May 20, 2015

Karen DeSalvo, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. DeSalvo,

The HIT Standards Committee (HITSC) gave the following broad charge to the Architecture, Services and Application Programming Interface (API) Workgroup:

Broad Charge for the Architecture, Services and API Workgroup:

The Architecture, Services and API Workgroup is charged with the defining of architectural patterns sufficient for an ecosystem of nationwide scale information sharing and modular applications serving patients, providers, provider-organizations, and researchers particularly as related to American Recovery and Reinvestment Act (ARRA) and the Affordable Care Act (ACA) which mandates a number of duties to the Office of the National Coordinator (ONC) relative to health information sharing. They make recommendations on standards, implementation guidance and certification criteria consistent with architectural patterns and make suggestions on how to achieve incremental progress towards proposed architectural patterns consistent with ONC roadmap and strategy. In close coordination with sister groups from HIT Policy Committee, they explore technology policy to promote the adoption and use of enabling technology consistent with the architectural patterns.

Background:

The Architecture, Services and Application Programming Interface (API) Workgroup was asked by the ONC and the HITSC to review, comment and make recommendations on the following sections of the 2015 Edition Health IT Certification Criteria (2015 Edition) proposed rule :

- § 170.315(g)(7) Application access to Common Clinical Data Set

- VDT - Application Access to Common Clinical Data Set
- § 170.315(b)(6) Data portability
- "Create" and Patient Matching Data Quality
- XDM Package Processing
- § 170.315(h)(4) Healthcare Provider Directory – Query Request
- § 170.315(h)(5) Healthcare Provider Directory – Query Response

This letter provides recommendations to the National Coordinator, Department of Health and Human Services (HHS) based on the discussions that have taken place within the Architecture, Services and API Workgroup.

These recommendations were presented to the HITSC and formally approved on Wednesday May 20, 2015.

Application Access to Common Clinical Data Set § 170.315(g)(7) and VDT

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

1. Long term, the API should be based on consensus-based standards that have sufficient production usage to be adequately tested and certified, and that HL7 FHIR and the Argonaut work is the most promising candidate for those consensus-based standards

2. HL7 FHIR and the Argonaut work has not currently been sufficiently tested in production and will not be sufficiently tested by the expected publication date for the Final Rule to be included in certification requirements

3. A purely functional API requirement can be a helpful flexible forcing function towards a standards-based approach if the functional API certification requirement is accompanied by clear regulatory intent and signaling to industry that this is intended as a transitional requirement towards a standards-based approach; a purely functional API requirement that does not lead towards Health IT developers and provider organizations to participate

in standards-based approaches will not achieve the national policy goals of a more interoperable API-driven ecosystem

4. Public-private organizations, such as HL7 and Argonaut, will be heavily involved in developing, documenting, and testing standards for APIs in the certification timeframe. Participation in such efforts is the best way for EHR developers and provider organizations using those EHRs to achieve the policy goals of interoperable APIs

Therefore, the Workgroup Recommends:

1. Inclusion of functional requirements accompanied by clear text documenting regulatory intent and signaling that 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. For example: "We are adopting functional certification requirements as a transitional strategy to encourage Health IT developers and provider organizations to participate in public-private governance efforts to develop, document, and test standards-oriented means of meeting these functional requirements. We note the presence of public-private efforts to develop such approaches, including work on HL7 FHIR DSTU2, the S&I DAF Initiative, and the Argonaut collaborative effort between HL7, provider organizations and Health IT developers to develop a standardized means of using HL7 FHIR profiles and Internet standards such as OAuth2 and Open ID Connect. We expect in a future cycle of rule-making to adopt certification criteria based on production tested standards-based approaches and note that Health IT developers who achieve certification to this functional requirement through other means may be at risk of not being certifiable in a future rule-making cycle."

2. Subregulatory flexibility to allow Health IT developers to be deemed to achieve certifiable status through participation in a public-private effort that provides adequate testing and other governance sufficient to achieve functional interoperability

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 Recommends:

1. Rather than require strict "by category" functional requirements, the certification requirements should instead 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").. It is possible that "by category" queries will provide useful in practice, but it is equally possible that other discrete queries may be more useful in practice.

2. Removal of the "XML or JSON" requirement. If the intent is to encourage Health IT developers to use HL7 FHIR, we would encourage a more explicit statement (as suggested above); otherwise, there are multiple alternative valid data formats that might be used by a functional implementation of an API (e.g., Protocol Buffers, Avro Thrift, HL7 V2 pipe-delimited message segments, etc.).

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. Accordingly, we recommend that ONC [allow any aggregate Common Clinical Data Set | signal that Health IT developers may experiment with alternative methods and allow such use in programs such as meaningful use]

4. It is our understanding that the functional requirement for patient lookup could be met through multiple means, including PIX-style identifier lookups, PDQ or XCPD style demographic queries, FHIR-based demographic queries, CommonWell-style patient link

queries, etc. The Workgroup believes this is desirable, but is concerned that 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 intent text a set of non-exhaustive means of achieving the intent of the functional requirement

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 that for maximal flexibility, 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. We understand that ONC intends the API to work together as a complete flow (e.g., request identifier, use identifier to request a document, use identifier to request discrete data), and has therefore written this as a single certification requirement. We are concerned, however, that real-world provider organizations may wish to couple or combine means of achieving these requirements. For example, a provider organization may wish to provide individual EHR discrete data access via API, participate in eHealthExchange, and participate in CommonWell, and participate in a state HIE, all of which provide means of achieving portions of these functional requirements. We therefore encourage ONC to allow means for Health IT modules to modularly certify towards 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. We believe that extant standards allow modularity, and that future standards-based approaches will continue to allow modularity.

With regard to documentation and terms of use, the Workgroup notes that multiple actors (not just developers of Certified Health IT) may place restrictions, and that access to documentation is only one of the possible barriers to develop and use APIs. The real-world test of a robust API ecosystem is that developers (including individual developers or small businesses, or developers of Health IT that is competitive with the developer 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, including a requirement to register as a developer to receive pre-release access to APIs and SDKs, requirements to digitally sign applications, requirements to sign license agreements, payment mechanisms, etc. 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 (e.g., to those modular application with good security policies) or less justifiable reasons (e.g., to limit access by competitors or create fee structures that limit participation by a wide range of developers).

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.

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.

§ 170.315(b)(6) Data portability

With regard to certification requirements for Data Portability, the Workgroup understands the stated policy goals of ensuring that functionality as certified is available in practice to provider organizations and users of Certified Health IT. However, 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. As stated, certification criteria could be interpreted to allow any user to use the portability features. Improper use could cause a performance issue or privacy breach. We therefore recommend that use of portability features should be limited to users with appropriate permissions

2. The certification criteria call for all C-CDA document types to be exportable. Many of these document types are meaningful only in context to specific workflows (e.g., reason for referral) and in specific provider settings. We therefore recommend that 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. The certification criteria call for a specific definition of data to be exported that is different from the Common Clinical Data Set required in other contexts (e.g., discharge). Requiring different definitions of minimal data for different workflows causes significant implementation burden. We recommend that ONC specify and refer to a consistent definition of the Common Clinical Data Set in all contexts, including Data Portability.

4. The proposed trigger conditions specification is inappropriate as a certification criterion for Data Portability, as it goes both beyond the policy goals of portability. 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).

5. We therefore recommend the following framework for certification criteria:

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

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. In particular:

1. With regard to date of birth, the Workgroup believes the certification criteria could be read to disallow sending as much of the date of birth as is available. Instead, we recommend that 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. Because the CAQH CORE implementation guide contains a large amount of information specific to ACS X12 documents, the certification criteria should point to the specific relevant sections of the CAQH CORE guide intended
   b. The CAQH guide is specific to normalization of information on receipt, rather than on send. 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

The Workgroup found proposed certification criteria on XDM Package Processing confusing and vaguely stated. For instance, the certification criterion points to the whole of IHE ITI Volume 2b, which contains a large number of profiles and implementation guides. Even the section specific to XDM contains material more specific to senders than receivers. In addition, the specification to extract "extract and process….relevant metadata" could be very broadly interpreted, as the IHE document and submission set metadata constitutes a large set of potential items. Broad interpretation of "relevant metadata" could imply certification criteria that are not otherwise specified, including patient matching, presentation of document and document type metadata, use of that metadata for document type identification, etc.

We therefore recommend that 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.

§170.315(h)(4) Healthcare Provider Directory Query Request and § 170.315(h)(5)) Healthcare Provider Directory Query Response

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

The Workgroup points back to previous recommendations of the Health IT Standards Committee to adopt certification criteria and implementation guidance only after real-world testing and production usage sufficient to demonstrate interoperability and associated relevant certification criteria. We recommend that ONC consider pilot testing and production implementation prior to certification; pursuant to our previous recommendations on Core Composables and Orchestration Patterns, we recommend that pilot testing and production implementation should be aligned with the healthcare hourglass and the overall Interoperability Roadmap. In particular, we suggest that ONC work with developer and standards bodies to explore the use of relevant FHIR standards for access to provider directories, given the stated intent to require FHIR-based API conformance in future certification standards.