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The Healthcare Information and Management Systems Society (HIMSS) is pleased to submit these comments for consideration by ONC to update the Interoperability Standards Advisory (ISA). These comments are one set in a series that HIMSS has provided on the content in the web-based version of the ISA. For more information on previous comments, please visit the HIMSS website.

Please find comments below as related to the current ONC Requests for Feedback.

19-1: 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.

HIMSS membership includes individual, organizational and corporate members who are end-users that work to develop and implement interoperable solutions within their organizations. Below are examples of interactions with ISA that our members have referenced:

- Members in consultancy roles leverage the ISA largely by utilizing it as a point of reference and as a means of understanding what standards exist and how those standards are being implemented within industry. Additionally, these members have noted that the ISA has proven to be a helpful tool. For example, it is used in contract negotiations between providers and vendors.
- Members in advocacy positions use the ISA to promote engagement opportunities with the goal of advancing patient interoperability from a number of stakeholder perspectives. For example, it can be used to introduce new stakeholders, such as consumers, to the work in standards-based interoperability and is a driver to work toward a more approachable document for use by consumers and other emerging stakeholders.
- Health systems have cited use of the ISA as a reference for IT planning and procurement needs.

However, HIMSS consistently receives feedback of unawareness or limited use from members, often stemming from a lack of awareness that the tool exists and of the value it ultimately provides. The ISA has the potential to be an even more impactful resource if more stakeholders were aware and referenced it to make strategic interoperability decisions. Furthermore, many have stated that the ISA is a helpful reference but would increase in relevance and use if there was a level of authority around the document. As standards adoption accelerates across the stakeholder community, HIMSS recommends harmonization between and amongst regulatory documents. Regulatory guidance from ONC, CMS and other federal agencies should point to ISA as a reference, and the Interoperability Needs within the ISA should be aligned with the guidance put forward from the Department of Health and Human Services and other government agencies. Standards harmonization should also extend to any quality measures initiated and should be reflected within the ISA. Also, government agencies with their own interoperability initiatives, such as the Department of Defense (DoD) and Veterans Health Administration (VA), should be actively engaged to reference and inform the content in the ISA.

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

One way to increase the usefulness of the ISA is through additional education on how it may be leveraged by different types of stakeholders. One recommendation is to include stakeholder-specific overview pages with a summary of how standards support that specific community. There is a need to succinctly communicate the business case and value of standards-based approaches to the non-technical community to accelerate the use of standards for data sharing and exchange. This overview could include reference to relevant Interoperability Needs, both established and emerging, and link to other areas of interest within the resource.

HIMSS urges ONC to consider adding more search capabilities and filters for users to leverage in exploring the ISA. For example, a valuable function would be the ability to filter by a specific federal regulation or requirement. It is helpful having links to federal requirements within the Interoperability Needs (though this isn't consistent and some federally-required standards are missing links), but it would be helpful to search across all the standards required for a specific regulation; this would give more power to health systems as they explore and negotiate adding products from EHR systems/market suppliers. In addition to searching each Interoperability Need, it would be helpful to have a view of each standard listed with the various data sets and Interoperability Needs referenced in the ISA.

Finally, the ISA's current navigational and search capabilities still have room for improvement. Currently the scroll is synchronized for the main ISA body as well as the index sidebar. Allowing the index sidebar to scroll separately from the body would enhance user experience. ONC may also want to consider adding the page-to-page navigation at both the bottom and top of the page. Additional tagging may need to be added to enhance the search functionality. For example, it wasn't obvious as to how to navigate to the specialty topics referenced in question 19-4. A search of the site for "Specialty Care" did not return the pages on "Pediatrics" and "Opioids" under this new section.

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?

HIMSS agrees that there is value in understanding the adoption levels of standards, as it informs implementers of the industry uptake and maturity of a standard. However, we believe there are more uniform approaches to identifying adoption than the current practice, which is based on anecdotal information.

HIMSS outlines a number of methods that should be explored to quantitatively measure adoption, and is willing to work with the ONC on the assessment and execution of any of these approaches:

- *Create an industry-wide annual interoperability survey*: Currently, many organizations conduct surveys with disparate methods, questions, response rates and results. HIMSS could assist in the creation and aggregation of a single survey that can be distributed widely and capture consistent data to inform the ISA and other interoperability efforts.
- *Use standards development organization events to gauge adoption:* Each year, standards development organizations hold conferences, connect-a-thons, implementation-a-thons, etc. with top health IT market suppliers in attendance. These specific events have great potential to leverage the attendees in the moment to conduct surveys and gather real-time feedback on standards included in their capabilities. For example, the IHE North American Connectathon occurs each January with hundreds of market suppliers available for surveys and/or interviews.
- *Leverage existing tracking and reporting efforts:* There are a number of testing requirements, recognition, and certification programs that capture data on standards included in capabilities. Also, existing national

networks and frameworks, such as CommonWell Health Alliance, eHealth Exchange, and Carequality, already track transactions that can inform adoption measurement. ONC may propose some measures to standardize the metrics these networks capture on their transactions and incorporate it in the ISA adoption information. Finally, as ONC seeks to improve the curation and use of the Interoperability Proving Ground, this may also serve as a resource to inform standards use and adoption.

These current suggestions focus on measuring volume of standards adoption in either capabilities or transaction-based data. It will be important in the future to expand this measure to capture the value and utility for the end users. This expanded measure would require information gathering from the end user to understand how data is integrated into workflow and consumed by end users, what data exchanged provides value and even what is not being used even if the capabilities exist. Measurements should also expand to include adoption beyond provider-to-provider exchange, and include transactions with the consumer and other stakeholders, such as payers and community-based organizations.

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?

HIMSS appreciates the addition of these new pages but believes there can be updates made to increase their value and functionality. First, their location within the ISA has poor visibility in the navigation and lacks an explanation of its purpose and objective. The specialty care/settings pages are not included as a defined section, and even searches of "pediatrics" and "opioids" do not yield these pages in the search results. Improved navigation and tagging would increase their value. Adding introductory language may better explain the value of these pages. This could include the "known barriers" of exchange for these specialty settings, giving context as to why this separate section was created, or include helpful tips for implementers to best leverage the information provided. If this section is expected to expand, HIMSS suggests separating "specialty care" and "settings" into two distinct groups. These two topics differ greatly and may require different guidance and explanations once settings are added. Finally, members expressed the value of creating their own specialty group or setting scenarios to assist with specific implementation needs. If feasible, ONC may want to explore adding a type of sandbox functionality that would allow developers to create their own specialty/setting scenarios, pulling together relevant Interoperability Needs to address their exchange goals.

While we recognize there may be many opportunities for expansion, HIMSS proposes the following settings and specialty care groups to be considered for initial inclusion in this new section:

- *Setting - Remote Monitoring, Home Health and Telehealth*: There are a number of applications in use and this setting requires work across a number of systems (EMS, hospital EMR, telemedicine system (both synchronous and asynchronous), remote patient monitoring, and device management). ISA can provide guidance on specific standards to assist in the exchange with this setting. Continua Design Guidelines, which encompass IHE profiles and HL7 standards, should be referenced and leveraged as a resource to develop this section.
- *Specialty Care - Military Health*: Interoperability between DoD, VA and external care settings is an ongoing challenge and one of importance with the ongoing transition of patients from DoD to VA care, and the number of VA patients receiving specialty care outside the VA system. HIMSS recommends a specialty collection of interoperability needs for this patient group to inform the exchange of information across these settings. Furthermore, ONC should explore leveraging SIREN, which includes resources on data sets to capture information on military service and linking diagnoses as an emerging tool for use in standardizing military data. Additionally, ONC should explore leveraging and aligning with the Million Veterans Program, a national research program collecting information on how genes, lifestyle, and military exposures affect health and illness.

- *Specialty Care - HIV/AIDS*: While robust HIV data exchange standards exist, in practice, clinical transfers of care are notoriously difficult in this space, particularly in the safety net healthcare system. Adding HIV in the ISA, either in this specialty section or as an Educational Appendix, could provide a venue to open up ongoing conversations about challenges specifically related to HIV and interoperability, and how to build HIV data exchange infrastructures and interoperability standards that facilitate the timely and respectful exchange of patients' HIV data in clinical settings and other contexts. Robust exchange standards exist for this data. The CDC HIV Surveillance branch in the Division of HIV/AIDS Prevention and the Ryan White HIV/AIDS Program in the HIV/AIDS Bureau at HRSA can provide resources on standards. The HL7 Implementation Guide for CDA® Release 2: HIV/AIDS Services Report also can be leveraged. The Federal Health IT Strategic Plan and the recent ONC Interoperability and Information Blocking NRPM flag HIV data as one of several classes of sensitive health data that patients ought to have consent controls over, though public health organizations have permissions for exchange without consent. This consent management should also be outlined in this section.

As ONC determines the direction for this new section, HIMSS encourages ONC to consider how consumers and emerging stakeholder groups may potentially interact with the ISA. In addition to outlining how standards can be leveraged for these specific scenarios, ONC may want to explore additional "user guides" to provide contextual guidance as to how these stakeholders may derive value from the ISA.

In our exploration of additional settings and specialty care, HIMSS explored the representation of consent management for sensitive data in the ISA. These classes of data may include but are not limited to behavioral health, psychiatric, HIV, or other social determinants of care. These types of data may be important in many care settings, however, the information exchange component poses many challenges due to the disclosures and consent requirements. HIMSS recognizes that there are two Interoperability Needs addressing consent management and segmentation of this sensitive data (Data Segmentation for Sensitive Information and Recording Patient Preferences for Electronic Consent to Access and/or Share their Health Information with Other Care Providers), but believes value exists in providing additional education on the nuances of this topic. HIMSS recommends adding an Educational Appendix to provide further resources on how consent management layers into a number of interoperability exchange scenarios. Government agencies and organizations such as the Substance Abuse and Mental Health Services Administration (SAMHSA), the Society for Shared Decision Making, and the Society for Participatory Medicine can be leveraged as resources in the development of this section.

Additional Opportunities for Expansion

In addition to providing feedback on ONC's four requested questions, HIMSS offers further recommendations to improve the functionality, accuracy, and usefulness of the ISA.

Updates to Include Emerging Standards throughout the ISA

Emerging standards require a continuous review of ISA's Interoperability Needs to identify standards that are deprecated or being less utilized because newer standards are available. For example, as Fast Healthcare Interoperability Resources (FHIR®) R4 is now the normative standard, HIMSS recommends that it be incorporated into the Interoperability Needs as appropriate, expanding beyond reference to FHIR® STU 2 and 3.

As ONC looks to play a role in global interoperability efforts, HIMSS recommends the inclusion of HL7's International Patient Summary as appropriate within the ISA. This specification is seeing high rates of adoption in other parts of the world, and ISA guidelines on its use would be helpful to promote adoption within the United States.

Also, as mobile standards grow in prevalence, ONC should conduct a complete review of the ISA to ensure that emerging mobile standards are incorporated as appropriate. Some suggested additions are included in the table

below. It may also be beneficial to add an educational appendix to provide an overview of these standards and their use.

There are a number of projects advancing the use of the FHIR® standard that should be outlined within the ISA. While many of these projects are still emerging, their recognition in ISA would be a positive step toward building greater awareness and further implementation and adoption around the standard.

- The HL7® FHIR® Accelerator, the Gravity Project has identified or is in the process of identifying a number of data sets and value sets to integrate social determinants of health (SDOH) into healthcare. These include:
    - Food Insecurity Data Set and Value Sets
    - Housing Instability and Quality Data Set and Value Sets
    - Transportation Access Data Set and Value Sets
    - HL7® FHIR® SDH Implementation Guide (in development)
- The Argonaut Project is referenced within the ISA for their Data Query and Provider Directory Implementation Guides. However, there are a number of Argonaut Implementation Guides that should be assessed for inclusion throughout the ISA.
- The CARIN Blue Button Implementation Guide was recently released and includes over 240 claims data elements making up a common payer consumer data set that has been mapped to FHIR® resources.
- The eLTSS FHIR Implementation Guide outlines the artifacts and documentation needed to enable exchange of the Electronic Long-Term Services & Supports (eLTSS) Dataset via FHIR®.
- The FHIRcast specification (1.0 release) describes the APIs used to synchronize disparate healthcare applications' user interfaces in real time, allowing them to show the same clinical content to a user.
- The HL7® CodeX initiative leverages the mCODE™ FHIR Implementation Guide standard (minimal Common Oncology Data Elements) to build a common language for cancer care and research data.
- IHE and Continua are also actively expanding their profiles to include FHIR® resources; these specifications should be added as appropriate.

Finally, as the US Core Data for Interoperability (USCDI) is cited in regulations and begins to expand, HIMSS is curious about the relationship of the USCDI to the ISA. Currently, USCDI lives as a static page within the resource, as a minimum list of standardized data sets, among a large repository of standards and specifications with varying degrees of adoption. Could there be an opportunity to leverage the ISA as a resource for understanding data elements that may qualify for the Data Element Promotion Process to get to USCDI while progress is tracked and monitored in ISA? HIMSS encourages ONC to consider the relationship and explore options for gleaning the most impact from the information included in the ISA.

General Interoperability Need Updates
HIMSS has identified several updates throughout the document to ensure accuracy in the Interoperability Needs, which have been outlined in the table below.

Section I	Representing Patient Allergies and Intolerances; Environmental Substances Representing Patient Allergies and Intolerances; Food Substances	LOINC is not mentioned however there are corresponding codes that could be found for such terms.

Section II	Images	From the IHE perspective, there are a number of core domains missing from these Interoperability Needs. For example, images for pathology and cardiology needs are not included. If this section aims to represent all types of images, there are a number of standards that are missing.
Section II	Images: Format of Radiation Exposure Dose Reports for Exchange and Distribution	IHE Radiation Exposure Monitoring for Nuclear Medicine (REM-NM) and IHE Radiation Exposure Monitoring (REM) should be added as Implementation Specifications. The DICOM entries say it shall be 2017e, and links point to the current version (at the moment is 2019c). Ideally there shouldn't be a version on the name of DICOM.
Section II	Patient Identification Management: Patient Demographic Record Matching	IHE Patient Identifier Cross-Reference for Mobile (PIXm) and IHE Patient Demographics Query for Mobile (PDQm) should be added as Implementation Specifications.
Section III	Push Exchange: An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Systems	This Interoperability Need includes FHIR® DSTU 2 and lists FHIR® generally as an emerging standard, which seems redundant.
Section III	Image Exchange: Exchanging Imaging Documents Outside a Specific Health Information Exchange Domain	Since IHE-PIX is included as a Specification, HIMSS recommends IHE-PIXm also be added.
Section III	Query: Query for Documents Within a Specific Health Information Exchange Domain	The IHE Mobile Access to Health Documents for Imaging (MHD-I) profile was deprecated on September 15, 2017, and replaced with WIA, as outlined in the IHE Technical Frameworks resource.

Section IV	Various Administrative Interoperability Needs	The HL7 FHIR DaVinci specifications are emerging standards that should be added accordingly throughout this Section.
Appendix I	Sources of Security Standards and Security Patterns	IHE RESTFul ATNA is missing from this list.