



February 15, 2011

Dear Dr. Blumenthal and members of the HIT Policy Committee and HIT Standards Committee PCAST Workgroup,

On behalf of the HIMSS Electronic Health Record Association (EHRA), we deeply appreciate being given an opportunity to testify before the PCAST Workgroup on the December 2010 report from the President's Council of Advisors on Science and Technology (PCAST), *"Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward."*

The EHRA previously submitted detailed written commentary on the PCAST Report to the Office of the National Coordinator for Health Information Technology. This document has been provided to the PCAST Workgroup to supplement this written testimony. It was drafted in response to a series of ONC questions about the PCAST Report and contains additional information. This written testimony has significant overlap with this document, but was created in response to the questions we were asked to address by the PCAST Workgroup.

Overview

We appreciate PCAST's recognition of the importance of healthcare data, and the essential requirements to share that data across time and locations for individuals and populations. We agree with PCAST that the exchange of healthcare data should be at a more robust level in future stages of meaningful use (MU) compared to Stage 1 criteria and the current proposals for Stage 2. However, we have some significant reservations regarding some of the proposals within this document. We will detail these through our responses to the questions provided by the PCAST Workgroup for this session.

General Questions for Panels:

1. **Please summarize your understanding of some of the key points in the PCAST report and how these recommendations would work in the health care environment.**
 - **We read the PCAST report with great interest and appreciation for their focus on consistent nation-wide health data exchange, and would like to note key areas of agreement:**
 - Our mutual commitment to advance connectivity in a manner that facilitates the improvements in the quality and efficiency of healthcare and clinical research.

- The call for a more robust HIE than required for Stage 1 meaningful use or first projected for Stage 2. (For example, the current inconsistencies between state and community HIEs for interfacing EHRs is an obstacle that needs to be addressed).
 - The focus on meta-tagging and XML.
 - The importance of clinicians being able to query for available and relevant patient data across multiple providers and systems.
 - The PCAST Report reflects the wide consensus that reusable data elements should be adopted.
 - A focus on managing protected health information in a way that encourages patients to have confidence in HIT
- **We do, however, have a few critical concerns, which we believe would prevent the PCAST Report recommendations from working in the healthcare environment:**
 - A focus in the PCAST Report on individual data elements, separated from specific documents and records. This separates data from its critical clinical and patient context.
 - The PCAST approach would impose unwarranted data overhead and substantial burdens on workflow to attach meta-tags to each data element; and creates substantial risks that data summaries created from such isolated data elements will not provide accurate or complete clinical information.
 - This approach to sharing data out of context and without its original organization will likely place an undue burden on clinicians as they attempt to interpret the data and make accurate patient care decisions.
 - The specific approach (DEAS) called for by PCAST poses substantial and unwarranted patient safety risks given the lack of key clinical context
 - **ONC and the industry should focus on “Data Elements within Documents” rather than isolated “Data Elements,” a focus that is consistent with and builds on Stage 1 meaningful use.**
 - Data elements managed with a document-centric approach, which maintains context and organization, can later be distilled to atomic element-centric data with context and provenance. The reverse, however, is unlikely to be done safely or easily as atomic-level data moves across systems.
 - A document-centric approach has been widely adopted by most national HIT programs. Some did try the “data elements without document packaging” and discarded this approach (at great cost and delay) in favor of Data Elements within Documents” (English NHS Spine PSIS/Care Record Summary, Austria).
 - *Meta-data tagging is central to sharing health information, and the key standards, implementation specifications, test tools, open source, and products exist to support more robust, bidirectional HIE.*
 - Interlinked standards (Consolidated CDA templates, XDS meta-data tagging and exchange (XCA) already provide the “universal exchange language” for healthcare

information called for by PCAST. They do so, however, in a manner that balances innovation, incremental development and deployment, and deep domain knowledge.

- ONC should, building on work done in the NW-HIN Connect and Exchange projects, implement a bi-directional, publish/query-based approach to HIE in Stages 2 and 3 meaningful use, utilizing proven approaches (e.g., those demonstrated by Integrating the Healthcare Enterprise (IHE) profiles as XCA and XDS).
 - XDS defines proven meta-data tagging for document discovery and enables robust interoperability between HIEs and EHRs.
 - Meta-data tagged document sharing has been evaluated and is deployed by several HIEs as well as national and regional programs around the world.
 - Several open source (OHT, NIST, Microsoft, openHIE, etc.), support by many HIE infrastructure products, and EHRs from small and large vendors, with robust NIST test tools used by national programs abroad.
 - ACOs and Patient Centered Homes will require such bi-directional exchange.
- Concern has also been raised that PCAST included the recommendation of putting patient identifiable information and locations where those patients have received care into a national internet based search engine similar to Google or Microsoft Bing. The report goes further to suggest that we recommend to patients that they allow medical information to be exposed to web crawlers and accumulated to indexes within this national search engine.
- Although there was some discussion about privacy protection, it remains unclear how privacy protections would be practically implemented so that patients would be able to adequately manage their own protected health information (e.g., change preference by updating hundreds of distributed tagged data elements). There are concerns about how wieldy this approach will be for patients, i.e., that the ongoing level of effort and medical knowledge required might make it difficult for patients to manage their own protected information at the data element level. Patients are most likely to trust a system that is simple and transparent, and that does not create anxiety or an undue burden.

2. **What parts of the PCAST recommendations can be achieved in the 2013 timeframe? 2015?**

- Elements of PCAST that are aligned with and build upon work that has already been accomplished, such as the those demonstrated by Integrating the Healthcare Enterprise (IHE) profiles as XCA and XDS, could be accomplished by 2013 via large scale pilots. However, we do not feel that it would be feasible to implement the universal exchange language as defined in the PCAST Report in this time frame, and would delay and negatively impact interoperability goals for Stages 2 and 3 of Meaningful Use.
- Regarding 2015, we feel that the following would allow many of the commendable goals of the PCAST Report to be realized by this date:
 - Build upon the progress made by groups such as IHE and HL7 towards document-centric interoperability

- Take steps that foster state and community HIE efforts to encourage compliance with methods that will accelerate the exchange of data.
- However, this would require immediate acceleration of current efforts, in particular pilot and infrastructure deployments (Standards/Architecture, then infrastructure deployment, then EHR alignment, and finally reaching the goals of Stage 3 MU). The pilot programs should supplement other efforts (e.g., SHARP and Beacon programs) and evaluate the impact on patient safety, patient privacy, workflow, data integrity, cost, patient acceptance and provider acceptance.

3. What aspects, of the PCAST report are consistent with your approach to interoperability? What represent a significant change in direction? Do you have any alternative suggestions to accomplish the same goals?

- Synergies between the PCAST Report and our approach have been detailed above.
- The most significant change in direction is the focus in the PCAST Report on individual data elements separated from specific documents, as detailed above. To reiterate, we have concerns over the safety of this approach, as it has the potential to rob data of its critical clinical and patient context. The PCAST approach would also impose unwarranted data overhead and substantial burdens on workflow to attach meta-tags to each data element, a process that would be better managed through document-centric data sharing.
- Our alternative suggestions are consistent with our approach to interoperability, as stated above, interlinked standards (Consolidated CDA templates, XDS meta-data tagging and exchange (XCA & XDS) already provide the “universal exchange language” for healthcare information called for by PCAST. They do so, however, in a manner that balances innovation, incremental development and deployment, and deep domain knowledge. Accelerated piloting of these advanced HIT constructs is also recommended.

4. How should ONC implement the basic concepts/directions that are described in the report? (not to operational suggestions, but directional).

- At a high level we support the strategic concepts and directions within the PCAST Report, in that there is a need to accelerate nation-wide consistency in interoperability in a manner that ensures that when data is shared it is accurate, complete, protected, and has its supporting context. This can be achieved most readily by building upon and supporting existing standards and interoperability efforts coupled with comprehensive piloting in representative environments. Creating new standards has the potential to derail a process that is approaching maturity and lead to a delay that could last several years. Using the existing standards and profiles and focusing on adoption/deployment at the HIE to EHR interface level, given that we already have the nation-wide backbone, is key.

5. Are there ways to meet PCAST objectives in an iterative, incremental approach?

- At its highest level PCAST seeks to create an environment that breaks down barriers to the exchange of health information. We feel this objective can readily be met by a coordinated effort that involves multiple stakeholders including the ONC, CMS, other federal, state and local government entities, standards organizations, provider organizations, consumer organizations and the HIT industry.
- The focus on meta-tagging and XML is already supported by the ONC via its Standards & Interoperability Framework initiatives. ONC is close to completing this task with the CDA Consolidation and Transfer of Care initiatives that build upon HITSP/C83 and leverage the support of HL7 and IHE. These efforts should be supported and accelerated.
- An incremental approach is possible. Alongside with Direct Project for point-to-point one way push, a “Publish/Pull Project in a state/regional/other HIE” is needed where the focus would be the transport services needed for the sharing of any document content. This project would solely focus on the document sharing meta-data tagging (separating concerns from the meta-data tagging within the documents that is currently addressed by the S&I CDA Consolidation project). The focus would be to address the most common interface challenges that exist between HIEs and EHRs. Privacy would be initially strictly managed at an encounter/document level. Once experience has been gained further refinements would be evaluated and migration would be facilitated through a common starting point; a shared information exchange paradigm.

6. What, if any, would be your recommended next steps?

- As outlined above, a focus on the promotion of interlinked standards (e.g., Consolidated CDA templates, XDS meta-data tagging and exchange (XCA & XDS)) that draws from the experience and work of hundreds of HIT professionals, coupled with the acceleration of pilot/adoption deployment, and having these components tested in appropriate in-vivo environments, are our recommended next steps.
- Accelerating existing efforts that focus on sharing metadata-tagged data packaged in documents (e.g., the CCD). These documents provide access to individual data elements with filtering and aggregation performed by the requesting IT system. This approach has several impressive advantages:
 - It enhances the ability to ensure patient safety.
 - It is consistent with provider workflow and cognitive processes.
 - It is consistent with the current NW-HIN Exchange design.
 - It fully leverages the Stage 1MU investment in CCD/C32.
 - It provides a ready “on ramp” for providers and HIT developers and vendors.
 - It easily coexists with the Direct Transport.
 - It has been implemented by close to 200 IT systems around the world, many of those being available in the US.
 - The test tools have already been developed by NIST and are widely used in IHE Connectathons.
 - Most HIE and EHR vendors in the USA are familiar with these profiles, and this strategy can be rolled out rapidly.

- It is consistent with several other national and regional HIT projects around the world including (EU-Level epSOS, Austria, France, Japan, China, Switzerland, Luxemburg, Wales, etc.).
- As detailed in the sections above this could be easily engaged through an incremental process. It can supplement or work in parallel with existing efforts such as NHIN Direct and established HIEs.
- Additional efforts that address the exchange of data between state and local HIEs and EHRs are needed. A “Publish/Pull” Project that targets state/regional and community HIEs is needed. These transport services will need to facilitate the sharing of document contents.
- Once experience has been gained through accelerated piloting efforts, further refinements would need to be evaluated.
- Agreement on a basic collection (or library) of data elements. We believe that starting with HITSP C83, the CDA Harmonization (S&I Framework Initiative) of section templates and header templates will provide such a basic collection (Stage 1 MU plus a few proposed Stage 2 additions).
 - For each section template, the necessary terminologies should be selected as value sets. This work was largely done by HITSP in C83 and can be also finalized by the CDA Harmonization (S&I Framework Initiative).
- The use of the CDA/CCD XML structure is further encouraged as it supports controlled vocabularies (e.g., SNOMED CT) without requiring mapping of the terminologies to tagged data elements.
- As technical and clinical experts across a wide range of organizations that use an even wider range of technologies reviewed in this report, we recognize that this report attempts to put forward a single technical solution to a problem whose solution is technology independent. XML, clinical vocabularies, data abstraction, and hosting strategies (Cloud, SaaS, ASP, Timeshare, RCO, etc.) are features easily supported in a wide variety of technologies and generally don’t require additional expensive middleware.
 - Although we do recognize the need for continued advancement in many of the areas discussed in the PCAST report, we believe that a broad range of currently available technical solutions would readily meet these challenges. Solving these problems doesn’t rely on or mandate any specific technical solution but does depend on adopting vocabulary and exchange standards.
- With regard to specific technical solutions, we recommend ONC and CMS factor in the thinking of many industry leading and highly innovative academic, commercial, and not-for-profit organizations that have helped make significant progress in healthcare automation through the last several decades and are leading innovation into the future.

- Emphasize data liquidity for effective care but also for public health and research. Once they are able to access documents that contain metadata tagged and structured coded data elements, applications that can support the proper indexing and extraction of these documents can be introduced into the market. They will have the potential to usher in innovative uses of healthcare data to improve patient care, quality analysis, public health monitoring, and perhaps many other ways that have not even been envisioned in the PCAST report.
 - CCD and other CDA type documents provide both an organizational framework that enables the continual care contextual integrity of information; and includes a substantive level of data tagging that accommodates extraction and computation of the data contained.
 - With clinical information available and organized in such a way, it is important to understand that any data managed with a document-centric approach, which maintains context and organization can subsequently be distilled to atomic element-centric data with context and provenance. The reverse, however, is unlikely to be done safely or easily in the general case as data moves all or in part across computer systems.

Technical Panel Questions

1. Please explain some of key technical recommendations in the PCAST report, how they would work, including workflow, and the activities that are necessary to implement these recommendations.

- This key technical components, concerns over how they would work, and the challenges associated with implementing the recommendations in the PCAST Report are addressed in the document in responses to previous questions and in greater detail in the attached EHRA PCAST Comments document (previously submitted to the ONC).
- In summary, while we are looking forward to future dialogues with the PCAST Report principles, for reasons previously stated we do not feel that the key technical recommendations, how they would work, and/or their resultant impact on workflow and health care activities warrant implementation in their current state. However, we do feel that current technologies will achieve the same overall goals that are promoted in the PCAST Report in a manner that is safer, more scalable, less expensive, and in a much shorter period of time.

2. What is your reaction to Page 60 of the PCAST report that describes costs? Do you have an estimate for your organization's costs to implement and deploy the PCAST recommendations? Where is the greatest expense, and what alternatives can you suggest that would help to mitigate the costs?

- The PCAST Report suggests that it may cost between \$5 and \$20 million dollars per vendor to implement although we would like to see further details as to how these sums were

calculated. MU Stage 1 certified EHR vendors that are required to support the CCD specification, which builds upon existing standards and vetted efforts in the interoperability space. For the majority of EHR vendors, the costs associated with converting to the universal exchange language described within the PCAST Report while simultaneously providing support to clients while they attain MU and transition to ICD-10-CM and X12 HIPAA 5010 would be challenging.

- The cost estimates vary widely depending on the vendor product, the provider environment and the level of customization performed by the customer. The document based publish approach has been proven to be low cost and is currently in use by ONC-ATCB certified vendors.
- With regard to standards, the primary cost is not about the engineering resource, it is related to the time and uncertainty associated with new standards development. Developing a new standard when several competing standards are already in existence may not be in the greatest interest of health care. Another consideration is how data could be shared with other countries, as any universal exchange language should be compliant with international standards.
- Costs, including data integrity validation, associated with migrating data contained within current EHR users systems to a new universal exchange language also need to be taken into consideration
- As echoed in this report, acceleration of the use of current standards and technologies that support metadata tagging and that constitute a universal exchange language would be a much lower cost alternative to what has been propose in the PCAST Report.

Summary

In conclusion, we support the application of robust healthcare information exchange to the goals of improving patient care coordination and providing the larger, cross-provider data set needed to address the needs of population health, biosurveillance, and clinical research. We recognize the importance of protecting every patient's privacy through appropriate security controls. We have attempted here to offer additional observations about the PCAST report's conceptual basis and assumptions that may have led to its recommendations.

To highlight our key points:

1. There is no need to "rip and replace" existing health IT systems.
2. To the contrary, we should build on existing standards work as a foundation to achieve broad interoperability.
3. We should avoid excessive granularity, reflecting our understanding of how healthcare data is generated and used.
4. We must maintain a focus on clinical context and patient safety.

5. Privacy and security should be implemented at aggregate level, not at the data element level.
6. As an industry, we need to step up to the development of the policies necessary to support and sustain HIE.
7. Government should work with the health IT industry and SDOs to get achieve the objectives of the PCAST report.
8. *All* existing efforts – MU, ICD-10, SNOMED, healthcare reform – must be coordinated to ensure the best solutions and use of resources among all health IT industry stakeholders.

We also look forward to open and mutually informative discussions with all stakeholder, including the ONC, members of the PCAST workgroup, and proponents of the PCAST Report recommendations.

On behalf of the EHRA, we would like to thank the ONC and members of the PCAST workgroup for the opportunity to share our thoughts on the PCAST Report recommendations.

Sincerely,

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President and CEO
e-MDs, Inc. (EHRA Member Organization)