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July 3, 2013

Jacob Reider, M.D.
Deputy National Coordinator
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services

P. Jon White, M.D.
Director of Health Information Technology
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services

Dear Dr. Reider and Dr. White,

Re: The JASON Report, A Robust Health Data Infrastructure, JSR-13-700 – Approved for publication 4/09/2014.

The EHR Association would like to provide comments and suggestions on the recently released JASON Report on “A Robust Health Data Infrastructure”. Our Standards and Interoperability Workgroup, comprised of experts in the areas on healthcare interoperability and very engaged in the development and promulgation of supporting standards, led our review of the report. We hope that these comments will inform this important work as it moves forward.

General Comments

We believe that the underlying goals of the JASON Report are generally good but that its analysis of the current state is not complete or current. Many of the principles presented are sound, but some do not reflect more recent developments. The detailed proposals for moving forward contain a number of good suggestions that are, unfortunately, mixed with some oversimplifications, unproven approaches and concepts not yet supported by market demand. Additionally, the proposed timeline for implementation is too aggressive to address the essential steps to achieve the desired level of interoperability, including an unrealistic recommendation for rapid (12 months) development and roll-out of a “new architecture” for our nation’s health IT, for implementation in Stage 3 of meaningful use (MU) (even understanding that the authors were speaking more of a framework than a technical architecture). The good news is that industry is further along than

the report portrays, pursuing an evolutionary approach that is more realistic and sustainable than the report's specific implementation of a shared vision of interoperability.

The attached document provides our detailed response to the JASON report, but a summary of those comments follows.

- The assessment of progress in interoperability does not seem to be well informed.
- The intent of the proposed JASON Health IT Software "Architecture" is confusing.
- The call for a "new architecture" is excessive, given that most of the criteria are already met fully or in part with current plans underway.
- The way in which it is suggested to enable patients/consumers to help manage the use of their data is laudable but inconsistent and somewhat superficial.
- The concept of atomicity is good, but it is approached in a simplistic and possibly hazardous manner.
- The suggested timing is unrealistic, and we recommend an approach that builds on existing Stage 2 specifications and standards – i.e., transition rather than a re-start.
- We do not see a need for a shared external terminology translation.
- The challenge of patient matching and disambiguation is not addressed in the report.
- Deployment models are not discussed.

We offer this feedback in the spirit of ongoing collaboration on this important topic, and we look forward to working with you to continue our progress toward a truly interoperable healthcare IT environment.

Sincerely,

/s/

Mark Segal, PhD
Chair, EHR Association
GE Healthcare IT

/s/

Sarah Corley, MD
Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee

/s/

Leigh Burchell
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/s/

Meg Marshall, JD
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/s/

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/s/

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About HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 40 companies that supply the vast majority of operational EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

CC:

Doug Fridsma, MD, Chief Science Officer, ONC

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**EHR Association (EHRA) Standards & Interoperability Workgroup
Comments on A Robust Health Data Infrastructure**

Prepared for the Agency for Healthcare Research and Quality by JASON, The MITRE Corporation
April 9, 2014

Overall, we have the following general comments on the JASON report:

- The goals of the report are good.
- Its analysis of the current state is not well informed.
- The principles presented are sound, but rather classical.
- The concrete proposals for moving forward contain a number of good suggestions which are, unfortunately, mixed with oversimplifications, unproven approaches and concepts not yet supported by market demand.
- The proposed timeline for implementation is too aggressive, including an unrealistic recommendation for rapid (12 months) development and roll-out of a “new architecture” for our nation’s health IT, for implementation in Stage 3 of meaningful use (MU), even understanding that the authors of the report were speaking more of a framework than a technical architecture.

The good news is that industry is further along than the report portrays, with an evolutionary approach that is more realistic and sustainable than the report’s timing vision.

More specifically:

1. The assessment of progress in interoperability does not seem to be well informed.

The elements presented do not reflect a good understanding of interoperability in MU Stage 2:

- Misstating and reducing Stage 2 information exchange requirements to “fax and display of documents”
- Portraying Stage 2 as the “adoption of a common mark-up language for storing electronic health records” is inaccurate, as the priority should not be seeking the means to store health records but to exchange them. We agree that “simply moving to a common mark-up language will not suffice”, but that is actually not the case in Stage 2, which does much more than this, including increasing standardization of terminology, data sets, data “packages” (including a with CDA document format that is precise enough to extract coded elements), and specification of data transport standards.

2. The intent of the proposed JASON Health IT Software “Architecture” is confusing.

When reviewing the language and the diagram, figure 5.1 in particular, we identify a number of ambiguities as to the intent of the architecture. On one hand, the impression is given that the proposal describes interoperability architecture, driving the definition of clearly defined APIs that enable consistent, predictable, secure exchange of data. On the other hand, the proposal reaches well beyond such an architecture into an application or implementation architecture prescribing different layers to which an individual health IT solution must adhere.

We suggest that the focus should remain primarily on describing an interoperability architecture, and not taking the broad brush approach that existing health IT is dysfunctional and must be replaced. Rather, the focus should be on implementing interoperability use cases to address the suggested priorities. Existing health IT should be able to accommodate the issues identified in the JASON Report, through various additive techniques, or through revisions, but in general, internal systems-specific changes should not be in the purview of policy follow-up to this report, which should focus on interoperability.

We can certainly envision that, for certain capabilities (e.g., patient matching and record locator), centralized capabilities could arise out of market demand, but the highly centralized data stores, middleware, and user interfaces as the diagram in the report implies, are expensive, impractical and unnecessary to address the fluid exchange and use of data across providers, patients, payers, researchers, and other stakeholders.

We do want to acknowledge our appreciation that the JASON report improves on the 2010 PCAST¹ report in that it recognizes the coexistence of an attestable “record” (e.g., such as a CDA document), along with the management of more granular atomic data. The JASON report would have benefited, however, from a clarification that atomic data is of value mainly to access specific elements of the record (i.e., pull).

3. The call for a “new architecture” is excessive, given that most of the criteria are already met fully or in part with current plans underway. The proposed criteria are:

- *Be agnostic as to the type, scale, platform, and storage location of the data*
 - This criterion is already addressed in Stage 2, except for the location of the data, where the current Stage 2 approach centering on point-to-point “push” of data is limiting. The EHR Association has been advocating for the ability to query and “pull” to deliver storage location independence in various comment forums for several years.
- *Use public APIs and open standards, interfaces, and protocols*
 - This general approach is consistent with ongoing standards work, such as Fast Healthcare Interoperability Resources (FHIR). However, the report’s intent is unclear about how such a query approach across thousands of healthcare IT systems would be made practical. Moreover, the creation of centralized data stores to be queried and/or enabled via APIs would not be acceptable to the range of affected stakeholders, including patients and consumers.
- The proposals for specific API requirements as part of ONC certification are neither realistic nor necessary; the growing industry adoption of APIs for a variety of purposes, as well as standards-based API work such as FHIR, are the more appropriate and sustainable path to accelerated use of APIs across the industry.
- Encrypt data at rest and in transit
 - This recommendation is in line with and consistent with Stage 2 requirements.
- *Separate key management from data management*
 - We agree with this principle, although the security approach proposed is generic and counter to current security thinking, as well as the security approach taken by the HIPAA Security Rule.
- *Include with the data the corresponding metadata, context, and provenance information*
 - This principle has been implemented and used by eHealth Exchange query/retrieve at the document level. Standards work associated with adding access to more granular data at the pull level is proceeding well. More work is needed to define what needs to be carried, however, including realistic and sustainable implementation methods and timelines.
- *Represent the data as atomic data with associated metadata*
 - We agree in general with this principle, which has been well-developed with the eHealth Exchange and Interoperability Workgroup (based on IHE XDS and XCA). The JASON report is, however, disproportionately focused on the concept of atomic data and tends to take an inappropriate “one size fits all” approach. In some cases, the document suggests the right level of atomic data but a general approach that would require a level of atomicity below

¹ <http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf>

the “clinical fact” would impose massive overhead costs for the industry as a whole and become potentially dangerous at the clinical level. Additionally, the report often confuses the way the data is structured to be interchanged (which is the focus of interoperability) with the way the data is stored internally by the EHR implementation which is not relevant (i.e., exposing the data should be the focus).

- *Follow the “robustness principle”: be liberal in what you accept and conservative in what you send*
 - We agree that this principle is well accepted but is not always well implemented.

4. Enabling patients/consumers to help manage how their data is used.

This goal is laudable in striving to ease access for purposes that go beyond the HIPAA Treatment, Payment, and Operations (TPO) concept. Unfortunately, the way that this concept is addressed by the report is inconsistent (e.g., for research) and somewhat superficial.

- We agree with the report’s suggestion to ensure privacy by focusing on controlling the use of the data rather than attempting an elusive de-identification. However, the report remains very vague on how to implement this.

5. Encryption and Patient Privacy Bundles

The report lacks clarity on the use of encryption. Encryption is a security tool that, when appropriately applied, can help safeguard data. However, encryption in all contexts is not always necessary, nor is it sufficient for patient privacy protection. We agree that communication of the metadata should be encrypted, as well as long-term storage. However, the report is not clear if it is expecting that all metadata is always encrypted. There are many other privacy concepts that need to be considered before the assertion can be made that an architecture “builds in patient privacy”. We suggest that only the appropriate type of encryption should be used, not a blanket encryption approach that may imply unnecessary overhead.

The introduction of granular permissions at an atomic level is a nice theoretical goal, but hiding its complexity through what is called “patient privacy bundles” to make it manageable by consumers seems to introduce another layer of complexity. The reality is that, until widely accepted standards exist, portable privacy policies will be challenging to implement. Furthermore, the combination of such granular permissions with different levels of data atomicity may result in an explosive compounding of complexity. This area will require much work and evaluation in real usage situations both from a clinician and patient point of view.

6. The concept of atomicity is good, but it is approached in a simplistic and possibly hazardous manner.

The writers of the JASON report seem to have been more focused on and oriented to research/population health than to direct patient care. The definition of atomic elements is very sensitive for data in the context of treatment decisions and the ability to manage “atoms” and, at the same time, the source “chart/record” level is critical. We feel that the report is not sufficiently careful about avoiding excessive and burdensome granularity (e.g., context is critical to safe care and page four is incorrect with the two examples provided).

7. Timing to realize. Transition rather than throw-away.

The report acknowledges that the definition and implementation of the proposed architecture may take many years. Therefore, the suggested timing for inclusion in a regulation such as Meaningful Use Stage 3 (with proposed rules expected in the latter part of 2014) is not well grounded and unrealistic. Recognizing the specific challenges that we have identified with some of the general concepts in the report, it is also too vague on many topics to support implementation timelines, let

alone one so aggressive. Certainly, the elements that are not fully defined would need to be specified first (e.g., the security concepts would require considerable work). Then, applicable standards work would need to be completed, using accepted and proven standards development processes. An initial subset of new work would then need to be piloted to assure that this path is realistic. Only then can stable specifications that are policy-relevant be ready for evaluation relative to policy implications, actual production and regulation.

A better alternative is to leverage the existing Stage 2 specifications and other standards/profiles in production (e.g., CDA document push and sharing) with specific extensions (e.g., adding a FHIR atomic pull across aggregated document content). This could be an effective evolutionary approach that preserves current MU2 investments while also saving time and money as progress is still made.

8. Terminology Management

We do not see a need for a shared external terminology translation. Rather, we should continue to move in the direction of having an agreed set of standard terminologies and have the connected systems perform the normalization to communicate using shared terminologies. In this case, no middle translation layer would be needed in a shared location.

9. Patient Matching

The challenge of patient matching and disambiguation is not addressed in the report, which seems to assume that it is solved. In reality, this remains a very significant challenge for the industry as a whole.

10. Deployment

Deployment models are not discussed, although parts of the report seem to imply that there will be centralization of patient data, while some other parts propose data distribution with some form of patient data locator. In any case, the drivers for guiding such deployment are not explicit, which is the situation we have currently.