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Donald Rucker, MD
Office of the 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 more than 30 members of the Electronic Health Record Association (EHRA), we are pleased to offer our input on the 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 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's 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

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.

EHRA Response: We appreciate the value the ISA can provide in understanding the landscape of applicable standards and implementation guides that should be

considered when enabling interoperability across health IT. We suggest that the ISA's value can be further increased if it can provide better insight into a roadmap toward inclusion in an upcoming certification edition that supports the various legislative and regulatory programs.

17-2. Over the course of 2017, various new functionality has 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?

EHRA Response: We appreciate the availability of a web-based publication besides a PDF. Various search tools make it easier to locate content. Some challenges still exist, with the navigation in particular:

- Forward/backward navigation across pages requires too many clicks or too much scrolling. Adding navigation to the top of each page would help avoid having to scroll to the bottom of a page in order to navigate from one page to the next.
- Page navigation appears backward. For example, on the Care Plan page the forward button actually goes to the last interoperability need on the list (Documenting and Sharing Care Plans for a Single Clinical Context) and then from that page goes to the second interoperability need and then first. This is counter-intuitive, yielding reduced user satisfaction.
- Providing separate scrolling of the index would enable searching within the context of the main pane.

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?

EHRA Response: We appreciate the addition of further documentation and references to understand the full breadth and depth of the interoperability landscape.

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?

EHRA Response: We have no input to this question.

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.

EHRA Response: We have no input to this question.

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.

EHRA Response: We appreciate the inclusion of the new sub-section, but suggest focusing in Section III on the infrastructure aspect of these use cases, while including the content related aspect within Section II. We suggest referencing both Argonaut and FHIR(R) US-Core as implementation guides/profiles, particularly as some opted to use these to enable their 2015 CEHRT API capabilities.

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?

EHRA Response: We suggest that ONC work with HL7 to include their published Functional Models, Functional Profiles, and Domain Analysis Models; they provide valuable context to the various implementation guides and profiles.

Section V: Administrative Standards and Implementation Specifications

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.

EHRA Response: We have no input to this question.

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

EHRA Response: We have no input to this question.

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.

EHRA Response: We have no input to this question.

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.

EHRA Response: We have no input to this question.

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.

EHRA Response: We have no input to this question.

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?

EHRA Response: We have no input to this question.

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.

EHRA Response: We have no input to this question.

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.

EHRA Response: We have no input to this question.

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.

EHRA Response: We have no input to this question.

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.

EHRA Response: We have no input to this question.

Detailed Comments

Introduction

Use of ISA by other agencies

- We support using the ISA to inform stakeholders on potential standards to be used for particular use cases. However, considering the current state of maturity/adoption information and options available, it appears premature for various stakeholders to consult the ISA directly for rulemaking, without ONC's involvement, in order to maintain well-coordinated references to the same standards across the regulations. We suggest clearly stating that agencies are expected to work with ONC to enable such coordination.
- With the emerging guidance in support of the 21st Century Cures Act (Cures), e.g., the Trusted Exchange Framework and Common Agreement (TEFCA), and other expected rulemaking around

conditions of certification, it is important that the ISA is not referenced in its current state as the full expectation for interoperability (i.e., if referenced in the ISA then HIT must support it now). Rather, ONC, HITAC, and the industry should use it as a reference of potential standards and particularly implementation guides/profiles to consider as Cures and other initiatives address interoperability.

Use Case Clarity

- We suggest that it would be helpful to describe each interoperability need beyond a title. For example, "Sharing Patient Care Plans for Multiple Clinical Contexts" is not sufficiently clear as to whether this means maintaining a single, "virtual" care plan across multiple providers, sharing care plans across different settings, or something else. Reviewing the referenced FHIR standard does not provide clarity, while the IHE Dynamic Care Planning profile further clarifies the statement starting on page 13. That is not helpful to the ISA reader.

Terminology Harmonization across standards

- We appreciate the challenges involved with harmonizing the use of vocabulary across standards, particularly when multiple standards development organizations (SDOs) are involved. We appreciate any facilitation that ONC can provide to encourage standards development organizations to harmonize variances.

Test Tool Availability

- We noticed that various links to test tools are available in the PDF version, though not in the web-based publication. Also, a number of standards are marked with having a test tool available, but no link is provided.
- We noticed some references to test tools point to a general test tool page rather than specific test tools. To encourage use of the same test tools for a particular standard, we suggest that references point to their specific test tool(s) to avoid confusion as to which test tool(s) were intended to be used.

Section I

I-C Family Health History

- *Patient Family Health History Observations:* This interoperability need was removed. We suggest 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, because the PDF versions appear not to be locked-in until the end of the year (e.g., the ISA 2017 PDF is reflective of the web version, not what was published originally). This would allow for explanations of why an interoperability need was archived or implementation guides removed.

I-D Patient Functional Status and/or Disability

- *Representing Patient Functional Status and/or Disability:* We suggest adding a link to the LOINC MDS value set referenced.

I-F Imaging

- *Representing Imaging Diagnostics, Interventions and Procedures:* The notes in the limitations section state, "The work is at the 'Balloted Draft' status in the Standards Process Maturity with no adoption level;" however, the table above the statement does not reflect this status. We suggest removing the statement from the limitations section while updating the table above it.

- 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.

I-I Laboratory Tests

- *Representing Laboratory Tests:* We note 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. This should reference the same sets as those listed in LOI, LRI, and eDOS implementation guides. We suggest adding Orders and AOE to the table as individual rows for better clarity.

I-L Nursing

- *All interoperability needs:* Considering that the standards point generally to LOINC and SNOMED for the observations and values, respectively, we suggest inclusion of references to the specific recommended value sets within LOINC or SNOMED.

II-A ADT

- *All interoperability needs:* We suggest clarifying that Direct is one of the transports that can be used to convey ADT notifications across organizations.
- *Sending a Notification of Patient's Admission, Discharge and/or Transfer Status to Other Providers:* We remain concerned that this interoperability need lists a base standard. We recognize that an implementation guide for these use cases is not yet available. Perhaps another purpose for the ISA could be to highlight areas, such as these, where an implementation guide/profile is highly desirable, thus encouraging those active in this space to propose such guidance. We suggest that ONC ask stakeholders to work with HL7 to define such guidance, including when to send notifications and what to include.

II-B Care Plan

- *Sharing Patient Care Plans for Multiple Clinical Context:* We suggest removing the reference to FHIR DSTU 2 as base standards should not be referenced. The suggested IHE Profile already references FHIR. We do note that the IHE Profile does not reference FHIR profiles on relevant resources, rather the resources directly, which increases the potential for incompatible implementations, thus supporting maintaining an Implementation Maturity of "Pilot."

II-C CDS

- *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. Similar to the Laboratory section, there should be a section for Radiology, or it could be put 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.

II-E Clinical Quality Reporting

- *Reporting Patient-level and Aggregate Quality Data for Quality Reporting and Evaluation:* We suggest that the references to FHIR be provided in the two respective interoperability needs rather than separately. This would be consistent with other interoperability needs where multiple standards could be used. We appreciate the reference to specific profiles and implementation guidance rather than a reference to the base standard.

II-F Data Provenance

- *Establishing the Authenticity, Reliability, and Trustworthiness of Content Between Trading Partners*: We suggest including references to the IHE XDS metadata standard, Direct, and FHIR Provenance resource, and the various other standards that include provenance data. The current representation may inadvertently be interpreted as only CDA documents being able to convey provenance, which is not accurate.

II-N Device Communication

- *Transmitting Patient Vital Signs from Medical Devices to other Information Systems/Technologies:* We suggest adding the following profiles:
    - IHE-PCD (Patient Care Device Profiles) - Communication Management (ACM)
    - IHE-PCD (Patient Care Device Profiles) - Device Enterprise Communication (DEC)
    - IHE-PCD (Patient Care Device Profiles) - Implantable Device – Cardiac Observation (IDCO)
    - IHE-PCD (Patient Care Device Profiles) - Point-of-Care Infusion Verification (PIV)
    - IHE-PCD (Patient Care Device Profiles) - Rosetta Terminology Mapping (RTM)
- These specifications are all final, in production, with an adoption level of two bullets, and freely available.

II-T Segmentation

- *Document-Level Segmentation for Sensitive Information:* We suggest including the DS4P subset defined by the IHE IT Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P), rather than the full DS4P specification that includes section level segmentation, which is not in the scope of this interoperability need, while noting that piloting is insufficient.

II-U Summary of Care Record

- *Support a Transition of Care or Referral to Another Health Care Provider:* We suggest including a reference to the IHE 360X Profile that supports closed loop referral as an emerging implementation specification. Also, we note that for referrals, it is relevant to specifically point to the C-CDA Referral Note document type to encourage focused communication of relevant data.

Section III

This section does not appear to be about services, but a mix of transport and foundational capabilities. We suggest renaming it "Infrastructure Standards and Implementation Guides" to avoid confusion.

III-A Push Exchange

- *An Unsolicited "Push" for Clinical Health Information to a Known Destination Between Systems:* We suggest removing the reference to FHIR STU 3 as the emerging standard, as it is 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, 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/.
- *Representing Path Traversal Expressions:* Unclear why the first bullet under Limitations is needed in this context. Suggest dropping it here and elsewhere.

III-C Image Exchange

- *Exchanging Imaging Documents Within a Specific Health Information Exchange Domain:* We suggest including PDQm, PIXm, and RESTful FHIR Document Reference-based API Specifications.

III-D Healthcare Directory, Provider Directory

- *Listing of Providers for Access by Potential Exchange Partners:* Considering the availability of implementation guidance, we suggest removing the FHIR DSTU 2 and FHIR STU 3 rows and replacing them with the Argonaut R1 and US-Core R1 implementation specifications.

III-E Patient Identification Management

- *Exchanging Patient Identification Management within a Community:* We suggest including PIXm and PDXm, which are based on FHIR STU 3.
- We suggest 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.

III-G Publish and Subscribe

- *Publish and Subscribe Message Exchange:* We suggest replacing the generic reference to the IHE test tool library with a link to the specific test tool. For DSUB, we suggest pointing to https://gazelle.ihe.net/content/xdstarclient.

III-J: 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 specifically 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 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.

Section IV

We suggest referencing the most current HL7 Functional Models, Functional Profiles, Functional Requirements, and Domain Analysis Models that have been published; they provide helpful context for the implementation guides and profiles referenced in the ISA.

Interoperability is essential to enable data to follow the patient, to assist providers in the coordination of care, provide the data to the patient, and to contribute data to public health, registries, and research to enable a learning health system. EHRA is supportive of efforts to promote implementation of interoperable and functional health information technology to advance clinical care and assist both patients and providers in decision-making.

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 technology.

Sincerely,

Sasha TerMaat
Chair, EHR Association
Epic

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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.