Health IT Standards Committee
A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

Architecture, Services, and APIs

HIT Standards Committee
Certification NPRM

May 20, 2015

Arien Malec, co-chair
David McCallie, co-chair

ASA Workgroup - Active Members

Name	Organization
David McCallie, co-chair	Cerner
Arien Malec, co-chair	RelayHealth Clinical Solutions
Janet Campbell	Epic
George Cole	Allscripts
Josh Mandel	Children's Hospital Boston
Jeff Gunther	Premier, Inc.
Gajen Sunthara, ex officio	Department of Health and Human Services (HHS)
Albert Bonnema	Defense Health Agency
Debbie Bucci, staff lead	HHS, Office of the National Coordinator

Architecture, Services and Application Program Interfaces (APIs) Workplan

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	Meetings	Task
✓	April 9, 2015 12:00 – 1:30pm ET	• Overview of Certification NPRM and prepare to comment
✓	***April 22, 2015 – HITSC meeting***	• **Interoperability Roadmap V.1 comments to the HITSC**
✓	April 23, 2015 12:00 – 1:30pm ET	• API Group to Comment on Certification NPRM
✓	May 5 , 2015 4:00 - 5:00pm ET	• Non-API Group to Comment on Certification NPRM
✓	May 7, 2015 12:00 – 1:30pm ET	• HPD Group to Comment on Certification NPRM
✓	May 13, 2015 9:00 – 10:00am ET	• Finalize comments on Certification NPRM
➔	***May 20, 2015 – HITSC Meeting***	• ***Present Certification NPRM Comments to the HITSC***

Application Access to Common Clinical Data Set

Workgroup Findings

With regard to ONC's policy approach of adopting functional certification requirements rather than formal certification criteria, the Workgroup found that:

1. APIs should be based on consensus-based standards that have sufficient production usage to be adequately tested and certified.

2. Functional API requirement accompanied by clear regulatory intent signals industry towards a standards-based approach.

3. Public-private organizations, such as HL7 and Argonaut, will be heavily involved in developing, documenting, and testing standards for APIs in the certification timeframe.

Application Access to Common Clinical Data Set, con't.

Workgroup Recommendations

With regard to ONC's policy approach of adopting functional certification requirements rather than formal certification criteria, the Workgroup recommends:

1. EHR developers who chose to meet the functional requirement through proprietary APIs should be aware that in a future regulatory cycle the API requirement will be based on standards-based APIs

2. Subregulatory flexibility to allow Health IT developers to be deemed via a public-private effort that provides adequate testing and governance achieve functional interoperability

Application Access to Common Clinical Data Set, con't.

Workgroup Recommendations

With regard to the transitional functional certification requirements, the Workgroup found that, as written, the requirements, and associated CMS Meaningful Use attestation requirements, are too rigid and could serve to limit or constrain achievement of policy goals. Therefore, the Workgroup recommend the following:

1. Generalize to require that discrete individual elements of any of the currently active data included in the Common Clinical Data Set be retrievable via the API through means that could include but are not limited to “by category”, “element retrieval” or other means (e.g., “active medication list”).

2. Removal of the “XML or JSON” requirement.

3. While we understand the intent of C-CDA as a transitional approach, we believe that other approaches (e.g., FHIR documents, FHIR bundles) may provide valuable experimentation and learning during the transition period.

4. The functional requirement for patient lookup could be met through multiple means. Certifying bodies may misconstrue this requirement as only allowing one of those query types (e.g., demographic queries). We recommend that ONC provide in regulatory the intent of the functional requirement.

Application Access to Common Clinical Data Set, con't.

Workgroup Recommendations

With regard to the transitional functional certification requirements, the Workgroup found that, as written, the requirements, and associated CMS Meaningful Use attestation requirements, are too rigid and could serve to limit or constrain achievement of policy goals. Therefore, the Workgroup recommend the following:

Workgroup Recommendations Continued:

5. It is our understanding that the meaningful use requirements allow provider organizations to meet VDT requirements through a portal OR through the API. We believe provider organizations should be able (but not required) to provide both means and allow each kind of access to be counted towards the numerator.

6. Certify each of the three API scenarios (get patient identifier, get document, get discrete data) individually, while stating the expectation that Health IT developers and provider organizations should ensure that the APIs work together functionally.

Application Access to Common Clinical Data Set, con't.

Workgroup Findings

The real-world test of a robust API ecosystem is that developers (including individual developers or small businesses, or vendors of Health IT that is competitive with the vendor of the Health IT that hosts the API) have fair, reasonable and non-discriminatory (FRAND) access both to develop and to implement applications using the APIs. We further noted that:

1. Extant API-based platforms and ecosystems (e.g., Apple iOS and the Apple AppStore, Android APIs and the Google Play store, Facebook APIs, etc) have a range of requirements and yet have functionally achieved a level of access whereby individual developers routinely develop and implement applications.

2. Applicable terms of use or other limits on access may be enforced by the provider organization, and either the Health IT developer or the provider organization may limit API access for justifiable reasons.

3. Documentation for the API may reference or be identical with standards and implementation guidance, or be obtained through participation in an open Data Sharing Arrangement (as defined by the JASON JTF report) or “public-private governance” efforts as defined in the Interoperability Roadmap.

Application Access to Common Clinical Data Set, con't.

Workgroup Recommendations

We are accordingly concerned that the hyperlink requirement as defined in the NPRM is insufficient to achieve the policy outcome of a robust and competitive ecosystem open to individual developers. We therefore recommend that ONC:

1. Look at existing (non-Health IT) developer ecosystem best practices and also collaborate with other applicable agencies on guidance on voluntary policy and governance practices sufficient to meet policy requirements.

2. Seek to achieve policy goals through Health IT and Provider organization participation in Data Sharing Arrangements and/or public-private governance efforts.

3. Include subregulatory flexibility to allow Health IT developers AND provider organizations to be deemed to achieve certifiable status with regard to FRAND status through participation in a public-private effort that provides adequate testing and other governance sufficient to achieve functional interoperability.

4. Accommodate documentation approaches that point (and link) to well-defined standards-based approaches or well-defined implementation guidance, rather than require Health IT developers to duplicate documentation for standards and implementation guidance.

Data Portability

Workgroup Recommendations

We found that the certification criteria as written are overly prescriptive in ways that add complexity without addressing the stated policy goals or add functionality that are not clearly tied to the policy goals of portability and data availability. We therefore recommend the following:

1. The use of portability features should be limited to users with appropriate permissions as Improper use could cause a performance issue or privacy breach.

2. Certification criteria only require use of the CCD, which is intended as a summary document and is therefore, of all the suggested document types, best suited for the purposes of portability.

3. ONC specify and refer to a consistent definition of the Common Clinical Data Set in all contexts, including Data Portability.

4. The workgroup acknowledges that richer trigger-based data retrieval would be useful, but believes that such functionality would be better positioned as future use of an API-based data retrieval framework delivered through one of the Orchestration Patterns already documented by the Workgroup (e.g., Publish/Subscribe).

Data Portability, con't.

Workgroup Recommendations

We found that the certification criteria as written are overly prescriptive in ways that add complexity without addressing the stated policy goals or add functionality that are not clearly tied to the policy goals of portability and data availability.

Proposed Framework for certification criteria :

a. An authorized user should be able to export data without vendor intervention.

b. At a minimum the export should be:

   i. limited to the CCD

   ii. available on demand – even if a manual process

   iii. allow the export of one patient, a subset of patients and the entire set of patients for the setting of care

"Create" and Patient Matching Data Quality

Workgroup Recommendations

With regard to certification criteria for patient matching data quality, the Workgroup found the certification criteria generally reasonable, but had specific suggestions regarding the specificity and applicability of the certification criteria. We therefore recommend the following:

1. Senders send as much of the date of birth is available. For example, if day of birth is missing, the Workgroup recommend that certification criteria specify senders should send year and month if available.

2. For administrative gender, we recommend that certification criteria should point to applicable sections of the C-CDA implementation guide, rather than create new implementation guidance through regulation.

3. For name normalization, the Workgroup recommends that:
   a. certification criteria should point to the specific relevant sections of the CAQH CORE guide intended .
   b. Because pre-normalization on send can lead to data loss (e.g., for receivers who may account for punctuation in matching rules), we recommend that ONC adopt these rules as best practice for receipt, rather than certification criteria on send.
   c. For send, we recommend that certification criteria clarify that Health IT systems should store last/family name distinct from suffix and populate for purposes of interoperability (for example, following C-CDA implementation guidance) accordingly.

XDM Package Processing

Workgroup Recommendations

The Workgroup found proposed certification criteria on XDM Package Processing confusing and vaguely stated. We therefore recommend the following:

That the certification criteria specifically point to section 3.32.4.1.4 of ITI 2b:

"The Portable Media Importer shall verify the integrity of the media by comparing their size and hash with the value of the corresponding entries in the METADATA.XML file of the relevant submission set directory. Mismatching documents shall be indicated to the user. Media faults shall be indicated to the user."

We recommend that in addition to these requirements, the valid documents corresponding to the metadata entries be extracted and, if appropriate, be presented to the user. We note that many Health IT systems suppress or allow to be suppressed by configuration certain file types for the protection of the user (e.g., executables), and recommend that certification criteria not inadvertently require that all documents, regardless of type or security risk, be extracted.

Healthcare Provider Directory (Query Request/Query Response)

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Workgroup Findings

With regard to use of HPD as a standard for provider directories, the Workgroup has not observed sufficient wide scale adoption and production utilization that would be sufficient to understand what relevant certification criteria should be.

Workgroup Recommendations

We therefore found that certification criteria are premature at this time and recommend that ONC not include these criteria in the final rule.