detection and Intervention (EHDI) Results Release 1	Balloted Draft	Pilot	One dot	No	Free	No

- We suggest that ONC add two interoperability needs: (1) Birth/Fetal Death Reporting to Federal, state and local agencies; and (2) Death Reporting to Federal, state and local agencies. The best available standards for birth/fetal death and death reporting are:
 - HL7 Version 2.6 Implementation Guide: Birth and Fetal Death Reporting, Release 1 STU Release 2 (US Realm - Standard for Trial Use)
 - HL7 Version 3 CDA R2 Implementation Guide: Birth and Fetal Death Reporting, Release 1 (US Realm - Standard for Trial Use)
 - HL7 Version 2.6 Implementation Guide: Vital Records Death Reporting, Release 1 (US Realm - Standard for Trial Use)
 - HL7 CDA R2 Implementation Guide: Vital Records Death Reporting, Release 1 STU 2 - (US Realm) (Standard for Trial Use)
 - IHE Birth and Fetal Death Reporting – Enhanced (BFDR-E)
 - IHE Vital Records Death Reporting (VRDR)
 - HL7 EHR-S FM Public Health Functional Profile, Release 2 (includes a Vital Records domain)
 - Interoperability Need: Electronic Transmission of Reportable Lab Results to Public Health Agencies
 - We recommend removing the reference to the Emerging Implementation Specification “ HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public health, Release 2 (US REALM), Draft Standard for Trial Use, Release 1.1. This guide was in DSTU however was not renewed or nor balloted as normative.
 - We recommend referencing in its place the Public Health Profile of the [HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm](#) in the table. This is currently referenced in the second bullet under Limitations, Dependencies, and Preconditions for Consideration.

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption level	Federally Required	Cost	Testing Tool Availability
<i>Emerging Implementation Specification</i>	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm	In Development	Pilot	One dot	No	Free	Yes

S - Research

- Interoperability Need: Pre-population of Research Forms from Electronic Health Records
 - We suggest that ONC add the FHIR Audit Event and FHIR Research Study and Research Subject resources as emerging approaches to conveying research information.
 - We suggest to add SDC Questionnaire/Questionnaire Response for pre-populating Research Forms.
 - We suggest to add FHIR Audit Events to generate FHIR Accounting of Disclosure resources for research.

T - Segmentation of sensitive information

- Interoperability Need: Document-Level Segmentation of Sensitive Information
 - We suggest that ONC increase the maturity and adoption levels of data segmentation at the CDA header level as specified in the HL7 Data Segmentation for Privacy CDA Implementation Guide as there is widespread implementation of C-CDAs to meet Meaningful US, which includes conformance to this standard. Effectively, every MU incented provider is already using a header level HL7 security label with the one mandatory privacy tag.
 - Implementation Maturity = Production at header and XD.*
 - Adoption Level = 61% to 80% adoption.
 - We suggest that ONC to change Regulated from “no” to “yes” for the HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition as it is the foundation for the implementation guide. Alternatively, where an implementation guide is available, there is no need to reference the underlying standard directly as the implementation guide will do so.

- We suggest that ONC add a new interoperability need to address Section-Level Segmentation of Sensitive Information referencing the same standards as the document-level use case, but indicate low level of maturity (Pilot) and adoption level (one dot). Inclusion intends to encourage the industry to begin adoption of section-level segmentation, particularly as the ONC Patient Choice Technical Project is launching consent pilots in 2018.
- We note that these interoperability needs should actually be listed as part of the interoperability needs they support, as it is to be integral part of those use cases.
- We ask ONC to help encourage the industry to address security labeling in V2 messages/segmentation to comply with laws, policies, and consent directives governing HIPAA PHI and specially protected information (SPI). HL7 has projects in place to create the necessary V2 implementation guidance. As the implementation guidance for FHIR and V2 are established, the ISA should include them as well.

U - Summary care record

- Interoperability Need: Support a Transition of Care or Referral to Another Health Care Provider
 - We suggest that ONC include the emerging Companion Guide for C-CDA R2.1.

Suggested Use Cases to Add

- **Referral Management** - We suggest that ONC add a new use case for Referral Management and reference both the emerging FHIR resources supporting referrals, as well as the IHE 360X profile addressing closed loop referral.
- **Care Team**: We suggest that ONC add a new use case Care Team that will be used to represent Dynamic Care Team Management. Dynamic Care Team Management provides the means for sharing care team information about a patient's care teams that meet the needs of many users, such as providers, patients and payers.

◦ **Rationale**

Person-centered collaborative, focused care teams are needed for effective care planning to occur. Care planning is vital for managing medically complex and/or functionally impaired individuals as they interact with the health care system. Often, these individuals require real time coordination of care as they receive care from multiple care providers and care settings. The IHE DCTM profile provides the ability to dynamically share care team information so effective care coordination can occur.

ISA Section II currently includes IHE Dynamic Care Planning (DCP) Profile. IHE DCTM Profile compliments IHE DCP to support real time coordination of care.

Proposed interoperability need: *Sharing Patient Care Teams for Multiple Clinical Contexts*

Type: *Emerging Implementation Specification*

Standard Implementation/Specification: [IHE Dynamic Care Team Management \(DCTM\), Rev 1.1 Trial Implementation](#)

Standards Process Maturity: *Balloted Draft*

Implementation Maturity: *Pilot*

Adoption Level: *Feedback Requested*

Federally Required: *No*

Cost: *Free*

Test Tool Availability: *Yes ([Forge](#))*

- We suggest that ONC adds a new use case for Auditing that entails collection (import and generation) access, use, and disclosure of health information. For this use case we suggest that ONC includes two interoperability needs:
 - Interoperability Need: Communicate Audit Records
 - IHE ATNA
 - FHIR AuditEvent
 - Interoperability Need: Accounting of Disclosure

- FHIR AuditEvent

- We suggest that ONC adds a new use for Trust with the following initial interoperability need.
 - Interoperability Need: Interactive Negotiation of Trust for Allowable Capabilities
 - TF4FA – Trust Framework for Federated Authorization²
 - FHIR Contract resource for App Terms of Service and for Trust Contract to determine trading partner capabilities for e.g., consuming and enforcing computable consent directives
- We suggest adding a new sub-section to section II: Occupational Data for Health (ODH). We also note that FHIR and V2 based capabilities are in progress as well.

Type	Standard Implementation/ Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	IHE Quality, Research and Public Health Technical Framework Supplement: Healthy Weight (HW). Rev. 2.2 – Trial Implementation, section 6.3.3.10.5, Occupational Data for Health Section, 1.3.6.1.4.1.19376.1.5.3.1.3.37, p. 127-128 and section 6.3.4, CDA Entry Content Modules, p. 129- 144.	Balloted Draft	Pilot	Feedback Requested	No	Free	Yes
Implementation Specification	HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes; Additional Templates, Release 1 - US Realm, Chapter 4, Occupational Data for Health, p. 41-74.	In Development		Feedback Requested	No	Free	No

² HL7 Version 3 Standard: Privacy and Security Architecture Framework (PSAF), [Trust Framework for Federated Authorization, Release 1](#) (TF4FA) was last published in the May 2017 Ballot. The Security Workgroup is actively refining TF4FA for ballot in January 2018.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
<ul style="list-style-type: none"> The Occupational Data for Health (ODH) CDA template is being balloted by HL7 as a supplemental template for incorporation in C-CDA 	

Section III

A – “Push” Exchange”

- Interoperability Need: An Unsolicited “Push” of Clinical Health Information to a Known Destination Between Systems
 - We suggest to include in the Applicable Security Patterns Considerations the use of FHIR security labels as described at <http://www.hl7.org/fhir/security-labels.html> to support compliance with laws, policies, and consent directives governing HIPAA PHI and specially protected information (SPI).

B – Clinical Decision Support Services

- Interoperability Need: Providing Patient Specific Assessments and Recommendations Based on Patient Data for Clinical Decision Support
 - We suggest that ONC add CDS Hooks as an emerging specification (not yet balloted). Once published we expect it to replace DSS R2, DSS IG R1.1
 - We suggest that the version of CQL should be updated to R1.2
 - We suggest that the version of QICore should be updated to STU Release 2 (publication in progress)
 - We suggest to include in the Applicable Security Patterns Considerations the use of FHIR security labels as described at <http://www.hl7.org/fhir/security-labels.html> to support compliance with laws, policies, and consent directives governing HIPAA PHI and specially protected information (SPI).

C – Image Exchange

- No comments

D – Healthcare Directory, Provider Directory

- Interoperability Need: Listing of Providers for Access by Potential Exchange Partners
 - We suggest to include in the Applicable Security Patterns Considerations the use of FHIR security labels as described at <http://www.hl7.org/fhir/security-labels.html> to support compliance with laws, policies, and consent directives governing HIPAA PHI and specially protected information (SPI).

E – Patient Identification Management

- No comments

F – Public Health Exchange

- No comments

G – Publish and Subscribe

- No comments

H – Query

- Interoperability Need: Data Element Based Query for Clinical Health Information

- We suggest that the references to FHIR R2 or R3 are replaced with RESTful FHIR API as this section appears to be about transport/infrastructure, as also implied by the references to RESTful FHIR API in the Limitation sections.
- We suggest that ONC include the Argonaut Implementation Guide and US Core into Section II for the query content.
 - Standards Process Maturity: Published
 - Implementation Maturity: Early stages of roll-out
 - Adoption Level: 1-2
 - Federally Required: No
 - Cost: Free
 - Test Tool Availability:
- We suggest to include in the Applicable Security Patterns Considerations the use of FHIR security labels as described at <http://www.hl7.org/fhir/security-labels.html> to support compliance with laws, policies, and consent directives governing HIPAA PHI and specially protected information (SPI).

Additional Use Case Suggestions

- We suggest that ONC include a separate use case/interoperability need to address a Secure Application Infrastructure and address SMART, OAuth 2.0., and OpenID as implementation guidance and standards.
- We suggest that it would be helpful to include terminology services as an interoperability need in Section III. We specifically suggest to reference CTS2 ([http://wiki.hl7.org/index.php?title=Common_Terminology_Services_-_Release_2_\(Normative\)\)](http://wiki.hl7.org/index.php?title=Common_Terminology_Services_-_Release_2_(Normative))).

Section IV

A – Functional Models

- We suggest adding the HL7 EHR-S FM Release 2: Functional Profile; Work and Health, Release 1 to section IV: Models and Profiles. Clinical users of EHR Systems can benefit from a targeted set of the patient's work and/or injury/poisoning causation data to provide care, create reports, and meet other stakeholders' expectations such as public health case reporting, surveillance, and investigative studies.
 - Type: Implementation Specification
 - Maturity: In development
 - Adoption level: none
 - Federally required: no
 - Cost: Free
 - Test Tool Availability: no

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption level	Federally Required	Cost	Testing Tool Availability
Specification	HL7 EHR-S FM Release 2: Functional Profile; Work and Health, Release 1 to section IV: Models and Profiles	In Development	Pilot	One dot	No	Free	No

- We suggest adding a not for Limitations, Dependencies, and Preconditions for Consideration that There is work underway to prepare a normative update to the Work and Health Functional Profile.

B – Functional Profiles

- We suggest that ONC include the following functional profiles specifically:
 - HL7 Record Lifecycle Event Implementation Guide, part of FHIR DSTU-2 (published September 2015), based on ISO/HL7 10781 EHR-S FM, Record Infrastructure Chapter, Record Entry Lifespan and Lifecycle (see: <http://hl7.org/fhir/ehrsrle/ehrsrle.html>)

- HL7 Meaningful Use Functional Profile for Stages 1&2 (published 2015), based on ISO/HL7 10781 EHR-S FM (see: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=409)
- Nutrition Care Process Functional Profile (see: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=369)
- Personal Health Record – Functional Model (see: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=88)
- HL7 EHR-System Public Health Functional Profile, Release 2 (see: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=278)

C – Information Models

- We suggest that ONC include references to the following HL7 Domain Analysis Models that provide helpful context for a wide variety of interoperability use cases:
 - [HL7 Cross-Paradigm Domain Analysis Model: Vital Records, Release 2](#)
 - [HL7 Domain Analysis Model: Clinical Sequencing, Release 1](#)
 - [HL7 Domain Analysis Model: Emergency Care, Release 1 – US Realm](#)
 - [HL7 Domain Analysis Model: Harmonization of Health Quality Artifact Reasoning and Expression Logic](#)
 - [HL7 Domain Analysis Model: Health Quality Improvement, Release 1](#)
 - [HL7 Domain Analysis Model: Immunization, Release 1](#)
 - [HL7 Domain Analysis Model: Specimen, Release 1](#)
 - [HL7 Service Functional Model; Coordination of Care Service \(CCS\), STU Release 1](#)
 - [HL7 Specification: Domain Analysis Model Specifications and Requirements - Canonical Definition, Release 1](#)
 - [HL7 Version 3 DAM: Biomedical Research Integrated Domain Group \(BRIDG\)](#)
 - [HL7 Version 3 Domain Analysis Model: Allergy and Intolerance, Release 1](#)
 - [HL7 Version 3 Domain Analysis Model: Behavioral Health Record, Release 2](#)
 - [HL7 Version 3 Domain Analysis Model: Cardiology, Release 2](#)
 - [HL7 Version 3 Domain Analysis Model: Care Plan, Release 1](#)
 - [HL7 Version 3 Domain Analysis Model: Clinical Trials Registration and Results \(CTR&R\), Release 1](#)
 - [HL7 Version 3 Domain Analysis Model: Composite Security and Privacy, Release 1, May 2014](#)
 - [HL7 Version 3 Domain Analysis Model: Detailed Clinical Models for Medical Devices, Release 1](#)
 - [HL7 Version 3 Domain Analysis Model: Diet and Nutrition Orders, Release 2](#)
 - [HL7 Version 3 Domain Analysis Model: Emergency Medical Services, Release 1](#)
 - [HL7 Version 3 Domain Analysis Model: Health Concern, Release 1](#)
 - [HL7 Version 3 Domain Analysis Model: Laboratory Orders, Release 1](#)
 - [HL7 Version 3 Domain Analysis Model: Major Depressive Disorder, Release 1](#)
 - [HL7 Version 3 Domain Analysis Model: Preoperative Anesthesiology, Release 1](#)
 - [HL7 Version 3 Domain Analysis Model: Schizophrenia, Release 1 - US Realm](#)
 - [HL7 Version 3 Domain Analysis Model: Trauma Registry Data Submission, Release 1](#)
 - [HL7 Version 3 Domain Analysis Model: Vital Records \(VR DAM\)](#)
 - [HL7 Version 3 Specification: Event Publish & Subscribe Service Interface – Release 1 – US Realm](#)
 - [HL7 Version 3 Specification: Ordering Service Interface – Release 1](#)
 - [HL7 Version 3 Specification: Unified Communication Service Interface – Release 1 – US Realm](#)
 - [HL7 Version 3 Standard: Public Health; Tuberculosis Domain Analysis Model, Release 1](#)

Section V

We propose the addition of the following use cases / interoperability needs, noting that all standards references are emerging standards and require further profiling and implementation guidance before this can be widely deployed.

- Exchange of clinical and administrative information between auxiliary providers who provide services in outpatient and inpatient settings
 - Use FHIR Billing specification to support information exchange models and messages needed for exchange of clinical and administrative information between auxiliary providers who provide services in outpatient and inpatient settings.

Rationale: Anesthetists often provide their services not within their own office but in the offices and operating rooms of other providers such as hospitals, clinics and dental offices. The clinical and

administrative information associated with the anesthesia service rendered onsite needs to be transmitted from the point of service EMR/EHR to the anesthesiologist's office or billing service to complete the serving providers EMR and to support billing for services. The HL7 Financial Management (FM) Work Group is working on defining in FHIR the information exchange models and messages to support this exchange of clinical and administrative information.

- Standard: [FHIR Billing Resource](#)
- Social services transactions not using X12 HIPAA transactions
 - There are intra-enterprise transactions that may be conducted using V2 and proprietary formats that might benefit from use of FHIR FM Resources as these systems are updated.
Rationale: Moving the industry toward internet-based protocols using standard healthcare models such as FHIR as the long term care and social services ecosystem transitions to interoperable exchanges where no electronic standards yet exist would benefit that community and their clients. Please note that the HL7 FM WG is in the process of setting up a relationship with X12 to encourage collaboration and interoperability between X12 and FM FHIR. This involves developing a SDO MOU.
 - Standard: [FHIR Financial Management Resources](#)
- Care coordination, ACO, and value based purchasing use cases.
 - There are inter-enterprise transaction needs that are just now becoming evident, which could benefit from use of FHIR FM Resources as these exchanges would be to a large extent conducted with “green field” RESTful protocols and systems.
Rationale: Moving the industry toward internet-based protocols using standard healthcare models such as FHIR before a multitude of alternative approaches, which may not be interoperable or consensus based, would help ensure limitations on information blocking that would otherwise ensue.
 - Standard: [FHIR Financial Management Resources](#)
- Explanation of Benefits
 - Dynamic access to explanation of benefits
Rationale: Currently ExplanationOfBenefit is limited to informing Medicare Beneficiaries about claims adjudicated on their behalf. Work is underway to expand that Resource to address more general Explanation of Benefit requirements, including decrements from out-of-pocket expenses, deductible levels, and additional services available where those have a set maximum, e.g., chiropractic visits. Moving the industry toward internet-based protocols using standard healthcare models such as FHIR before a multitude of alternative approaches, which may not be interoperable or consensus based, would help ensure limitations on information blocking that would otherwise ensue.
 - Standard: [ExplanationOfBenefit](#).

Appendix I

We suggest the following changes to the references:

- Replace [NIST Special Publication: 800-63-2. Electronic Authentication Guideline. August 2013](#)
- Replace [NIST Special Publication 800-53. Security and Privacy Controls for Federal Information Systems and Organizations Revision 4. April 2013](#)
- Include NIST 8062
- Include FHIR Security and Privacy Module - <http://www.hl7.org/fhir/secpriv-module.html>.
- Include [HL7 Version 3 Standard: Healthcare \(Security and Privacy\) Access Control Catalog, Release 3](#)