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.

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 and formally approved by the HITSC on April 22, 2015.

**Background:**

Insert NPRM Tasking

**Application Access to Common Clinical Data Set**

With regard to ONC’s policy approach of adopting functional certification requirements rather than formal certification criteria, 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; 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 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 are at risk in a future regulatory cycle where 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, 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 standard-based approaches, and note that Health IT developers who achieve certification to this functional requirement through proprietary 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 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 subsets of any of the data included in the Common Clinical Data Set be reachable via the API. 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 prove more useful during the certification and meaningful use period. Accordingly, we recommend that ONC [allow any aggregate Common Clinical Data Set | signal that Health IT developers may implement 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 to provide both means and allow either 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 an state HIE, all of which provide means of achieving portions of these functional requirements. We therefore encourage ONC to allow means to modularly certify towards each of the three API scenarios (get patient identifier, get document, get discrete data), 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:

1. The real-world test is that individual developers or small businesses should have fair, reasonable and non-discriminatory (FRAND) requirements both to develop and to implement applications using the APIs.
2. Extant API-based platforms and ecosystem (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 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.
3. Applicable terms of use or other limits on access may be enforced by the provider organization.
4. 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 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. Work with FTC and other applicable agencies on policy and governance sufficient to meet policy requirements
2. Seek to achieve policy goals through Health IT and Provider organization participation in Data Sharing Arrangements or public-private governance efforts
3. 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