

January 20, 2014

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

Dear Dr. DeSalvo:

The Health IT Policy Committee and Health IT Standards Committee gave the following charge to the JASON Task Force:

Analyze and synthesize feedback on the JASON report

- Discuss the implications of the report and its impact on HHS, other Federal agencies and their strategies
- Assess the feasibility and impact of the JASON report on HHS and the broader HIT ecosystem
- Identify use cases and lessons learned from current experience
- Establish specific recommendations that can be integrated into the Federal Health IT Strategic
 Plan and the ONC interoperability roadmap
- Provide a high-level mapping of the PCAST 2010 report with the JASON report

Background

The 2013 JASON Report "A Robust Health Data Infrastructure" is highly critical of the status and trajectory of healthcare interoperability. It points to lack of an architecture supporting standardized APIs and EHR vendor technology and business practices as impediments to interoperability.

JASON recommends the creation of a "unifying software architecture" to migrate data from legacy systems to a new centrally orchestrated architecture to better serve clinical, research, and patient uses. In particular, the report recommends that ONC define "an overarching software architecture for the health data infrastructure" within 12 months

The JASON Task Force of the Health IT Policy Committee and Health IT Standards Committee strongly supports three main conclusions from the JASON Report:

- 1. Foundation of interoperability should be an orchestrated architecture based on Public APIs
- 2. Current interoperability approaches are functionally limited and need to be supplemented and gradually replaced with more comprehensive API-based models

3. MU Stage 3 should be used as a pivot point to initiate this transition

The JASON Task Force of the Health IT Policy Committee and Health IT Standards Committee disagrees with several findings and conclusions of the JASON Report:

- 1. We believe that the JASON report does not accurately characterize the current state of interoperability.
- 2. We do not agree that an evolution toward an API-based architecture should, or could, require "migration" from current clinical and financial systems.
- 3. We do not agree that the barriers to interoperability are primarily a software engineering problem.
- 4. We do not agree with the JASON Report's strong implicit assumption that market mechanisms are ineffectual, if not harmful, means of advancing interoperability. We believe that market mechanisms will be the primary driver of enhanced interoperability, and minimal, if any, federal regulatory intervention is desirable at the current stage of market development.
- 5. We do not agree with the JASON Report's implicit assumption that strong top-down control of a "unifying software architecture" is either feasible or desirable in today's healthcare market.

Recommendations

1. Focus on Interoperability. ONC and CMS should re-align the MU program to shift focus to expanding interoperability, and initiating adoption of Public APIs.

Recommendation: Limit the breadth of MU to shift the focus to interoperability

- MU Stage 2 experience shows that overly broad and complex requirements slow progress on all fronts.
- Focused on interoperability will send strong signal to market and allow providers and vendors to focus resources.

Recommendation: Three complementary HITECH levers should be exercised

- Add certification of highly constrained Public API to CEHRT standards.
- Encourage and motivate vendors to grant third-party access to Public APIs based on appropriate business and legal conventions.
- Structure incentive requirement programs (MU Stage 3 and others) so that providers grant third-party access to Public APIs based on appropriate business and legal conventions.

<u>Recommendation</u>: ONC and CMS should act with urgency to use HITECH to motivate industry-wide API-based capabilities

• ONC should immediately engage the FACAs to further flesh out JTF recommendations on Public API-based architecture

- ONC should immediately contract with an SDO or other recognized operationally active industry consortium to accelerate focused development of initial Public API and Core Data Services and Profiles for inclusion in MU Stage 3 and associated certification
- CMS and ONC should consider mechanisms to accommodate an accelerated development process for a feasible initial Public API specification
- 2. Industry-Based Ecosystem. A Coordinated Architecture based on market-based arrangements should be defined to create an ecosystem to support API-based interoperability.

<u>Recommendation</u>: A market-based exchange architecture should be defined by industry and government to meet the nation's current and future interoperability needs based on the following key concepts:

- <u>Coordinated architecture</u>. A loosely couple architecture with sufficient coordination to ensure that a market-driven ecosystem emerges for API-based exchange.
- <u>Data Sharing Networks (DSN</u>). An interoperable data sharing arrangement whose participants have established the legal and business frameworks necessary for data sharing.
 - Conform to the Coordinated Architecture and use the public API.
 - Could include, but is certainly not restricted to, existing networks such as those run by vendors or providers or health information exchange organizations.
- <u>Public API</u>. A standards-based API that is to be implemented with certain obligations and expectations governing "public" access to the API.
- <u>Core Data Services</u>. Fundamental, standards-based data services that implementations of the Public API are expected to provide.
- The Coordinated Architecture
 - Should not be single, top-down architecture
 - Loosely coupled based on scalable internet principles to accommodate implementation heterogeneity
 - Leverage and build upon existing networks, while encouraging new networks
 - Do not envision that the Coordinated Architecture is necessarily an entity or actual implementation, but rather, standards and principles based on internet principles and building blocks
- **3.** Data Sharing Networks in a Coordinated Architecture. The architecture should be based on a Coordinated Architecture that loosely couples market-based Data Sharing Networks.

<u>Recommendation</u>: The nationwide exchange network should be based on a Coordinated Architecture that "loosely couples" market-based Data Sharing Networks

• The Data Sharing Networks

- Data sharing arrangements that provide facilitating policy and infrastructure to support use of Public APIs
- Within the DSN:
 - Facilitating API-based exchange among entities. This has a technical component (e.g., what technologies are used to identify patients or authenticate users across entities?), and a policy component (e.g., what data or documents are accessible through a Public API, and what are the allowed purposes for data or documents accessed through a Public API?)
- Across DSNs:
 - Implementing services to be used to bridge across different DSNs, when this is deemed necessary. This will have cross-network technical components (e.g., which standards and protocols are used for different DSNs' patient-matching or authentication technologies to interact with each other?), and policy components (e.g., how are "out of network" entities authorized, and what data or documents are accessible to authorized "out of network" entities?)
- Clinical and financial systems that expose the Public API will have the ability to exchange data without needing a DSN
- **4. Public API as basic conduit of interoperability.** The Public API should enable data- and document-level access to clinical and financial systems according to contemporary internet principles.

<u>Recommendation</u>: The "Public API" should enable data- and document-level access to clinical and financial systems in accordance with Internet-style interoperability design principles and patterns. The Coordinated Architecture and Data Sharing Networks create an ecosystem to facilitate use of the Public API.

- The Public API
 - Comprises two components
 - an implementation of certain technical standards (the "API")
 - an agreement to meet certain obligations governing "public" access to the API
 - What makes an API a "Public API" is a set of conventions defining "public" access to the API
 - A "Public API" does not imply that data is exposed without regard to privacy and security. However, there are legal and business considerations that must be addressed before any given healthcare provider and/or vendor would allow another party to use the API to access information.
 - What is "public" in a "public API" is that the means for interfacing to it are uniformly available, it is based on non-proprietary standards, it is tested for conformance to such standards by trusted third parties, and there are welldefined, fairly-applied, business and legal frameworks for using the API.
- 5. Priority API Services. Core Data Services and Profiles should define the minimal data and document types supported by Public APIs.

<u>Recommendation</u>: Core Data Services and Profiles should define the minimal data and document types supported by all Public APIs. HITECH should focus initially on Clinician-to-Clinician Exchange and

Consumer Access use cases.

- The Core Data Services
 - Read/write access to both clinical documents (e.g., CCDA, discharge summary, etc.) and discrete clinical data elements (e.g., problems, medications, allergies, etc.)
 - Initial focus areas for the industry:
 - Clinician-to-clinician exchange (including ancillary service providers)
 - Consumer access
 - "Pluggable" apps for consumers and for clinicians
 - Population health and research
 - Administrative transactions
- The Core Data Profiles
 - Tightly specify data elements and formats used in Core Data Services
 - Priority profiles should be developed for Clinician-to-Clinician Exchange and Consumer Access
- Initial recommended focus of HITECH
 - Clinician-to-Clinician Exchange
 - Complement current document-centric approaches that exist in the market today
 - Consumer access
 - Natural extension of View/Download/Transmit and Blue Button
 - Leverage account services already provided by entities hosting patient portals and patient applications
 - Could open wide avenues of growth from mHealth and "pluggable app" companies who are not tied to legacy software
- **6. Government as market motivator.** ONC should assertively monitor the progress of exchange and implement non-regulatory steps to catalyze the adoption of Public APIs

<u>Recommendation</u>: Federal government *should* take the following actions to help the industry overcome barriers:

- <u>Transparency</u>. Aggressive and ongoing public monitoring of the pace of development and use of network mechanisms through collection of API usage data and development of an adoption evaluation framework to facilitate Public API-based exchange
- <u>Guidance</u>. Issuing authoritative, ongoing guidance to provide industry-wide direction and benchmarks, and to encourage specific actions for the development of DSNs and the Coordinated Architecture
- <u>Organization</u>. Convening existing exchange networks (i.e., prospective DSNs) to catalyze adoption of the Public API and development of industry-based governance mechanisms
- <u>Incentive alignment</u>. Aligning incentive programs and existing regulatory processes to stimulate use of the Public APIs, such as ACO contracts, LTPAC regulation, lab regulation, etc.
- <u>Federal operational alignment</u>. Requiring federal healthcare entities to adopt the Public APIs in their technology procurement activities and day-to-day market interactions, such as

Medicare/Medicaid, Department of Defense, Department of Veterans Affairs, Indian Health Services, NASA, etc.

<u>Recommendation</u>: Federal government *should consider* taking the following steps to enable orchestration of Core Services across the DSNs:

- <u>DSN bridging standards</u>. Developing voluntary standards for vendor-neutral, cross-DSN bridging to fully enable the narrow set of robust transactions required for the loosely coupled architecture (such as patient identity reconciliation, authorization/authentication, key management, etc.)
- <u>Nationwide shared services</u>. Developing standards for, and ensuring deployment of, universally
 necessary shared services that are highly sought after and thus would facilitate DSN alignment,
 such as public use licensed vocabularies, and perhaps nationwide healthcare provider and entity
 directories, etc.

<u>Recommendation</u>: The government *may* choose to consider direct regulation of DSNs in the event that the market does not develop effective coordination mechanisms

- Such actions would involve a significant increase in the government's regulatory authority over health information exchange activities, which would have high risk of unintended consequences that could slow market progress.
- Any such increase in regulatory authority should be carefully considered through evaluation of reasonable and meaningful benchmarks, and specifically calibrated to address any remaining barriers that the market has failed to overcome.

The Health IT Policy Committee and Health IT Standards Committee adopted these recommendations at their joint October 15, 2014 meeting. We appreciate the opportunity to provide these recommendations and look forward to discussing next steps.

Sincerely yours,

/s/

Paul Tang Vice Chair, HIT Policy Committee /s/

John Halamka Vice Chair, Health IT Standards Committee