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September 23, 2019

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 33 members of the HIMSS Electronic Health Record (EHR) Association, we are pleased to offer our input on the 2019 Interoperability Standards Advisory (ISA).

EHR Association members serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our core objectives focus on collaborative efforts to accelerate health information and technology adoption, advance information exchange between interoperable systems, and improve the quality and efficiency of care through the use of these important technologies.

We appreciate the opportunity to review the most recent updates made to the ISA, and to identify further updates to be part of the annual publication. In general, the ISA is an increasingly complete and accurate reflection of the current state of available standards and implementation guides, as well as emerging standards and implementation guides, enabling an ever expanding list of interoperability needs. Having an inventory of the wider spectrum of interoperability needs, beyond document exchange and web-based APIs, is a useful resource to illuminate the breadth and depth of interoperability and the value it can provide.

EHR Association members appreciate that a number of updates were made in response to our feedback provided to the ONC last year. We note that some suggestions have not yet been addressed; for those which we believe are still relevant, we include and further clarify them in this year's input.

Our comments are organized into responses to specific questions from the ONC, a general section that addresses topics in the introductory materials and across the

advisory, followed by feedback specific to each of the major sections and the interoperability needs within them.

Thank you for this opportunity to contribute. The EHR Association would be happy to address any questions for clarifications or rationale. We look forward to continuing to work with the 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,



Cherie Holmes-Henry
Chair, EHR Association
NextGen Healthcare



Hans J. Buitendijk
Vice Chair, EHR Association
Cerner Corporation

HIMSS EHR Association Executive Committee



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About the HIMSS 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.

HIMSS Electronic Health Record Association

Comments on 2019 Interoperability Standards Advisory

Questions and Requests for Stakeholder Feedback

9-1: 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.

EHR Association Response: As EHR developers, we already have compiled, collectively and individually, substantial information on the standards reference, thus the ISA provides limited additional support for our needs. However, the information is very helpful for those entering this space and seeking to understand the breadth and depth of existing and emerging specifications.

19-2: Are there additional features or functionality ONC could make to the ISA website that would enhance the user experience?

EHR Association Response: As Association members suggested in prior feedback, we believe that the navigation can be substantially improved by providing forward and backward navigation at the top of the page in addition to the bottom of the page. Frequently one must scroll down, through lengthy sections with many comments, in order to navigate to the next (or prior) interoperability need.

19-3: The adoption level, along with other informative characteristics about standards/implementation specifications, was introduced to the ISA in August, 2015, and currently represents ONC's "best guess" at current adoption based on a number of factors. Is the adoption level characteristic as it stands valuable information for stakeholders, or should it be retired or replaced with other information?

EHR Association Response: We believe this information could be valuable, but not as currently documented. We recommend that at least it be made clear, via a narrative, the source of the rating for each standard, as there are no quantitative measures that we are aware of that would support any of the ratings. In the absence of those clarifications we do not see value with the ratings provided, as we cannot assess their reliability.

19-4. The specialty care/settings pages were added in 2019, and represent a collection of related Interoperability Needs that pertain to a particular setting or type of specialty care (i.e., pediatrics, treatment for opioid use disorder). Are there additional specialty care/settings specific collections that would be beneficial for inclusion?

EHR Association Response: While the general outline of a subset is a good start—although in many cases many settings/specialties will quickly reference everything anyway—it is unclear what, specifically, within each of these categories is unique to that setting/specialty. For example, what care plan

capabilities are unique to pediatrics that one could “ignore” for non-pediatrics? Without that level of specificity, we are concerned that implementing the standards referenced in the interoperability needs will not necessarily yield the needed support for the setting or specialty, while certain audiences will expect that it will.

General

The EHR Association is pleased with the replacement of specific lists of functional and information models from the IS, with references to the respective websites where these models can be accessed. Having awareness of these models is very helpful and we appreciate that references are still included. As these models have predominantly been used to inform interoperability standards and/or describe the context in which they are used, we agree that they do not need to be maintained in the main body of the ISA.

We note that the Purpose section characterizes the standards as “...can best be used...” and that when multiple choices are provided, it is not clear whether they are indeed the “best” or rather just “available” or “emerging.” We suggest indicating that the standards included are those that are currently in use for the interoperability need, or are emerging to be available for use to support interoperability.

We recommend that with the shift of the ISA addressing interoperability needs beyond EHRs, that all references to “EHR” be replaced with “HIT,” and that the purpose of the ISA not be limited to “clinical Health IT interoperability purpose.”

ONC Standards

ARCH

In the EHR Association’s comments in response to the “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” NPRM, members questioned the need for the API Resource Collection in Health (ARCH), considering the availability of USCDI and HL7® FHIR® R4 US Core 3.0.0 (and upcoming updates). We believe ARCH creates an unnecessary level of complexity without increased clarity. However, if ARCH is to be maintained, we recommend including a version and clarifying the purpose it serves.

USCDI

The EHR Association appreciates the inclusion of the definition of the US Common Data for Interoperability (USCDI) in general. This provides one place to view all relevant elements necessary to understand the interoperability landscape. However, as currently included it misses a connection with the standards that aim to support it.

We suggest an addition to this section, in the context of the ISA, of the standards that support the static access and exchange of this data, i.e., not the standards that enable maintenance and workflow management of this data, particularly C-CDA and FHIR. This addition, along with the applicable vocabulary, would enhance the value of this section. Specifically, if for each data class the section would reference the applicable C-CDA section and FHIR US Core resource profile, in addition to the applicable vocabulary, the relationship between the ISA and the supporting standards would be more clear. This would further remove the need for ARCH as well.

We note that the USCDI pdf contains more details than the webpage. We suggest that all details should be included on the main webpage.

Vocabulary

Emergency Medical Services

Representing Health Care Data for Emergency Medical Services:

The EHR Association suggests adjusting the reference to NEMESIS from 3 to 3.4. as companies certified to NEMESIS would support that version.

Laboratory

Representing Laboratory Tests:

The EHR Association appreciates the updates to the standards for observation values. We note though that only SNOMED is listed, while in practice LOINC is used for certain observation values as well. We recommend adding an observation value line for LOINC.

Also, we note that for laboratory orders, the order can be accompanied with answers to Ask at Order Entry questions that are necessary to perform and report on the test. The questions, akin to “observations,” are recommended to be encoded where possible using LOINC codes (<https://search.loinc.org/searchLOINC/search.zul?query=aoeobservation%3Anotnull>). We suggest that this standard be included with a maturity of final and production, and with a low adoption level.

Nursing

Representing Outcomes for Nursing:

While value set references were included for the other nursing interoperability needs, none were referenced for this interoperability need. The EHR Association suggests using the Standard Nursing Terminologies in this ONC document:

https://www.healthit.gov/sites/default/files/snt_final_05302017.pdf.

Tobacco Use

Representing Patient Electronic Cigarette Use (Vaping):

The EHR Association supports the inclusion of this interoperability need with the associated standards and value set.

Representing Patient Second Hand Tobacco Smoke Exposure:

The EHR Association supports the inclusion of this interoperability need with the associated standards and value set.

Unique Device Identification

The EHR Association agrees with removing this topic from the vocabulary section.

Content/Structure

Admission, Discharge, Transfer

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

Considering that the intent of the ISA is to promote the use of common standards, the EHR Association believes including references to foundational standards that provide overly, flexible, and optional methods to communicate data should be avoided. Referencing HL7 v2.5.1 would not support that intent.

Unless there is clarity on why a foundational standard is referenced, we suggest this be removed. If it remains included as-is, we are concerned that it may lead to programs and initiatives, such as the recent Interoperability and Patient Access NPRM by CMS, referencing a standard that when implemented, does not yield the desired consistency across implementations.

Care Plan

Documenting and Sharing Care Plans for a Single Clinical Context:

The EHR Association suggests replacing the FHIR STU3 and the HL7 Resource Care Plan rows with a single row pointing to the US Core R3.0.0 (<https://hl7.org/fhir/us/core/>), which includes a profile for Care Plan (<https://hl7.org/fhir/us/core/StructureDefinition-us-core-careplan.html>).

Additionally, it would be helpful to point to Argonaut R1 (based on FHIR DSTU2), considering that many implementations in support of the 2015 Certification Edition use that specification and that it currently has wider implementation than US Core R3. We recognize that Argonaut is not a balloted implementation specification, but is nonetheless 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.

Documenting and Sharing Medication-Related Care Plans by Pharmacists:

The EHR Association suggests including the same FHIR references as we recommend for *Documenting and Sharing Care Plans for a Single Clinical Context*, as it would support this interoperability need as well. It should be noted as an emerging standard.

Domain or Disease-Specific Care Plan Standards:

The EHR Association suggests including the same FHIR references as we recommend for *Documenting and Sharing Care Plans for a Single Clinical Context*, as it would be able to support this interoperability need as well. It should be noted as an emerging standard.

Sharing Patient Care Plans for Multiple Clinical Contexts:

The EHR Association suggests including the same FHIR references as we recommend for *Documenting and Sharing Care Plans for a Single Clinical Context*, as it would be able to support this interoperability need as well. It should be noted as an emerging standard.

Clinical Decision Support

Shareable Clinical Decision Support:

The EHR Association notes that various updates need to be applied to reflect more current versions. In addition, it should include a reference to CDS Hooks implementation specifications (<https://cds-hooks.org/>) that started to go through ballot.

Communicate Appropriate Use Criteria with the Order and Charge to the Filling Provider and Billing System for Inclusion on Claims:

The EHR Association appreciates the update to the profile referenced.

Data Provenance

Establishing the Authenticity, Reliability, and Trustworthiness of Content Between Trading Partners:

The EHR Association notes that for provenance to be meaningful and complete, relevant data must be conveyed beyond documents and FHIR-based implementations, currently primarily web-based APIs. We suggest including either a note in the limitations sections that other standards enable communication of provenance as well (e.g., HL7 v2 using the ARV segment), or specific rows for each of the other specifications. Without consideration of interoperability beyond documents and web-based APIs, provenance would be incomplete. We recognize that further guidance is necessary on what data is intended to support provenance to establish consistent inclusion of that data in the respective transactions and standards.

Specific to the reference to the HL7 FHIR Provenance Resource, we suggest this be replaced with a reference to the FHIR R4 US Core R3.1.0 as soon as it is published later this year, as it includes a profile for Provenance.

Diet and Nutrition

Exchanging Diet and Nutrition Orders Across the Continuum of Care:

The EHR Association notes 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.

Electronic Prescribing

Allows a Prescriber to Request a Patient's Medication History from a State Prescription Drug Monitoring Program (PDMP):

The EHR Association suggests renaming this interoperability need as, "Allows a Provider to Request a Patient's Medication History from a State Prescription Drug Monitoring Program (PDMP)," as the need applies to providers who might not be prescribers also.

Allows for Communication of Information Between Prescribers and Dispensers:

The EHR Association notes that the NCPDP SCRIPT v 10.6 and v 2017071 standard messages for Status, Verify, Error are widely adopted, working well, and already required for all e-prescribing participants. However, GetMessage is less widely adopted because it is one method to check for and download messages into a system if the system is not already receiving pushed messages. That aspect should be indicated as a single bullet point.

Allows a Prescriber to Communicate with a REMS Administrator:

The EHR Association notes that the NCPDP SCRIPT v10.6 and v2017071 standard REMS messages are not widely adopted yet. Surescripts doesn't support them on its network, as there is not yet sufficient demand. This would benefit from more widespread deployment in order to be considered a vetted standard. We suggest the adoption level is one bullet.

Allows a Prescriber to Recertify the Continued Administration of a Medication Order:

The EHR Association notes that the NCPDP SCRIPT v2017071 Recertification messages are new to the 2017071 version going into effect on January 1, and are for LTPAC organizations only. For Surescripts Certification for LTPAC organizations, it is an optional transaction. Therefore, while we don't believe there has been widespread live usage yet, some LTPAC organizations are likely using or planning to use and it will be valuable to them. Also, this could be valuable for pain clinics. We suggest the adoption level is one bullet.

Allows for the Exchange of State Prescription Drug Monitoring Program (PDMP) Data:

There are multiple standards referenced on this page. EHR Association members know that NCPDP SCRIPT v10.6 has been adopted by some states for their PDMP interoperability, while there is limited information on the use of others. We suggest the adoption level is one bullet.

Allows a Prescriber to Communicate Drug Administration Events:

The EHR Association notes that the NCPDP SCRIPT v2017071 DrugAdministration messages are new to the 2017071 version going into effect on January 1, and are for LTPAC organizations only. For Surescripts Certification for LTPAC organizations, it is an optional transaction. Therefore, we don't believe there has been widespread live usage yet, but we think some LTPAC organizations are using or planning to use it.

We do not currently have customer inquiries on this standard. We suggest the adoption level is one bullet.

Allows a Long Term or Post-Acute Care to Request to Send an Additional Supply of Medication:

The EHR Association notes that the NCPDP SCRIPT v2017071 Resupply messages are new to the 2017071 version going into effect on January 1, and are for LTPAC organizations only. For Surescripts Certification for LTPAC organizations, it is a required transaction. Therefore, we don't believe there has been widespread live usage yet, but there will be LTPAC organizations that are using, at least after January 1. We support this standard for LTPAC health organizations. We suggest the adoption level is one bullet.

Family Health History (Clinical Genomics)

Representing Family Health History for Clinical Genomics:

The EHR Association suggests 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.

Patient Education Materials

Clinical Information Systems to Request Context-Specific Clinical Knowledge from Online Resources:

The EHR Association suggests including CDS Hooks as an emerging standard.

Patient Preference/Consent

Recording Patient Preferences for Electronic Consent to Access and/or Share their Health Information with Other Care Providers:

The EHR Association suggests moving Consent2Share to the emerging standard bucket if there is clarity on continued ownership of the specification/open source, as we understand that further maintenance is not available. This would be particularly important when FHIR R4 is to be adopted as a floor standard for standard, web-based APIs. Also, we suggest that the ONC work with the owners to collaborate.

Public Health Reporting

Reporting Syndromic Surveillance to Public Health (Emergency Department, Inpatient, and Urgent Care Settings):

The EHR Association notes that the URL links go to a page that does not appear to include the guides referenced. The names on the ISA page do not match the names on the PHIN page.

Research

Pre-Population of Research Forms from Electronic Health Records:

The EHR Association appreciates the reference to specific, applicable FHIR core resources as emerging standards rather than emerging implementation specifications.

Segmentation of Sensitive Information

Data Segmentation of Sensitive Information:

The EHR Association suggests that for data to be identifiable as sensitive, the communication through all channels need to have the ability to be labeled appropriately. The standards that enable that should therefore be listed to have awareness of those abilities. The HL7 v2 ARV segment enables this for v2 messages. The upcoming HL7 v2.9 will be further synchronized with C-CDA and FHIR capabilities and vocabulary. We note that adoption is low.

Also, we suggest inclusion of HL7 FHIR Security Labeling, while moving Consent2Share to Patient Preference/Consent interoperability needs.

Unique Device Identifier

Representing Unique Implantable Device Identifiers and Transmitting a Unique Device Identifier:

The EHR Association suggests adding the FHIR US Core Implantable Device Profile, as well as the C-CDA Template for Implantable Devices.

Services

“Push” Exchange

An Unsolicited “Push” of Clinical Health Information to a Known Destination Between Systems:

The EHR Association notes that if a reference to HL7 FHIR is included, then other standards that focus on payload of a service should be included as well, e.g., HL7 CDA. Rather, we suggest that the reference to HL7 FHIR be removed from the first table and that the first table focus on RESTful.

Clinical Decision Support Services

Providing Patient-Specific Assessments and Recommendations Based on Patient Data for Clinical Decision Support:

The EHR Association recommends removing reference to the IHE GAO profile, which is old and has not been updated to reflect current AUC requirements. We understand that HL7 has plans to develop a CDS Hooks-based approach. Therefore, the current reference to CDS Hooks as an emerging standard is appropriate and sufficient.

Retrieval of Contextually Relevant, Patient-Specific Knowledge Resources from Within Clinical Information Systems to Answer Clinical Questions Raised by Patients in the Course of Care:

The EHR Association suggests adding CDS Hooks as an emerging specification.

Consumer Access/Exchange of Health Information

Remote Patient Authorization and Submission of EHR Data for Research:

The EHRA Association notes 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. We suggest adding the SMART implementation specification as well.

Patient Exchanging Secure Messages with Care Providers:

The EHRA Association suggests 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:

The EHRA Association suggests replacing the reference to FHIR with a reference directly to the RESTful FHIR API as that is, per the limitations section, the intended reference.

Patient Exchanging Secure Messages with Providers:

It is not clear why FHIR is listed here in general. Direct is reasonably listed as a transport capability to enable secure messaging with varied payload, but the FHIR reference primarily focuses on the content of the message, not a RESTful API or other alternative to Direct.

Push Patient-Generated Health Data into Integrated EHR:

The EHRA Association suggests replacing the reference to FHIR with a reference directly to the RESTful FHIR API as that is, per the limitations section, the intended reference.

Image Exchange

Exchanging Imaging Documents Within a Specific Health Information Exchange Domain:

The EHRA Association appreciates the inclusion of IHE's PIXm, and we suggest that it would be appropriate to include IHE's PDQm and RESTful HL7 FHIR Document Reference-based API Specifications as well.

Query

Data Element Based Query for Clinical Health Information:

The EHRA Association suggests that, as this is intended to focus on RESTful, the reference to Argonaut should be replaced with a reference to RESTful. Argonaut, and now US Core, are payload-focused implementation guides that should be referenced in Section II.

Query for Documents Outside a Specific Health Information Exchange Domain:

It is unclear why the eHealth Exchange specifications are listed, but not others. The EHRA Association can appreciate that this could be a large reference list, but perhaps a focus on those used at a national level can help to keep it manageable. This would then suggest possible inclusion of Carequality and CommonWell specifications as well.

Proposed Interoperability Needs

Admission, Discharge, and Transfer

The EHRA Association suggests adding an interoperability need to address record location: "Sending a notification of a Patient's encounter to a Record Locator Service." This would follow the same standards as Sending a Notification of a Patient's Admission, Discharge and/or Transfer Status to Other Providers, where FHIR is an emerging standard to support these notifications as well.

Appendix IV

The EHRA Association supports and appreciates the inclusion of links to State and Local Public Health Agencies and their interoperability efforts.