

Document name: Comment and Review In Advance of 2018 "ISA Reference Edition" Publication.

INSTRUCTIONS: ALL comments will be identified as Critical, Substantive or Administrative. Comments not marked will be considered Administrative.

Critical - Indicates non-concurrence with the document until the comment is satisfactorily resolved; convincing support for critical comments must be provided.

Substantive - Indicates that a section in the document appears to be or is potentially unnecessary, incorrect, misleading, confusing or inconsistent with other sections; requires convincing support.

Administrative - corrects what appears to be a typographical, format or grammatical error.

All comments with a request for action must have a complete recommended change with a complete rationale provided.

Please submit comments to: diana.m.novak.ctr@mail.mil and Christopher.hills@navy.mil by COB 3 Nov 2017

Page # or Section VI Question #	Section	Name of "Interoperability Need"	Name of Standard Implementation Specification	Comment type (C, S, A)	Rationale	Commenter Name/Organization	Commenter Email/Phone
N/A	II-B: Care Plan	Documenting and Sharing Care Plans for a Single Clinical Context	HL7 Fast Healthcare Interoperability Resources (FHIR), STU 3	S	Update FHIR STU3 link to the published spec, hl7.org/fhir	Dave Carlson/ Department of Veterans Affairs	dave.carlson@bookzurman.com/
N/A	II-B: Care Plan	Documenting and Sharing Care Plans for a Single Clinical Context	HL7 Resource Care Plan (v1.0.2)	S	Reference to HL7 FHIR Care Plan resource should be v3.0.1, not v1.0.2 (which is DSTU2)	Dave Carlson/ Department of Veterans Affairs	dave.carlson@bookzurman.com/
N/A	III-B: Clinical Decision Support Services	Providing Patient-Specific Assessments and Recommendations Based on Patient Data for Clinical Decision Support	HL7 Fast Healthcare Interoperability Resources (FHIR Implementation Guide:) Clinical Reasoning STU Release 2	S	Update link to FHIR spec from hl7.org/fhir/2016Sep to hl7.org/fhir	Dave Carlson/ Department of Veterans Affairs	dave.carlson@bookzurman.com/
N/A	III-B: Clinical Decision Support Services	Providing Patient-Specific Assessments and Recommendations Based on Patient Data for Clinical Decision Support	HL7 CDS Hooks	S	Add a new row for "CDS Hooks", http://cds-hooks.org/ , an emerging HL7 Cross-Paradigm Specification that is expected to be the most widely implemented standard by EHR and other product vendors for returning patient-specific assessments and recommendations from CDS services.	Dave Carlson/ Department of Veterans Affairs	dave.carlson@bookzurman.com/
N/A	II-B: Care Plan	Sharing Patient Care Plans for Multiple Clinical Contexts	HL7 Fast Healthcare Interoperability Resources (FHIR), DSTU 2	S	Replace FHIR DSTU2 reference to be FHIR STU3	Dave Carlson/ Department of Veterans Affairs	dave.carlson@bookzurman.com/
N/A	II-B: Care Plan	Sharing Patient Care Plans for Multiple Clinical Contexts	IHE Dynamic Care Planning (DCP), Rev 1.1 Trial Implementation	S	Update the IHE spec reference for dynamic care planning, it has now been updated to use FHIR STU3	Dave Carlson/ Department of Veterans Affairs	dave.carlson@bookzurman.com/
N/A	III-H: Query	Data Element Based Query for Clinical Health Information	HL7 Fast Healthcare Interoperability Resources (FHIR), STU 3	S	FHIR STU3 should be listed with same maturity as DSTU2, or preferably remove DSTU2 replaced by STU3. Both should are type=Standard, maturity=Balloted Draft	Dave Carlson/ Department of Veterans Affairs	dave.carlson@bookzurman.com/
N/A	III-H: Query	Data Element Based Query for Clinical Health Information	HL7 Fast Healthcare Interoperability Resources (FHIR), STU 3	S	Update link to FHIR spec from hl7.org/fhir/2016Sept to hl7.org/fhir/	Dave Carlson/ Department of Veterans Affairs	dave.carlson@bookzurman.com/
Entire Document	Entire document	Entire document	HL7 Fast Healthcare Interoperability Resources (FHIR), DSTU 2	S	Search entire ISA content for outdated references, replace: hl7.org/fhir/2016Sep with: hl7.org/fhir/ (the current balloted and published FHIR STU3). I found two, as documented here, and there are probably others.	Dave Carlson/ Department of Veterans Affairs	dave.carlson@bookzurman.com/
N/A	II - L: Medical Device Communication to Other Information Systems/Technologies:	Transmitting Patient Vital Signs from Medical Devices to Other Information Systems/Technologies	Regenstrief "LOINC/IEEE Medical Device Code Mapping Table" published as a part of LOINC	S	This mapping file allows enterprise information system (i.e. "Other Information Systems/Technologies") to process vital signs and combine those observations with other types of information; it bridges the semantic map between IEEE 11073 10101 conformant medical devices and Meaningful Use certified or aligned information systems that use LOINC already for laboratory reports, document taxonomies, standard forms, questionnaires, assessments, social determinants, and screeners	Ioana Singureanu/Department of Veterans Affairs	ioana.singureanu@bookzurman.com
N/A	I-U: Unique Device Identification	Representing Unique Implantable Device Identifiers	IHE Patient Care Coordination (PCC) Point-of-Care Medical Device Tracking (PMDT) Profile Supplement, FHIR Procedure, FHIR Device	S	Provider organizations such as VHA are currently in the process of deploying to solutions to capture the identity (UDI) of implantable and other types of devices at the point-of-care and communicate that information along with procedure details from the point-of-care to enterprise systems. This profile addresses the needs of provider organizations to capture the information and convey it to medical device registries, inventory systems, and EHR systems. This specification illustrates how the UDI is captured and sent from the point-of-care to the enterprise. This specification was developed based on business requirements provided by VHA and the Association of periOperative Registered Nurses (AORN).	Ioana Singureanu/Department of Veterans Affairs	ioana.singureanu@bookzurman.com
	#3 Adoption Level	N/A	N/A	S	What are the objective criteria used to assess the adoption level of a standard? This seems very subjective, i.e. there are no tangible criteria noted to measure actual industry adoption level.	Greg Staudenmaier / VA	greg.staudenmaier@va.gov
	Entire document	Medical Device Identification & Communication	N/A	S	I would recommend grouping all of the medical device interoperability entries together under 1 consolidated heading. I would also include the FDA UDI entries so that all of the medical device information is consolidated in one section.	Greg Staudenmaier / VA	greg.staudenmaier@va.gov
	I-U: Unique Device Identification	Unique Device Identification	FDA UDI	S	There are 3 entries for FDA UDI (not including GUIDID). The content is the same for all 3 entries. I recommend replacing 3 entries with 1 entry which represents all 3 interoperability needs, because it is the same standard.	Greg Staudenmaier / VA	greg.staudenmaier@va.gov
85-88	Appendix I	Standard missing	OASIS XACML 2.0/3.0	S	Add this standard for identity Assertion	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	ASTM 2147	S	Add this standard for Standard Specification for Audit and Disclosure Logs	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	ASTM 1985	S	Add this standard for User Authentication and Authorization	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	ASTM 1986	S	Add this standard for Standard Guide for Information Access Privileges to Health Information	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	ISO 17522	S	Add this standard for Health Informatics -- Provisions for Health Applications on Mobile/Smart Devices	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	ISO 10181-3	S	Add this standard for 3 Information technology: Open Systems Interconnection-Security frameworks for open systems: Access control framework	DoD/VA Interagency Program Office (IPO)	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	ISO 22600:2014	S	Add this standard for 2014 Health informatics -- Privilege management and access control (Vol 1-3)	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	ISO 27789:2013	S	Add this standard for Health informatics -- Audit trails for electronic health records	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	ISO/IEC 10181-2:1996	S	Add this standard for information technology -- Open Systems Interconnection -- Security frameworks for open systems: Authentication framework	DoD/VA Interagency Program Office (IPO)	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	ISO/IEC 24760-2:2015	S	Add this standard for information technology -- Security techniques -- A framework for identity management -- Part 2: Reference architecture and requirements	DoD/VA Interagency Program Office (IPO)	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	ISO/IEC 29115:2013	S	Add this standard for information technology - Security techniques: Entity authentication assurance framework	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	ISO 27001	S	Add this standard for information Security Management	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NIST FIPS 180-2	S	Add this standard for Secure Hash (NIST SP 800)	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NIST 800-57	S	Add this standard for NIST Special Publication 800-57 Recommendation for Key Management: Part 1: General (Revision 3)	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NIST 800-131A	S	Add this standard for NIST Special Publication 800-131A, Transitions: Recommendation for Transitioning the Use of Cryptographic Algorithms and Key Lengths, January 2011	DoD/VA Interagency Program Office (IPO)	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NIST FIPS 201-2	S	Add this standard for PIV	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NIST FIPS 140-2	S	Add this standard for Security Requirements for Cryptographic Modules	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NIST 800-52	S	Add this standard for TLS	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NIST FIPS 197	S	Add this standard for AES	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NACI	S	Add this standard for Background Investigations	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	OASIS WS-TRUST 1.4	S	Add this standard for STS	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NIST 800-101	S	Add this standard	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NIST 800-124	S	Add this standard for NIST SP 800-124 Rev 1 Guidelines for Managing the Security of Mobile Devices in the Enterprise	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	IHE XDR	S	Add this standard for IHE Cross-Enterprise Document Reliable Interchange (XDR)	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	IHE XDS	S	Add this standard for IHE Cross-Enterprise Document Sharing (XDS)	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NIST 800-12	S	Add this standard	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NIST 800-92	S	Add this standard	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NIST 800-63	S	Add this standard for Electronic Authentication Guide	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	ITU-T X.509	S	Add this standard for Certification	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	HL7 FHIR Release 3 (STU)	S	Add this standard for assessing authenticity, enable trust	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	HL7 PASS-SLS	S	Add this standard for HL7 Privacy, Access and Security Services (PASS); Security Labeling Service (SLS), V3 r1, June 2014	DoD/VA Interagency Program Office (IPO)	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	ICAM Federal Bridge	S	Add this standard for Certification Authority (FBCA) Certificate Policy	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NIST 800-163	S	Add this standard for NIST SP 800-163 Technical Considerations for Vetting 3rd Party Mobile Applications (Draft)	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NIST 800-164	S	Add this standard for Guidelines on Hardware-Rooted Security in Mobile Devices (Draft)	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	OASIS SAML	S	Add this standard for Assertions and Protocols for the OASIS Security Assertion Markup Language (SAML) V2.0, OASIS Standard, 15 March 2005	DoD/VA Interagency Program Office (IPO)	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	NISTR 8062	S	Add this standard for An Introduction to Privacy Engineering and Risk Management in Federal Systems	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil
85-88	Appendix I	Standard missing	ITUX - 841	S	Add this standard	DoD/VA Interagency Program Office	christopher.i.hills.civ@mail.mil

14	I-H Lab tests	Method less should be methodless or "Method not indicated"	Lab Tests	A	Correct grammar	DoD/VA Interagency Program Office (IPO)	christopher.j.hills.civ@mail.mil
2	Scope	and is not mean to explicitly direct "how" the standards and implementation -not meant		A	Correct grammar	DoD/VA Interagency Program Office (IPO)	christopher.j.hills.civ@mail.mil
12	I-F Imaging	Radlex is not as globally available as LOINC at this time	Radlex	S		DoD/VA Interagency Program Office (IPO)	christopher.j.hills.civ@mail.mil
11	I-E: Health Care Providers	Representing Health Care Providers	NUCC	A	The NUCC codes are now the same as the Healthcare Provider Taxonomy (HIPAA) code set. The old HCPT code set is now obsolete, as of about 2010. The HL7 Registry has Healthcare Provider Taxonomy Code (NUCC) Value set OID: 2.16.840.1.113883.11.19465, which could be added to the Applicable Value Set(s) and Starter Set(s): section.	DoD/VA Interagency Program Office (IPO)	christopher.j.hills.civ@mail.mil
11	I-E: Health Care Providers	Representing Provider Role in Team Care Settings		A	Applicable Value Set(s) and Starter Set(s): • Healthcare Provider Taxonomy (HIPAA): 2.16.840.1.114222.4.11.1066 is listed but this is an obsolete value set. It should use the HL7 Value Set Healthcare Provider Taxonomy Code (NUCC) Value set OID: 2.16.840.1.113883.11.19465	DoD/VA Interagency Program Office (IPO)	christopher.j.hills.civ@mail.mil
12	I-G: Immunizations	Representing Immunizations – Historical	HL7 Standard Code Set MXV - Manufacturing Vaccine Formulation	A	• The link above leads to the Immunization Information Systems (IIS) web page, where it says "The CDC's National Center for Immunization and Respiratory Diseases (NCIRD) developed and maintains HL7 Table 0227, Manufacturers of Vaccines (MVX)" • FROM HL7 OID Registry: HL7 version 2.x Manufacturers of vaccines (code=MVX) used in chapter(s) 4; HL7 table 0227. The most current version of this code system, which is considered the source of truth, may be found at: http://www2a.cdc.gov/vaccines/iis/standards/vaccines.asp?rpt=mxv . For convenience of access, the content may also be accessed through the CDC PHINVADS system at https://phinivads.cdc.gov/vads/ViewCodeSystem.action?id=2.16.840.1.113883.12.227	DoD/VA Interagency Program Office (IPO)	christopher.j.hills.civ@mail.mil
13	I-G: Immunizations	Representing Immunizations – Administered	HL7 Standard Code Set MXV - Manufacturing Vaccine Formulation	A	• The link above leads to the Immunization Information Systems (IIS) web page, where it says "The CDC's National Center for Immunization and Respiratory Diseases (NCIRD) developed and maintains HL7 Table 0227, Manufacturers of Vaccines (MVX)" • FROM HL7 OID Registry: HL7 version 2.x Manufacturers of vaccines (code=MVX) used in chapter(s) 4; HL7 table 0227. The most current version of this code system, which is considered the source of truth, may be found at: http://www2a.cdc.gov/vaccines/iis/standards/vaccines.asp?rpt=mxv . For convenience of access, the content may also be accessed through the CDC PHINVADS system at https://phinivads.cdc.gov/vads/ViewCodeSystem.action?id=2.16.840.1.113883.12.227	DoD/VA Interagency Program Office (IPO)	christopher.j.hills.civ@mail.mil
13	I-H: Industry and Occupation	Representing Patient Industry and Occupation	CDC Census Coding System	A	Think it would be better to call out the Standard/Implementation Specification as "NIOSH Industry and Occupation Computerized Coding System (NIOCCS)". Or better yet, change the Standards part to clarify that there are two code systems in use: "North American Industry Classification System (NAICS)" The North American Industry Classification System (NAICS) consists of a set of six digit codes that classify and categorize industries. It also organizes the categories on a production/process-oriented basis. This new, uniform, industry-wide classification system has been designed as the index for statistical reporting of all economic activities of the U.S., Canada, and Mexico. North American Industry Classification System(NAICS) for the United States, a new economic classification system that replaces the 1987 Standard Industrial Classification (SIC) for statistical purposes. NAICS is a system for classifying establishments by type of economic activity. Its purposes are: (1) to facilitate the collection, tabulation, presentation, and analysis of data relating to establishments, and (2) to promote uniformity and comparability in the presentation of statistical data describing the economy. NAICS will be used by Federal statistical agencies that collect or publish data by industry. More information may be found at http://www.census.gov/eprd/www/naicsusr.html and AND "Occupation (SOC 2000)" The 2000 Standard Occupational Classification (SOC) system is used by Federal statistical agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data	DoD/VA Interagency Program Office (IPO)	christopher.j.hills.civ@mail.mil
7	I-A	Representing Patient Allergies and Intolerances: Medications		S	Request ISA define Drug Class Allergen and specify the terminology	DoD/VA Interagency Program Office (IPO)	christopher.j.hills.civ@mail.mil
8	I-A	Representing Patient Allergies and Intolerances		S	Consider deprecating UNII as standard on Food and Environmental Substances	DoD/VA Interagency Program Office (IPO)	christopher.j.hills.civ@mail.mil
	Vocabulary/Code Set/Terminology			S	Consider addition of Document Type using LOINC as terminology since HL7 broadly recommends the use of LOINC codes, and specifically those with the Scale = "Doc" within LOINC	DoD/VA Interagency Program Office (IPO)	christopher.j.hills.civ@mail.mil
	I-B	Representing Patient Medical Encounter Diagnosis		S	ISA only contains Encounter Diagnosis, it does not have an Encounter Type attribute. ISA should add encounter type with OPT/SNOMED	DoD/VA Interagency Program Office (IPO)	christopher.j.hills.civ@mail.mil
#8	Vocabulary/Code Set/Terminology	Medical Device Communication to Other Information Systems/Technologies		S	Consider addition of Medical Device Type for nomenclature standardization. Propose using UMLS- SNOMED CT/ Global Medical Device Nomenclature (GMDN)	DoD/VA Interagency Program Office (IPO)	christopher.j.hills.civ@mail.mil
	Content/Structure Standards and Implementation Specifications			S	For FHIR Base Version Draft Standard for Trial Use 2 (DSTU2) - required and Standard for Trial Use 3 (STU3) - emerging	DoD/VA Interagency Program Office (IPO)	christopher.j.hills.civ@mail.mil