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October 1, 2018

Donald Rucker, MD
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Rucker,

On behalf of the 34 members of the Electronic Health Record Association (EHRA), we are pleased to offer our input on the 2018 Interoperability Standards Advisory (ISA).

EHRA members serve the vast majority of hospitals and ambulatory care organizations that use electronic health records (EHRs) and other health information technology to deliver high quality, efficient care to their patients. The Association operates on the premise that the rapid, widespread adoption of health information and technology (IT) has and will continue to help improve the quality of patient care as well as the productivity and sustainability of the healthcare system.

Robust standards and implementation guidance provide the foundation to enable consistent and predictable data exchange. Because EHR software developers must always be looking forward to what is next, a document that references existing rather than emerging standards limits the day-to-day usefulness of the ISA to our organizations. However, we are grateful for the value the ISA resource provides to many stakeholders with whom we collaborate, and we offer our expertise in suggesting improvements for future editions.

Responses to Questions Raised by ONC

18-1. 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 policymakers.

While the ISA is not a tool our membership uses frequently, it is a helpful library for those becoming familiar with the interoperability landscape to understand the breadth and depth of standards and implementation specifications available to

consider. It remains challenging to ensure readers clearly understand that adherence to all standards and specifications is not directly required by them being listed in the ISA. Rather, it is through programs, initiatives, and agreements that particular standards and specifications become a requirement. Additionally, particularly with standards and specifications focused on public health, the reader must realize that individual states frequently require support for their own variants, which are not included in the ISA. We suggest that inclusion of state agencies' specifications may actually be a helpful addition.

18-2. Over the course of 2018, some new functionality has been added to the ISA, with more enhancements expected through 2018 and 2019. Are there additional features or functionality that would enhance the user experience?

We appreciate the updates made to improve navigation. We noticed the following challenges:

- When navigating from, e.g., <https://www.healthit.gov/isa/representing-patient-allergies-and-intolerances-environmental-substances> to the next page, Emergency Medical Services interoperability needs are skipped and the user is put on the Encounter Diagnosis page. When on Emergency Medical Services page that can use forward is Race and Ethnicity. This navigation is confusing as it does not follow the table of contents. We suggest repairing the links navigation so that it follows the table of contents.
- We suggest that having the ability to navigate forward/backward between interoperability needs would be enhanced by providing forward/backward at the top of the page, in addition to the bottom of the page.
- In prior versions we suggested it be helpful to have use cases better described, beyond the title, to better understand the intended use and scope of the suggested standard. Another example in the current ISA would be "Representing Patient Preferred Language (Presently)." What does that mean, particularly the use of the word 'presently'? A short paragraph would resolve this challenge.

18-3. 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? Are models and profiles useful for inclusion in the ISA?

Functional Models, Functional Profiles, and Information Models are generally informative, akin to reference guides and dictionaries, thus the qualifications around adoption levels and maturity are more challenging to assess. We believe that it is challenging to attempt for health to meaningfully document what functional models and profiles they support, as frequently the specific user/client requirements either need capabilities that are not included, and/or fewer capabilities in order to support that organization's needs. The information models typically represent logical/conceptual representations and may be implemented in various ways based on data scope and use.

EHRA suggests that, therefore, the information about these documents be limited to their availability (including links), development status, and a short paragraph on its focus/purpose and remove the maturity and adoption levels.

Also, we suggest introducing these sections for general educational and reference purposes, as specific use cases drive actual capabilities that are essential and how best to represent the data.

18-4. Are there additional informative or educational resources that can be provided to help stakeholders better understand the ISA, health IT standards, interoperability, etc.?

We have no further suggestions at this time beyond those provided throughout our responses to other questions and detailed review below.

Introduction/General

The Association appreciates the various updates to continue clarifying the role of the ISA to industry. We believe that this can be further clarified and would like to make the following suggestions:

- Under Purpose, the first bullet states “To provide the industry with a single, public list of the standards and implementation specifications that can best be used to address specific clinical health information interoperability needs. Currently, the ISA is focused on interoperability for sharing information between entities and not on intra-organizational uses.” We submit that the standards included cannot always be “best be used to address specific clinical health information interoperability needs.” While certainly they can and should be considered, they may not be mature enough, unambiguous enough, and/or widely adopted enough to be adopted for a certain purpose. We suggest clarifying that the standards listed represent those known to focus on these interoperability needs, but based on maturity, specificity, and/or adoption levels may not always be ready for certain purposes. For example, they may be very suitable for pilot adoption, but not for regulatory endorsement or contractual inclusion.
- In Section II, standards and implementation specifications are referenced inconsistently. Sometimes an implementation specification is listed with or without the standard it is based on. For example, the HL7 CDA standard is not referenced when C-CDA or other implementation specifications based on CDA are referenced. But when the IHE PAM Profile is referenced for ADT, the underlying standard HL7 V2 is referenced, or HL7 FHIR is listed when the HL7 Resource Care Plan implementation specification is listed, which is based on HL7 FHIR. Unless the intent is to consider the base standard sufficiently specific to serve as an implementation specification that drives consistent implementations across health IT (e.g., NCPDP Script versions), we suggest not including the base standards, but only the implementation specification that in turn references the standard.

- We note inconsistent references to FHIR core resources, e.g., HL7 FHIR Resource Care Plan and HL7 FHIR Nutrition Order Resource. We suggest to follow the formal title on the FHIR pages, thus it would be HL7 FHIR Resource Nutrition Order.
- We suggest including the Common Clinical Data Set (CCDS), as well as the US Core Data for Interoperability (USCDI) once its first version is published, highlighting the target data set to enable electronic access under HIPAA's data access requirements of the Designated Record Set and a key focus of the Trusted Exchange Framework (TEF) as it takes shape under the 21st Century Cures Act. This may either be done as a subsection of Section I to set the context for many of the standards and implementation specifications in the ISA, or as an interoperability need to provide access to this data set listing the available implementation specifications, e.g., HL7 FHIR US Core and Argonaut, while considering CMS' BlueButton 2.0 specifications.

Section I: Vocabulary/Code Set/Terminology

Allergies and Intolerances

We have no input to this question.

Emergency Medical Services

Representing Health Care Data for Emergency Medical Services: We suggest adjusting the reference to NEMESIS from 3 to 3.4. as companies certified to NEMESIS would support that version.

Encounter Diagnosis

We have no input to this question.

Family Health History

Patient Family Health History Observations: This interoperability need was removed in the 2018 ISA, but was not highlighted on the ISA Updates page. We suggested adding an archive of interoperability needs that were removed (e.g., diminished value or became irrelevant) or a description of where prior versions remain accessible. This would allow for explanations of why an interoperability need was archived or implementation guides removed. We believe this to have value therefore restate this suggestion for the 2019 ISA.

Functional Status/Disability

We have no input to this question.

Health Care Providers

We have no input to this question.

Imaging (Diagnostics, Interventions and Procedures)

Representing Imaging Diagnostics, Interventions and Procedures: We note that CPT4 is typically used rather than LOINC, although once Radlex and LOINC are unified there may be an opportunity to consider shifting to LOINC. We suggest, at a minimum, adding CPT4 in this section.

Representing Imaging Diagnostics, Interventions and Procedures: We note a typo in the reference to Regenstreif Institute - Regenstreif should be Regenstrief.

Immunizations

We have no input to this question.

Industry and Occupation

We have no input to this question.

Lab Tests

EHRA notes that within laboratory there are orderable lab tests, lab results, result values, as well as Ask-At-Order-Entry questions that are supported by LOINC and SNOMED. Distinguishing these concepts would provide helpful guidance and reinforce which code sets are intended to be used for which concept. We suggest adding a new interoperability need, Representing Ask-at-Order Entry questions, where LOINC is used for the questions and as applicable, SNOMED for the answers. For the LOINC value set, the following lookup identifies the current list:

<https://search.loinc.org/searchLOINC/search.zul?query=aoeobservation%3Anotnull>.

Medications

We have no input to this question.

Nursing

Various Interoperability Needs: We appreciate the inclusion of references to specific SNOMED value sets for Representing Nursing Interventions. We suggest that, unless similar references can be made to LOINC and SNOMED value sets for Representing Outcomes for Nursing and Representing Clinical/Nursing Assessments, they should be removed. Generally pointing to LOINC and SNOMED is not helpful.

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

We have no input to this question.

Preferred Language

We have no input to this question.

Pregnancy Status

We have no input to this question.

Procedures

We have no input to this question.

Race and Ethnicity

We have no input to this question.

Research

We have no input to this question.

Sex at Birth, Sexual Orientation and Gender Identity

Representing Patient-Identified Sexual Orientation: We suggest that the Implementation Maturity for both LOINC and SNOMED should be Production while the adoption level is still low.

Social, Psychological, and Behavioral Data

We have no input to this question.

Tobacco Use (Smoking Status)

We have no input to this question.

Unique Device Identification

Representing Unique Implantable Device Identifier: We suggest that the reference to the HL7 Harmonization Pattern for UDI’s be replaced with the HL7 UDI Pattern Implementation Guide R1, as well as adding a reference to the HL7 C-CDA UDI Template R1. As FHIR evolves, the HL7 UDI Pattern Implementation Guide R1 is expected to be updated. Check with HL7 on specifics.

Units of Measure

We have no input to this question.

Vital Signs

We have no input to this question.

Section II: Content/Structure

Admission, Discharge, and Transfer

Sending a Notification of a Patient's Admission, Discharge and/or Transfer Status to Other Providers:

While responses in the introduction suggest to not list a base standard when an implementation specification based on that standard is referenced; in this case, given the variety of implementations in place not using IHE PAM, we believe that it is appropriate to list the base standard, but suggest to explain the rationale for why the base standard is referenced.

Sending a Notification of a Long Term Care Patient's Admission, Discharge and/or Transfer Status to the Servicing Pharmacy: We suggest adjusting the reference from SCRIPT 10.6 to 2017071 as that is the currently established target to implement.

Care Plan

Documenting and Sharing Care Plans for a Single Clinical Context: We suggest removal of the FHIR STU3 and HL7 Resource Care Plan row and replacing them with a single row pointing to the US Core R1.0.1 (<https://hl7.org/fhir/us/core/> based on FHIR STU3) that includes a profile for Care Plan (<https://hl7.org/fhir/us/core/StructureDefinition-us-core-careplan.html>). This then would not require direct inclusion of the base standards in total (FHIR STU3) or the base standard resource (Care Plan). Additionally, it would be helpful to point to Argonaut R1 (based on FHIR DSTU2), considering many implementations in support of the 2015 Certification Edition use that specification and it probably has wider implementation than US Core R1 at this point.

We recognize that Argonaut is not a balloted implementation specification, but is worthy to note as it feeds into US Core. We suggest that Argonaut would have an adoption level of 1-2, while US Core can be reflected with a 1.

Clinical Decision Support

Shareable Clinical Decision Support: We note that various updates need to be applied to reflect more current versions, as well as that this should include a reference to CDS Hooks implementation specifications (<https://cds-hooks.org/>) that started to go through ballot.

Provide Access to Appropriate Use Criteria: We suggest clarifying that an AUC specific implementation specification using CDS Hooks is expected to be developed later this year. The HL7 CDS workgroup would already have more specifics on timeline/approach that may provide input to the limitations and dependencies table. Until that is available, standards based implementations to interact with AUC CDSMs are not expected, thus the adoption level is probably zero bullets.

Communicate Appropriate Use Criteria with the Order and Charge to the Filling Provider and Billing System for Inclusion on Claims: We suggest that this interoperability need is misplaced under CDS, as it is not a profile for decision support, rather a profile for communicating orders and charges for images requiring appropriate use criteria (AUC) information. Consequently, this should be listed under Images.

Also, we note that based on the 2018 Physician Fee Schedule rule that this profile should not be used in its current form as adjustments are needed to reflect the decisions targeted to be made in 2018. Once finalized, it must be clear that this profile does not consider the IHE Radiology order and charge profiles a prerequisite to implementation, rather that the sections on use of the OBX segments can be used as an extension on any V2 orders and charge message currently in use. This would avoid costly upgrades to the IHE Profile without any real benefit when done to support transmission of AUC data.

Clinical Quality Measurement and Reporting

Reporting Patient-level Quality Data for Quality Reporting initiatives: We note that the Da Vinci initiative is progressing a first version of a FHIR based implementation specification to exchange HEDIS measures data between providers and payers. It should be marked as In Development and a maturity of Pilot (more specifically, it is preparing for connectathons and pilots) with no adoption in the near future. It is worth including as it would address both single measure and multi-measure data exchange using FHIR.

Da Vinci is expected to provide various reference implementation tools as well by the time the 2019 ISA is expected to be published. Note that depending on the scope of the use case (we reiterate our suggestion that a short description beyond a use case title would be very helpful), the better place to update this use case is the *Sharing Quality Measure Artifacts for Quality Reporting Initiatives*.

Data Provenance

Establishing the Authenticity, Reliability, and Trustworthiness of Content Between Trading Partners: We appreciate the inclusion of the HL7 FHIR Resource Provenance. We note that this should be referenced as an Emerging Standard, not an Emerging Implementation Specification, as the necessary profiling and implementation specifications are not yet available to enable consistent implementations.

We suggest that provenance is also maintained through IHE XDS metadata and Direct protocol. However, it is not clear from the use case title whether the focus is only on the provenance that is the payload for a particular exchange (e.g., C-CDA document, FHIR resource) or the transactions themselves as well. Furthermore, depending on the scope of the provenance data of interest, other standards may

already support such data already, e.g., HL7 V2, NCPDP Script.

Regarding the adoption level of the HL7 FHIR Resource Provenance, we suggest this be 1 bullet as there are no known production implementations at this time.

Diet and Nutrition

Exchanging Diet and Nutrition Orders Across the Continuum of Care: We note that the HL7 FHIR Resource Nutrition Order is referenced as an Emerging Implementation Specification. We suggest that in the absence of an actual implementation specification that this be referenced as an Emerging Standard.

Drug Formulary & Benefits

We have no input to this question.

Electronic Prescribing

Allows a Prescriber to Request a Patient's Medication History from a PDMP: We suggest that the Adoption Level is lower as we are not aware of state PDMPs having implemented medication histories using NCPDP Script. Rather, proprietary, view-only displays are provided. We do suggest that data level interoperability would be very beneficial to support clinical decision making and believe that a combination of the HL7 FHIR Meds Implementation Guide and CDS Hooks shows promise to address this level of interaction with a medication history, thus both should be referenced.

We suggest that the interoperability need for medication history is not only for the prescriber and pharmacy, but any authorized provider making care decisions. Having access to this data, specifically through a medication history look-up, is relevant at any stage of delivering care, not only at time of prescribing new/updated medications. Also, we suggest that this be recognized by including the other the interoperability need outside of e-prescribing under Clinical Decision Support.

Family Health History (Clinical Genomics)

Representing Family Health History for Clinical Genomics: We suggest that the reference to the HL7 FHIR STU3 implementation specification be changed to the HL7 FHIR Resource FamilyMemberHistory and the associated FamilyMemberHistory-Genetic profile. Referencing the full standard where there are specific resources and profiles available should be avoided.

Healthy Weight

We have no input to this question.

Images

We have no input to this question.

Laboratory

Receive Electronic Laboratory Test Results: We suggest to update the reference to the most current version of the LRI IG to HL7 V2.5.1 Implementation guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm.

Receive Electronic Laboratory Test Results: We suggest to remove the reference to HL7 V2.5.1 to help encourage new implementations for this use case to adopt the latest LRI implementation guide, which in turn references V2.5.1 and pre-adopts various capabilities from more current HL7 V2 versions.

Ordering Labs for a Patient: We suggest to update the reference to the most current version of the LOI IG to HL7 V2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI), Release 1, STU Release 3 – US Realm

Ordering Labs for a Patient: We suggest to remove the reference to HL7 V2.5.1 to help encourage new implementations for this use case to adopt the latest LOI implementation guide, which in turn references V2.5.1 and pre-adopts various capabilities from more current HL7 V2 versions.

Support the Transmission of a Laboratory's Directory of Services to Provider's Health IT or EHR System: We suggest to update the reference to the most current version of the eDOS IG to HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework (eDOS), Release 2, STU Release 3 – US Realm

Support the Transmission of a Laboratory's Directory of Services to Provider's Health IT or EHR System: We suggest to remove the reference to HL7 V2.5.1 to help encourage new implementations for this use case to adopt the latest LOI implementation guide, which in turn references V2.5.1 and pre-adopts various capabilities from more current HL7 V2 versions.

Identify Linkages Between Vendor IVD Test Results and Standard Codes: We note that a FHIR based implementation guide went through the September 2018 HL7 Ballot cycle. While not expected to be published until early 2019 after additional connectathons and balloting, it may already be worthwhile to reference it as being in development.

Medical Device Communication to Other Information Systems/Technologies

We have no input to this question.

Patient Education Materials

We have no input to this question.

Patient Identification Management

Patient Demographic Record Matching: We agree with commenters that, generally, only minimum necessary data is exchanged and retained, particularly if an identification/match cannot be made. However, particularly for purposes of Treatment, Payment, and Operations (TPO), we should not unnecessarily limit data that can be retained once a positive identification/match is made, nor when data is retained for record location services in support of TPO in particular to improve on accessing more complete and accurate record sets.

Patient Preference/Consent

We note that the HL7 FHIR Resource Consent and HL7 FHIR Resource Contract are referenced as Emerging Implementation Specifications. These should be referenced as Emerging Standards. We note that neither Argonaut, Da Vinci, nor US Core has provided further profiling and implementation specifications. Until such time, referencing the core standard is reasonable, but implementers must be aware that they may not implement them in a fully interoperable fashion.

Public Health Reporting

We have no input to this question.

Research

We have no input to this question.

Segmentation of Sensitive Information

We appreciate the scope of the use case having been extended to be any segmentation of sensitive data. However, in the process, the impression has been created that DS4P is required for federal purposes given “Federally Required” is checked, while it is only required at the Document level through certification. We suggest that the first bullet and second to last bullet that indicates only the need for document level DS4P are combined.

Since the interoperability need appears to have been extended beyond documents, we suggest that a use case description is included to clarify the scope and assumption that it is not limited to documents that efforts in other standards be highlighted as well. For example, HL7 V2.8.2 already includes an ability to identify sensitive information that currently is going through various updates for V2.9. As the same data is communicated via messages, documents, and services, continuity of segmentation is important. We recognize that this complex are still requires much maturation and guidance before it can be

practically deployed beyond the document level. However, recognizing the availability of standards capabilities across all areas would help focus the industry on areas that need further definition and development.

Summary Care Record

We have no input to this question.

Section III: Services

“Push” Exchange

An Unsolicited “Push” for Clinical Health Information to a Known Destination Between Systems: We suggest removing the reference to FHIR DSTU 2 and STU 3 as the emerging standards, as these references are too broad and covers a number of resources that the comments in the limitations section rightfully would not consider. Rather, we suggest directly including “RESTful FHIR API” as the referenced standard in the top table.

We suggest removing the sixth bullet in the Limitations section as this is not relevant to this interoperability need focusing on transport. The payload could include a variety of content, not limited to the FHIR resources referenced in this bullet. Additionally, we suggest including a second test tool link for the IHE-XDR Profile: <http://ihexds.nist.gov/>.

Clinical Decision Support Services

Providing Patient-Specific Assessments and Recommendations Based on Patient Data for Clinical Decision Support: We suggest including HL7 CDS Hooks as a method/transport to enable CDS for this interoperability need. That would be an Emerging Implementation Specification that is in development.

Consumer Access/Exchange of Health Information

Remote Patient Authorization and Submission of EHR Data for Research: We note that the third bullet under Limitations is confusing. We suggest referencing RESTful FHIR API directly as the Emerging Implementation Specification rather than FHIR STU 3. Also, we suggest adding the SMART implementation specification as well.

Push Patient-Generated Health Data into Integrated EHR: We suggest adding SMART as an implementation guide, particularly as it is now merging into HL7 and the guidance is about to go through balloting. We suggest that the reference to FHIR be specific to the RESTful FHIR API, considering this section is about infrastructure. To the extent that this use case needs to cover content/structure, we suggest moving those aspects to Section II where emerging FHIR profiles/IG could be referenced, e.g., Argonaut and/or US Core implementation guides for such content.

Patient Exchanging Secure Messages with Care Providers: We suggest replacing the reference to FHIR STU 3 with a reference directly to the RESTful FHIR API, as that is, per the limitations section, the intended reference.

View, Download, and Transmit Data from EHR: We suggest replacing the reference to FHIR with a reference directly to the RESTful FHIR API, as that is, per the limitations section, the intended reference.

Healthcare Directory, Provider Directory

Listing of Providers for Access by Potential Exchange Partners: EHRA appreciates the inclusion of the Argonaut and US Core implementation guides. We do suggest that having included these implementation guides, there is no need including FHIR STU 3 as the standard as it is effectively referenced through the implementation guides and has the risk of leading to unnecessary variations in implementations for this interoperability need.

Image Exchange

Exchanging Imaging Documents Within a Specific Health Information Exchange Domain: We appreciate the inclusion of IHE's PIXm and suggest that it would be appropriate including IHE's PDQm and RESTful HL7 FHIR Document Reference-based API Specifications as well.

Patient Identification Management

Exchanging Patient Identification Management within a Community: We appreciate the inclusion of IHE's PIXm and suggest to also include PDXm, which are based on FHIR STU 3. EHRA suggests adding the interoperability need to address record location. IHE's XCPD should be included for that purpose rather than only being embedded in other use cases. This could include a reference to ADT notifications to enable RLS services to be kept current on where a patient has been, and thus records could be located.

Public Health Exchange

We have no input to this question.

Publish and Subscribe

We have no input to this question.

Query

We have no input to this question.

Resource Location

We have no input to this question.

Section IV: Models and Profiles

Functional Models

We have no input to this question.

Functional Profiles

We have no input to this question.

Information Models

We appreciate the inclusion of the information models and support inclusion of other balloted HL7 Domain Analysis Models, or those from other standards organizations. However, we suggest including in the Limitations section that these models are meant to provide context to the various interoperability standards and implementation specification to inform how relevant data should be able to be communicated and are in no way intended to be standards for specific HIT database schemas and implementations.

Section V: Administrative

Health Care Claims and Coordination of Benefits

We have no input to this question.

Administrative Transactions - Non-Claims

We have no input to this question.

Administrative Transactions to Financial Exchanges

We have no input to this question.

Administrative Transactions to Support Clinical Care

We have no input to this question.

Operating Rules to Support Administrative Transactions

We have no input to this question.

Appendix I: Security Sources and Patterns

We have no input to this question.

Appendix II: Educational Resources

We have no input to this question.

Thank you for this opportunity to contribute. We look forward to continuing to work with ONC and other stakeholders to advance interoperability and support patient care through the best use of electronic health records and other health information and technology.

Sincerely,

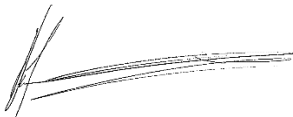


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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.