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On behalf of the HIMSS Electronic Health Record (EHR) Association, we are pleased to submit these comments 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".

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. In the spirit of advancing our progress in achieving broad and effective interoperability of healthcare systems, we offer some specific comments on the PCAST report.

- **Build on Progress to Date**
  We appreciate Dr. Blumenthal's recent statements indicating the need to be more "forward leaning" for health information exchange (HIE) in Stage 2 MU than had been initially anticipated. We urge ONC to build on work that has already been done in the Nation-wide Health Information Network (NW-HIN) Connect and Exchange projects to implement a bi-directional, publish/query-based approach to HIE in Stages 2 and 3 MU, utilizing such proven approaches as those demonstrated by Integrating the Healthcare Enterprise (IHE) profiles as XCA and XDS. In this regard, we agree with PCAST that it is important to more explicitly address data transport methods for Stage 2 MU. Standards are already in use providing many successful interoperable health record exchanges across the country.

We wish to emphasize strongly that virtually all PCAST use cases and specific technical requirements (e.g., the use of meta-tagged, searchable and indexable XML) can be met with existing and emerging standards, particularly those developed by HL7, IHE, and such controlled vocabularies as ICD-10, SNOMED, and LOINC. Much progress has been made in development and deployment of such standards and associated technologies, including very innovative work in areas such as making CDA documents accessible via web-type indexing, crawling, and browsers. There is important evidence of this progress, notably the ability to generate and receive CCD clinical document summaries, which is part of Stage 1 EHR certification requirements*. In essence, these various interlinked standards already provide the universal exchange language for healthcare information called for by PCAST. They do so, however, in a manner that carefully balances innovation, incremental development and deployment, and deep domain knowledge.*

- **Documents vs. Data Elements**

  We do, however, have serious reservations with the PCAST assertion that the central element of a universal exchange language for healthcare information must be meta-tagged *individual* data elements. In contrast, we believe it much more appropriate to focus on a "document" or record-centric approach to healthcare information, as used in the HL7 CDA documents, recognizing that HL7 also supports data organization and exchange of non-document data as needed. CCD and other CDA documents use highly extensible meta-tagged XML.

  Based on careful review and consultation with many technical and clinical experts as represented by our member companies and other healthcare IT leaders, we have concluded that a focus on individual data elements, separated from specific documents and records, robs these data of critical clinical and patient context which is vital for the proper care of patients. This approach imposes unwarranted data overhead and substantial burdens on workflow to attach meta-tags to each data element; and creates substantial risks that data summaries created out of 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.

  To expand on this point, the individual data element approach divorces data elements from key contextual information, such as associated structured data and non-structured data (e.g., clinical impressions), and creates a serious risk that virtual records created by the use of a browser will not provide a sufficiently complete or accurate basis for safe and effective clinical care. We also believe that, contrary to the conclusions of the PCAST report, patient identification and matching across healthcare data is substantially less precise when the unit of analysis is the individual data element rather than a more complete clinical document, such as an encounter summary. Finally, the potential workflow disruptions associated with a highly granular meta-tagging approach could harm the patient care process. *Overall, we believe that the specific approach called for by PCAST poses substantial and unwarranted patient safety risks.*

  While maintaining clinical and patient context is vital for the comprehensive care of patients, we recognize the existence of use cases that lend themselves well to a data element-centric approach. In the direct care of patients, activities necessary to support more narrowly focused

care processes (e.g., determining a patient's immunization history) can be greatly assisted by the availability of data elements specifically presented for that purpose. It is likely that there are numerous such use cases that would benefit most from this type of approach. Additionally, there are uses of data that go beyond the direct care of patients, which would significantly benefit from the availability of targeted data elements. The PCAST report mentions a number of these use cases including syndromic surveillance and public health monitoring, tracking healthcare quality metrics, and healthcare research. 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.

Regardless of the use case however, all of the data needed from these additional uses is generated by the use of health IT in the direct care of patients. It is imperative that this information is collected in a manner that supports ongoing medical care, and that it be captured and tagged in such a way as to be made accessible for the additional uses we envision. HL7's CDA documents support both of those needs. CCD and other CDA type documents provide both an organizational framework that enables the continual contextual integrity of information; and includes a substantive level of data tagging that accommodates extraction and computation of the data contained within. With clinical information available and organized in such a way, applications that can support the proper indexing and extraction of these documents be introduced into the market and 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.

- **Negative Impact on Privacy and Patient Preferences for Data Sharing**
  We believe that PCAST's proposal to manage clinical data and security at the individual data element level, with an unprecedented and highly granular privacy management scheme, is unworkable. Decisions on such a technology approach should only follow a careful and balanced policy development process. From a technical standpoint, the need to maintain privacy preferences via individual data element meta-tags could present obstacles in being responsive to dynamic changes in privacy policies and patient preferences. It would be far better to take an approach that allows patients to change preferences over time, without requiring a complex update process in every location where such data elements are stored. Patients would, in general, be unable to manage privacy in any meaningful way without clear and simple data organization that reflects their experience as they access healthcare. In addition, as data elements move across systems, both patients and providers would be unlikely to properly understand or interpret privacy preferences without appropriate context. Privacy would quickly be broadly compromised.

- **Potential Impacts on Clinicians, Patients, and the Industry Overall**
  We also believe that the PCAST recommendations could lead to substantial negative disruptions that could impose clinical risks and additional costs that are not offset by foreseeable benefits. Not only are we unaware of any industry that has adopted this approach to the extent envisioned in the PCAST report, but we must also recognize that healthcare data is both more complex and

more contextual than other industries. Clearly, healthcare information technologists and standards experts draw on work from broader informatics domains. But the risks associated with inaccurate or misleading healthcare data dwarf those that would be felt in any other industry.

Moreover, although we are pleased that PCAST recognizes the negative implications of a "rip and replace" approach to current health IT systems, we believe that the report is overly optimistic about the ability of "middleware" to efficiently and accurately generate the meta-tagged data called for in their proposal. In addition, the approach outlined would simply impose unwarranted and additional strain on a healthcare system already facing the challenges of MU requirements, ICD-10 and SNOMED-CT implementation, HIPAA 5010 transaction standards, value-based payment, quality reporting, and accountable care organizations. PCAST's recommendations could also be highly disruptive of ONC's efforts to effectively develop future MU criteria and the Standards and Interoperability (S&I) Framework. The substantial changes associated with implementing HITECH have already delayed planned implementation of key aspects of standards-based health information exchange (HIE). The industry simply does not need further disruption that doesn't meaningfully advance the care of our citizens while reducing the overall cost of healthcare.

- **Critical Timing Issues**

  This timing issue is especially acute regarding Stage 2 MU. ONC, CMS, and the HIT Policy Committee have already acknowledged the very tight timing associated with connecting the Stage 2 regulatory process to the realities of software development and deployment. Adopting the specifics of the PCAST proposals for Stage 2, even if they were warranted on their face, is simply unrealistic. It will be far more productive to focus Stage 2 requirements, the S&I Framework, and ONC's state HIE funding on making more robust use of the fundamental capabilities established in Stage 1; and ensuring that the Stage 2 requirements achieve the stated goal of moving to a standards approach for clinical summaries which we believe should be CDA-based, such as the CCD and associated document formats.

  We also recognize that challenges faced by HIE organizations as summarized by PCAST, including sustainability and complex privacy policy issues. At the same time, much of this critique is grounded in a pre-HITECH environment. We believe that, with the right MU incentives, progress on the S&I Framework, and appropriate resourcing via state HIE funding, further progress on privacy policy and NW-HIN governance, major and sufficient progress can be made in the areas or HIE policies, governance, and sustainability.

- **Innovation Could be at Risk**

  PCAST appropriately emphasizes the importance of innovation in healthcare and healthcare data. We agree. The HIT and EHR industries have engaged in substantial and productive innovation over the past several years. The EHR of today is very different than that of even five years ago, and roadmaps for the near-term future promise even more innovative and patient-centered developments. The PCAST report's critique of EHRs as being primarily billing focused is out-dated and does not reflect newer technologies and standards work that is already widely deployed.

EHR Association member companies are highly innovative and have many new initiatives under way that could provide the positive disruptive innovations any industry needs to continue to grow. At the same time, we are reminded every day that the fundamental purpose of healthcare information is to facilitate the care of individual patients and of patient populations. Collection of related data is not an end in itself. Rather, we must first and always focus on the extent to which the collection and use of healthcare data benefits patients and their loved ones.

- **Creative and Appropriate Use of Technologies**

  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.

  Appropriate use of technology will also ensure that investments made in HIT today to accomplish national objectives towards meaningful use and interoperability will maintain future compatibility and utility. No technology lasts forever and healthcare IT vendors have generally recognized that, with many of them have providing solutions that have continued to be effective and support current standards in a timely and agile manner. The number of vendors that were rapidly able to achieve certification serves as a good example of this.

  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.

Summary

The access and sharing of metadata-tagged data elements can be best implemented by sharing metadata-tagged data packaged in documents. 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.
- This approach 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.).

Responses to ONC's Solicitation of Comments, Federal Register, December 10, 2010

The EHR Association offers the following responses to specific questions posed by ONC relative to the PCAST report. We hope our input to this process guides regulators as they considering these challenging issues.

1. What standards, implementation specifications, certification criteria, and certification processes for electronic health record (EHR) technology and other HIT would be required to implement the following specific recommendations from the PCAST report:

a. That ONC establish minimal standards for the metadata associated with tagged data elements

The PCAST report's assumption that the same set of metadata will be used for any tagged data to be exchanged is an oversimplification. The first task must be to architect metadata by identifying the different aspects of information sharing the metadata will need to support. This step will likely lead to categorizing and organizing metadata in levels.

There are three fundamental issues overlooked by the PCAST proposed that, if ignored, would result is clinical safety issues and extremely complex implementation when scaled beyond a single system:

1. PCAST is correct in stating that metadata tagged healthcare data elements are critical to organize the data to be shared. However, clinicians have stated that collection of data elements attested by them during an encounter often conveys much more semantic context than the individual data elements do. Such implicit context is especially critical with human-captured information. By discounting such a safety critical grouping of data elements, the PCAST report is missing a vital point.

   ➔The accurate grouping of a set of data elements (often called a "document") by a clinical source is critical in cross-organizational health information exchange, where such context is not provided by a single HIE, personal health record (PHR), or EHR in a hospital or practice.

2. PCAST is correct in stating that ubiquitous data access services are needed, and proposes a solution where each individually metadata-tagged data element must be individually accessed and returned from the remote location where it is stored. While such services are needed, the proposed implementation is overly complex and does not scale to widely distributed sources of data elements for any one patient, introducing significant risks of undetected and undetectable software/clinical errors (e.g., in patient identity matching).

   ➔ We strongly recommend that data elements remain grouped in documents or data sets,

with the needed filtering/aggregation best performed by the requesting systems. This filtering and aggregation can be easily done by the requesting system once the data elements have been rationalized and harmonized.

3. PCAST is correct in proposing that metadata-tagging be associated to individual data elements. But the "association" should remain "virtual" and not become "physical" as suggested by the report. Three important facts should be considered.

    a. First the level of granularity to be considered a "data element" is unlikely to be an individual numeric/code value but rather a composite data element such as a prescribed medications (about 40 data values), or a lab result (10 data values), or a diagnosis (5 data values).

    b. Second, even at this composite data element level, the amount of contextual information needed to be conveyed by the metadata-tagging in the PCAST proposed solutions would be very large and variable. Some implementation "factoring" is needed, as all data elements from the same source and encounter would likely share the same metadata-tags.

    c. Third, there are some metadata-tags, especially those related to privacy that should not be attached to the data element, but should reference it to support patient preferences that might be changed over time, without requiring a complex update process in every location where such data elements would be stored.

➔ The tagging of data elements is indeed a needed concept, but the metadata should be factored at three levels:

(1) like data elements (e.g., a medication list) should be tagged at what CDA calls the template section level;
(2) all data elements coming from a single source and sharing the same clinical context should be tagged at the set of data elements (or document header) level; and
(3) groups of documents to be shared together should be tagged at the highest level. This level is critical for searches, but should be limited to be kept clinically non-specific to minimize privacy issues.

In conclusion, the high-level analysis performed by PCAST, which is good, has, in fact, already largely been considered by many other national HIT programs around the world, and is currently specified in IHE profiles such as XDS and XCA. The IHE XDS/XCA profiles along with HL7 CDA (and other content such as DICOM) already address the most obvious weaknesses of the solution sketched by PCAST, and should be considered as a starting point.

➔The PCAST report called-for access to reusable and metadata-tagged data elements should be provided through document sharing, where the content of these documents can be flexible and the specific data elements selected by the source, as enabled by the CDA.

As an example, the exchange of CCD documents now enables use of those same documents to provide clinical decision support (e.g., through the RAND/Partners project and other CDS efforts). Those same documents can be indexed and the resulting data accessed through other interfaces to support medication reconciliation, access to disaggregated data for quality measurement, population surveillance, clinical decision support, and chronic disease management.
Based on the above consideration, the following approach is recommended:

- Step 1 - Architect the levels of needed metadata and then the specific elements. Do not start from scratch, but begin by evaluating/reviewing the metadata provided by HL7 CDA at (1) the section level (this needs to account for metadata likely specific to each data element) and (2) document header level, and (3) the metadata provided by IHE XDS/XCA for the search top-level.

- Step 2 - For each metadata element across the three levels, ensure that a specific value set is defined (finalize the work done by HITSP/NHIN).

In particular, metadata used to identify patients and healthcare providers should be consistent across healthcare payer and provider organizations, and might benefit from establishing operating rules used in the exchange of such data. This metadata is currently supported in the exchange standards in use, but lack of consistent operating rules across various organizations could prevent accurate and consistent identification of individuals and organizations involved in healthcare transactions.

Operating rules should be set by a broad industry consensus-based process consistent with OMB Circular A-119, rather than through a top down, federal mandate.

If reuse of XCA/XDS and CDA section/header metadata is found acceptable with minor adjustments, this can easily be performed in 2011, with large scale testing at the IHE Connect-a-thon in January 2012.

b. That ONC facilitate the rapid mapping of existing semantic taxonomies into tagged data elements:

Such mapping requires:

1. 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).

2. 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).

Mapping of existing semantic taxonomies would include SNOMED, ICD, RxNORM, LOINC, and CPT. These terminologies need *not* be mapped into a tagged data element *if* the XML supports use of controlled vocabularies, as it should. In fact, existing standards already support use of these semantic taxonomies in standards developed for exchange of terminology driven data. When SARS or H1N1 variants of existing diseases were discovered, these standards needed *no* changes to support exchange of new codes for these diseases. For example, when new vaccines or treatments were added to CVX or CPT codes, they could immediately be used in the CDA/CCD standard.

The major challenges in healthcare around taxonomies are in making them available in a consistent, standardized format, ensuring that they are freely available, and mapping them with related terminologies when necessary. For example, SNOMED CT has been largely established as the best terminology to use for clinical care, as it supports the appropriate granularity and knowledge based representation and ontology for that purpose. However, for billing, organizations are required to use ICD-9 and soon will be required to use ICD-10. *A federally supported, widely available mapping from SNOMED CT to ICD-9/ICD-10 would greatly facilitate use of the appropriate terminologies for clinical care without requiring extensive technology investments in mapping to codes used for billing.*

Finally, we were puzzled by the discussion on p. 72 of the PCAST report regarding the need for standardized vocabularies. PCAST seems very negative regarding standards harmonization and also overly focused on challenges of vocabulary harmonization, while seemingly characterizing standardized vocabularies as "government controlled." We do not believe that this is an accurate characterization of the harmonization process nor of current standardized vocabularies, which are generally maintained within the private sector and highly dynamic over time. We believe that the use of standards and standardized vocabularies is essential to true data liquidity and exchange, and that it will minimize the extent to which users are locked into proprietary data formats and systems, whether legacy or newly developed systems.

c. That certification of EHR technology and other HIT should focus on interoperability with reference implementations developed by ONC.

Building reference implementations is a way for ONC to support those organizations that cannot develop implementations on their own. These reference implementations should focus on development using existing standards (e.g., IHE XDS/XCA and CDA/CCD template documents) and implementation guides, rather than trying to reinvent new standards for the same purposes. Work such as the Model-Driven Health Tools project (MDHT CDATools.org) supports development and implementation of the CDA standard. Additional work on this project could support other programming environments that have fewer open source efforts available (e.g., C#/.Net). Also, this link -- www.tinyurl.com/wwxds -- shows locations where several of these healthcare standards and profiles are in active use.

We would like to emphasize, however, that the availability of stable implementation specifications is the absolute foundation. Reference implementations can only be a facilitator to initial adoption, but should never be assumed to be required for implementation interoperability

compliance. Responsiveness, maintenance, and innovation cannot be constrained by reference implementation that will always be lagging and defuse the implementers' ultimate responsibility to test for interoperability compliance.

2. What processes and approaches would facilitate the rapid development and use of these standards, implementation specifications, certification criteria and certification processes?

ONC should use existing standards and implementation guides wherever possible, consistent with OMB Circular A-119, to avoid introducing costly retraining, reengineering, and redevelopment especially when standards have been previously tested or deployed in HIT. Rapid development and use will best be supported by providing more coordinated documentation, training, and sample implementations on the most commonly supported platforms.

Most importantly, the process needs to be stable and organized in a way that is not highly sensitive to changes in federal policy and regulations. The EHR Association has provided support with significant resources to the first IHE profiles definition and Connect-a-thon testing in an international context; then in the 2007-2009 timeframe the HITSP process; and now the Standards and Interoperability process set by the current administration. The issues raised by the PCAST report and their proposed solutions have already been considered, analyzed, and addressed multiple times over the past six years. Other countries have implemented the IHE profiles (XDS, XCA/XCPD, and other related profiles), and in 18 months have reached a stable and simple interoperable environment, sufficient to focus on other adoption challenges.

Development of our nation's healthcare infrastructure needs to follow an evolutionary path to support the demands of healthcare providers in the use and deployment of HIT. Our nation's HIT environment is a large-scale system, with complex interactions, and emergent behaviors that include not just the IT systems that it uses, but also the people and processes of the organizations that interact with these systems. Any innovation perceived as a major disruption to those processes will be resisted if it is not cost effective. What is needed is an evolutionary strategy working with existing standards to migrate implementation toward the goals established in the PCAST report. Such a strategy will encourage broaden adoption and use.

3. Given currently implemented information technology (IT) architectures and enterprises, what challenges will the industry face with respect to transitioning to the approach discussed in the PCAST report?

The biggest challenge is in avoiding the desire to reinvent what already exists.

As correctly stated in the PCAST report, it is possible to adapt existing HIT systems to extract metadata elements and tag them. There are, however, critical improvements that are needed to the PCAST solution to realize the promise of such an implementation for existing systems, including a focus on document rather than highly granular data elements. These improvements are needed on three points to ensure viable implementation, both from a clinical safety point of view and to address scalability.

- **See 1.a.1. through 1.a.3 above**

a. Given currently implemented provider workflows, what are some challenges to populating the metadata that may be necessary to implement the approach discussed in the PCAST report?

There will be some efforts by EHR product implementers to integrate the ability to share information into existing EHR local workflows. There is much innovation possible in this area, which has not been fully realized due to four challenges:

1. Data elements (with tagged metadata) definition must be stable and easily reusable (recognized by HITSP in C83 and restated by PCAST). Once this baseline is established, the sections (or data elements) may appear across different types of documents. This goal is 98% realized with the various CDA templates definitions and should be completed in a few months with the harmonization by the S&I framework initiative co-sponsored by IHE, HL7, and Health Story.

2. A stable single service definition to access data elements based on a XDS/XCA query and retrieval of documents (i.e., a set of metadata tagged data elements) is needed. Wide implementation experience exists, and the simplicity of this approach is evidenced by the variety of organizations that are using it.

3. We need stability and consensus on the above two interoperability services and data content to enable rapid innovation on provider HIT applications. In other words, innovation comes with stability and world-wide adoption of a common approach to interoperability. The benefits of this approach have been repeatedly demonstrated over the past 20 years by the Internet. (e.g., SMTP is 20 years old and innovative e-mail applications continue to be released).

4. From a provider perspective, the biggest challenge is in establishing *working policies* rather than technologies. The complex evolution of laws protecting privacy and ensuring security that vary across state lines, and the lack of publically available policy frameworks that navigate these challenges, are bigger barriers than the technology challenges.

Finally, overall we believe that the PCAST report is much too optimistic about the ability of "middleware" to efficiently and accurately generate the specific, highly atomic meta-tagged data called for in their proposal.

b. Alternatively, what are proposed solutions, or best practices from other industries, that could be leveraged to expedite these transitions?

Green fields offer more opportunities for change than does replacement of legacy systems. A legacy solution that supports a significant majority of the workflows that a healthcare organization depends on is often more expensive to replace than the potential benefits that could be realized with newer technology.

We encourage ONC to trust the many stakeholders that have been working to achieve the PCAST report recommendations for the past six years and have realized interoperability specifications (IHE profiles) that have been implemented in close to 200 HIT systems, world-wide, tested and deployed in clinical operations that manage the health information for millions of patients.

4. What technological developments and policy actions would be required to assure the privacy and security of health data in a national infrastructure for HIT that embodies the PCAST vision and recommendations?

The principal challenge for HIE is *not* in finding appropriate technology to assure privacy and security. The main issue is in establishing effective polices that support exchange of health information. By far, more time is spent on developing policies that are consistent with local policies as well as state laws and regulations, especially when cross [state] border exchanges are considered.

We recommend that:

1. ONC and the HIT Policy Committee work on development of policy frameworks that can be customized and used at the state and local levels to support implementation of HIE.

Simplify the development and acceptance of policies starting with simple modes of information sharing. In particular, we urge that ONC not start with the PCAST recommendation to control privacy at the data element level. Such controls, where more granular controls are deemed workable and needed, should be at the "set of data elements level" to ensure that both providers and patients understand the controls and their limitations. Several national programs have learned the hard way that providing control that is too granular adds risks, is easy to challenge, and has been rejected by consumers as a complex barrier in managing privacy. In addition, as stated by John Halamka, MD, MS (vice chair of the Health IT Standards Committee) "Although this is a noble goal, the reality of implementing this is quite difficult. Deciding if a data element does or does not imply a condition is a major informatics challenge."

A common set of standards is already in use in a number of different environments to support a variety of policies. These standards are already deployed, for example, in the CONNECT project, NHIN and interconnected HIEs, KeyHIE (www.keyhie.org), and VITL (www.vitl.net) using different sets policies. The ability of this technology to adapt to policy changes indicates that the problem is NOT in the technology.

5. How might a system of data element access services (DEAS), as described in the report, be established, and what role should the federal government assume in the oversight and/or governance of such a system?

The DEAS approach as described in the report needs important conceptual and design adjustments to be effective and clinically reliable, including a focus on tagged data at the document level. These are discussed throughout our comments.
The role of the federal government should be limited to:

1. Host an HIE Interface Initiative for an implementation specification of the EHR-to-HIE interface consistent with the NHIN Exchange (HIE-to-HIE interface) in the S&I Interoperability Framework. Engage the various state HIEs (to which edge EHR are to be connected), HIE vendors, EHR vendors, and other stakeholders in this definition to ensure consistency across all state/regional/community HIEs.

2. Include this implementation specification for EHRs in future stages of MU criteria.

3. Establish a voluntary HIE testing program, based on this implementation specification.

6. How might ONC best integrate the changes envisioned by the PCAST report into its work in preparation for Stage 2 of Meaningful Use?

Current stages of meaningful use describe and provide incentives for the use of EHR technology, but place no demands on HIE or other HIT related technology to conform to the same set of standards or support robust exchange of information (e.g., for laboratory results, immunizations, or exchange of clinical summaries). Stage 2 MU should consider how to encourage the use of exchange technologies for robust information exchange supporting access to longitudinal data and to encourage state HIEs, Beacon communities, and other ONC- and AHRQ-sponsored HIEs to implement an agreed-to HIE-to-EHR interface.

Timing is especially tight regarding Stage 2 MU. ONC, CMS, and the HIT Policy Committee have already acknowledged the very tight timing associated with the Stage 2 regulatory process and the timelines required for effective software development and deployment. Adopting the specifics of the PCAST proposals for Stage 2, even if they are warranted as proposed, is simply unrealistic.

It will be most productive to focus Stage 2 requirements, the S&I Framework, and ONC's state HIE funding on making more robust use of the fundamental capabilities established in Stage 1, as well as ensuring that the Stage 2 requirements do achieve the stated goal of moving to a standards approach for clinical summaries, which we believe should be CDA-based, such as the CCD and associated document formats.

7. What are the implications of the PCAST report on HIT programs and activities, specifically, health information exchange and federal agency activities and how could ONC address those implications?

The implications of the PCAST report on HIE and federal activities is that there should be more linkage between exchange as required by MU and related federal HIE-related funding, with more focus on robust exchange and access to longitudinal rather than encounter data.

8. Are there lessons learned regarding metadata tagging in other industries that ONC should be aware of?

There is significant experience with metadata- tagging and the specification of DEAS-like services in other national programs, which provide lessons critical to improving the PCAST solution design

and to avoid repeating errors identified by others. Some of the major references are:

1. The English Spine Care Record Service was in its two initial designs, operating as an atomic data element query (like proposed by PCAST DEAS). This design had to be abandoned after three years of investment and piloting for many of the reasons explained in this response. The current English Spine design, which is now operational, relies on the grouping of data elements in HL7 CDA templated documents. In a study conducted in 2010, the National Health Service concluded that its document sharing design would be aligned with the XDS design (and its metadata).

2. The European health information network, called epSOS (www.epsos.eu), has made the same design choice to rely on sharing CDA documents along with the use of the IHE XCA and XCPD profiles (as used by NHIN exchange).

3. Austria and France have analyzed carefully their metadata tagging and elected to rely on the CDA section tagging at the lowest level, the CDA document header, and the XDS metadata. They have carefully specified the terminology value sets to be placed in this third level of metadata for document search.

9. Are there lessons learned from initiatives to establish information-sharing languages ("universal languages") in other sectors?

There are no business sectors of which we are aware where a single "universal language" covers the scope of the business, from supply chain to production to delivery of goods and services, to billing, et cetera. The analogy of the web is not accurate. HTML is a language for dealing with the display of text and multimedia content, not semantics and meaning. Until recently, tags with semantic meaning were rarely used on the web, and have only just recently come into vogue for names and addresses. They are still the exception, not the norm.

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 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.

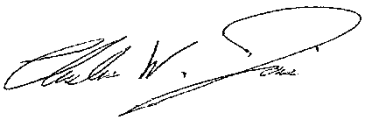
7. Government should work with the health IT industry and SDOs to get achieve the objectives of the PCAST report.

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 look forward to working with ONC to meet the challenges of achieving meaningful use of EHRs, including the secure exchange of health information to support our nation's objectives to provide quality healthcare services to more Americans.

Sincerely,

Carl Dvorak
Chair, EHR Association
Epic



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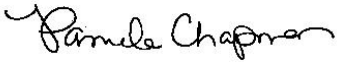
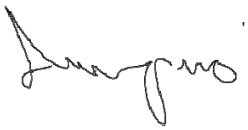
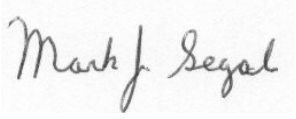


e-MDs
Pamela Chapman



Jacob Reider, MD
Allscripts Healthcare Solutions

Siemens
Michele McGlynn



GE Healthcare IT
Mark Segal

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EHR Association Executive Committee

About HIMSS EHR Association

HIMSS EHR Association is a trade association of Electronic Health Record (EHR) companies that join together to lead the health information technology industry in the accelerated adoption of EHRs in hospital and ambulatory care settings in the US. Representing a substantial portion of the installed EHR systems in the US, the association provides a forum for the EHR community to speak with a unified voice relative to standards development, the EHR certification process, interoperability, performance and quality measures, and other EHR issues as they become subject to increasing government, insurance and provider driven initiatives and requests. Membership is open to HIMSS corporate members with legally formed companies designing, developing and marketing their own commercially available EHRs with installations in the US. The association, comprised of more than 40 member companies, is a partner of the Healthcare Information and Management Systems Society (HIMSS) and operates as an organizational unit within HIMSS. For more information, visit http://www.himssehra.org.