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The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

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200 Independence Avenue, SW
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Dear Secretary Sebelius and Dr. Blumenthal:

On behalf of the Board of Directors and members of HIMSS, we are pleased to submit written comments on the Department of Health and Human Services (HHS) Office of the National Coordinator for Health IT (ONC) Request for Public Comment on the recommendations made by the President's Advisory Council on Science and Technology (PCAST) in their report, entitled, "Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward" published December 10, 2010 (75 Fed. Reg. pages 76986-7).

HIMSS is a cause-based not-for-profit organization exclusively focused on providing global leadership for the optimal use of information technology (IT) and management systems for the betterment of healthcare. Founded 50 years ago, HIMSS and its related organizations have offices in Chicago, Washington, DC, Brussels, Singapore, Leipzig, and other locations across the United States. HIMSS represents more than 34,000 individual members, of which two thirds work in healthcare provider, governmental and not-for-profit organizations. HIMSS also includes over 470 corporate members and more than 85 not-for-profit organizations that share our mission of transforming healthcare through the effective use of information technology and management systems. HIMSS frames and leads healthcare practices and public policy through its content expertise, professional development, and research initiatives designed to promote information and management systems' contributions to improving the quality, safety, access, and cost-effectiveness of patient care.

HIMSS appreciates the opportunity presented by ONC to comment on the important discussion on the roadmap for achieving interoperable health data exchange. We concur with the PCAST Report's assessment of health IT today; its current state, barriers and challenges. Most health IT systems are proprietary, do not adapt well to workflow changes, and have difficulty supporting interoperable exchange. And the ability to integrate electronic health information about a patient and exchange it among clinical providers remains the exception rather than the rule. The ability to efficiently exchange patients' healthcare information as they cross "transitions" in location or care setting (inpatient/outpatient/rehabilitation/long-term care/skilled nursing care) poses a challenge and an opportunity to increase value (quality, outcomes) while reducing costs associated with readmissions and duplication of services.

In spite of the many adoption, implementation, and interoperability challenges in the current system, there are real and tangible examples to be observed. Most notable are recipients of the HIMSS Nicholas E. Davies Awards of Excellence[1] and HIMSS EMR Adoption Model (EMRAM) Stage 7[2].

The HIMSS Davies Awards of Excellence evaluates management, functionality, technology and value of IT to improve care access, safety, quality and efficiency. Established in 1994, the Davies highlights case studies in enterprises, ambulatory, public health, and community health organizations; understanding and sharing documented value of EHR systems; visibility and recognition for high-impact EHR systems; and widely disseminates successful EHR implementation strategies.

Since 2005, HIMSS Analytics has been able to track adoption of EHR applications within hospitals and health systems across the U.S. and around the world. The multi-stage process measures progress toward an environment where paper charts are no longer used to deliver patient care. At the highest level – Stage 7 – a hospital is paperless. Clinical information can be readily shared via standard electronic transactions (i.e. CDA, CCR, CCD or state mandated transactions) with all entities within health information exchange networks (i.e. other hospitals, ambulatory clinics, sub-acute environments, employers, payers and patients). Stage 7 healthcare organizations support true sharing and use of health and wellness information by consumers and providers alike. Also, Stage 7 healthcare organizations use data warehousing and mining techniques to capture and analyze care data for performance improvement and advancing clinical decision support protocols.

We encourage ONC to work in collaboration with HIMSS Analytics to further study the success of these organizations to determine a best practice model for the industry for removing barriers to innovation.

In commenting on the PCAST Report, we would like to work with HHS/ONC regarding PCAST's assertion that rapid progress can **only** be made through technology choices that open up markets to competition and innovation. And, the Report's assertion that this goal requires a **new** universal exchange language for healthcare information, as well as a **new** digital infrastructure for locating patient records while strictly ensuring patient privacy.

In fact, over the past decade, the health IT community has been working collaboratively and diligently on a number of standards-based approaches that support health information exchange within provider organizations and across provider organizations that address optimal privacy and security needs; these innovative approaches are advancing via pilots, demonstrations, production implementations and supports the activities of information exchange within local, regional and state level information exchange networks and health information exchange organizations (HIOs.) Indeed, many of these capabilities are being adopted in production in many EHRs and healthcare institutions today. The Obama Administration and Congress have recently made major investments through HITECH to promote the adoption of electronic health systems, and to ensure that the full promise of health IT is realized. The programs stemming from these investments are just now being launched and publicized. While some may describe the overall progress of these collective efforts as slow, we are indeed steadily advancing at an accelerating pace towards the adoption of interoperable solutions at the provider organization level as well as at an health information exchange organization level , built on a consensus-based foundation of standards and implementation guides, including many that are available today to achieve the goals of the PCAST Report.

[1] Information on HIMSS Nicholas E. Davies Awards available online

[2] Information on HIMSS Analytics Stage 7 available online

HIMSS appreciates that these issues are complex and that rapid progress is necessary to achieve a nationwide health IT infrastructure. Success requires a vision the future and laying out a roadmap. No magic bullet exists. Success is predicated upon building on an existing foundation, acting consistently to leverage existing investments. We suggest that if we, as a nation, continually change direction and fail to leverage the best of existing efforts, the U.S. will never reach the optimal end state. Without stable direction, not only will we jeopardize our progress, we will risk losing the commitment and energy of the key stakeholders who, like us, are working to realize this vision.

With respect to the questions posted by ONC in the *Federal Register* request for public comment, HIMSS offers the following comments:

ONC Question #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;

Standardized metadata tags that can be used by a diverse community of independent caregivers with a consistent underlying semantics will be a bedrock capability that enables this project to succeed. These tags will need to be identified and maintained by some central authority that can ensure they are consistent, complete and do not conflict with each other. A parallel requirement is the ability to establish standardized data *values* for certain data fields to make sure that they can be interpreted with semantic integrity by any recipient.

The metadata system should be scalable which implies that unforeseen metadata labels may need to be included and propagated across the mapping system. Additionally, this requires a system to cleanse the metadata system of erroneous or incorrectly-entered metadata labels. The metadata system should include a process for resolving conflicts between labels that relate to the same semantic concepts but have different values. The metadata system must ensure that the metadata label and values are stored, transmitted and processed in a secure and privacy-preserving manner (as the labels and values are potentially sensitive themselves).

This effort can leverage HL7 CDA and CCD standards which already use meta-tagged XML. There is work underway in HL7 to index CDA data access it via web browsing. A universal language currently exists through use of HL7, IHE, in combination with various controlled vocabularies and taxonomies.

The ability to include the context of the patient may be compromised by the PCAST focus on a data element focused meta-tags vs. document or record-based approach. Accessing atomic level data alone may lose the context of the information for clinical use which may compromise patient safety and impose meta-tagging overhead without commensurate value.

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

The ONC will need to certify various medical ontologies that can be used to contribute to the universal exchange language. To permit system-wide proper interpretation of patient privacy requirements, the capture and documentation of patient privacy preferences will need to be standardized. To make it feasible for patients to express consistent privacy requirements, and for vendors to honor those requirements, it will be necessary to develop standard definitions of clinical data segmentations such as 'psychiatric data', 'genetics', 'pediatric', 'cancer-related', etc. This will provide vendors with a set of achievable goals as they attempt to segment the information in their EHRs and clinical data warehouses in order to be able to respond to patient privacy restrictions. These same data segments can then serve as the basis for more granular patient privacy permissions.

The metadata specification should leverage existing ontology and terminology work, as new metadata specification languages would only exacerbate and delay addressing current problems. For rapid development and quick uptake, the base metadata language should be bootstrapped to the existing ontology standard for care delivery. For the rapid mapping of metadata to existing semantic taxonomies, a global architecture for general mapping must be articulated; and as the metadata language leverages existing work, existing mapping schemes are immediately applicable.

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

Incorporating interoperability into EHR certification is desirable to ensure that functionality to support interoperability is adopted, but it comes with a cost in terms of resources for EHR vendors and covered entities. Reference implementations currently exist for successful health information exchange models. Existing reference implementations for interoperability should be leveraged such as those being demonstrated in the *Live Exchange* area of the HIMSS11 Interoperability Showcase.

Finally, HIMSS encourages HHS/ONC to look closely at the global implications of this recommendation because it may appear to create a process that is a direct contradiction to the approach other countries are taking to encourage health information throughout the broader healthcare community.

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

HIMSS appreciates the opportunity to address ONC's question. An essential aspect of transforming healthcare in the United States is to have interoperability across applications, systems, and settings that facilitate patient care. All forms of interoperability (transaction-based, document exchange, semantic, etc.) enable authorized professionals and consumers to access relevant healthcare information regardless of where the patient has been seen and where the professional is located. To be effective, however, interoperability requires the widespread adoption of standards by both healthcare entities and vendors within and across medical referral regions. Despite the emerging consensus on the need for local, regional, and nationwide health information exchange, the task is daunting and the barriers are many. Barriers to achieving this vision include lack of adoption of effective standards, incompatibility among different IS solutions, failure to align technology solutions to process and workflow requirements of the

end user, and policies that are only now emerging related to the ownership of, access to, and the use of data.

One notable standards profiling effort that has the ability and capacity to mobilize essential healthcare entities toward interoperability is "Integrating the Healthcare Enterprise" (IHE). IHE is a major, multi-year, global interoperability initiative including the United States, Canada, Asia and Europe. Leadership in the United States is provided by IHE USA. IHE's initial work in defining the interaction of general healthcare IT and imaging systems has been widely implemented by industry and user sites and has greatly improved efficiency and information integrity in the radiology domain. For example, IHE profiles have been implemented by more than 95% of radiology vendors world-wide.

IHE has expanded steadily to incorporate new domain areas, including Cardiology, Eye Care, IT Infrastructure, Laboratory, Pathology, Pharmacy, Nuclear Medicine, Patient Care Coordination, Patient Care Devices and Radiation Oncology. The approach employed in the IHE technical framework is not to define new standards, but rather to leverage existing standards such as ISO, DICOM, HL7, IETF, ASTM, OASIS, and many others. These standards are incorporated as appropriate to a given healthcare domain--in an integrated manner, defining configuration choices when necessary.

IHE has defined a common framework to deliver the basic interoperability needed for local and regional health information exchanges. It has developed a foundational set of standards-based integration profiles for information exchange with these interrelated efforts:

- Cross-Enterprise Document Sharing (XDS) support for document content interoperability. This supports a standards-based EHR across clinical encounters and care settings.
- A security framework for protecting the confidentiality, authenticity and integrity of patient care data.
- Cross-domain patient identification management to ensure consistent patient information and effective searches for EHRs.

For example, IHE capabilities are being leveraged today by the Direct Project and a number of health information exchange organizations today to provide many components for an interoperable Nationwide Health Information Network architecture. IHE is also being leveraged in Europe by the ePSOS project to achieve European regional objectives for health information exchange. The IHE process accelerates standards adoption and deployment to achieve a truly interoperable patient care experience.

In addition, as indicated in our March 2010 comments to the Office of the National Coordinator for Health IT on the Standards, Implementation Specifications, and Certification Criteria Interim Final Rule, HIMSS endorses the adoption of one patient record summary standard to support Meaningful Use (MU) in Stage II and beyond and the use of CCD or CCR for Stage I as a glide path to a single standard. This means that the selection of the single standard needs to occur within a six-month time window so that vendors and providers have the lead time to factor changes into their product and implementation plans. Our members are concerned that several key items in the required certification criteria are not clearly defined, and short timelines present huge challenges. It is critical for health IT stakeholders to have consistency in terminology. Stakeholders need significant advance time to deliver and test the products. They must have clearly understandable language to do that – a deficit in this area raises the risk of failure and the likelihood that we cannot deliver a quality outcome in time.

Finally, HHS/ONC will need to find a way to realign financial incentives to reward organizations that develop PCAST Universal Health Data Exchange Language (UHDEL) capabilities. Simultaneously, they

will need to develop techniques to document the clinical value of the UHDEL in actual practice. This will likely involve the deployment of pilot implementations that demonstrate real-world benefits derived by organizations that begin to use UHDEL capabilities. Incorporating the UHDEL in stages 2 and 3 of meaningful use is one lever that HHS can use to accelerate adoption.

ONC Question #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?

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?
Currently, populating metadata can be difficult when patients have very little personally identifiable information (lack of accurate DOB, SSN, similar name). There is lack of patient involvement in the process. Further, without reimbursement, lack of funding for smaller entities to put all this in place is a significant obstacle.

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

Once the semantics of the PCAST UHDEL metadata tags have been established, it will be important for each EHR vendor to begin work on a bi-directional translator that can both receive data from a UHDEL message and place it into the EHR, and generate a UHDEL message from EHR data. Since it will be a long time before the UHDEL can become truly comprehensive, it will be important for it to have the ability to mix discretely coded data with text data.

Since medical text is the primary current 'universal' method for expressing medical information, it would appear that currently-existing medical natural language processing capabilities should be incorporated as a key technology enabling the creation and use of the UHDEL language.

Vendors with clients using legacy technology may require significant upgrades to their underlying cores. However, these changes are dependent on the product, the vendor and the client environment. With newer technologies, this concern **may** be lessened. However, each product must be individually examined.

HIMSS members have experience with best practices from other industries, including the banking and energy sectors. First, the banking community has examples of industry-wide involvement in overcoming data sharing challenges.

The specific learning example can be drawn from the development of the automatic teller machine network. The commoditized ATM offers a level of seamless interoperability which could be considered as an example for healthcare interoperability in the future. The customer (patient) can retrieve cash (health information) from any ATM (provider). This functionality is available to the customer (patient), regardless of the location of the ATM (provider location). The customer's money may be stored in any of a number of different banks, credit unions, or securities brokers (physicians' offices, hospitals, or ACOs). Independent of the location of the money (health information), it is available to the customer (patient), in real time, on the customer's (patients) demand.

This functionality has not always existed. Decades ago, customers could only retrieve cash from a branch of their own bank. This fragmentation, from the customer's experience, no longer exists. Effectively, the banking industry underwent a transformation that created the interoperability necessary for the customer (patient) to be able to retrieve funds (health information) quickly, efficiently, and securely. Much of the learning experience gained by the banks may prove beneficial to the healthcare industry in its trek towards interoperability.

Second, our members encourage HHS/ONC to consider the energy industry and how utilities exchange power and electricity across the "grid". Even today, utilities companies regularly meet to continually refine standards so that more efficient and timely exchange of power occurs. It is not a perfect analogy, but there are enough similarities to demonstrate the complexity and challenge, realities and costs.

ONC Question #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?

HIMSS appreciates the opportunity to respond to the question. The PCAST Report makes several assumptions/recommendations relating to privacy and security upon which HIMSS would like to comment. These comments include discussion of recommendations for technology developments and policy actions, as requested in this question:

- **The PCAST Report states that "a universal exchange language, based on meta-data tagged data elements will allow the design of much better privacy and security protection for patient data."**

    - HIMSS understands PCAST's assertion that tagged data enables more sophisticated privacy management and that privacy requirements should be set in advance of encountering a serious medical problem. However, patient privacy choices are context-dependent and not necessarily persistent across all contexts or across time. For example, diagnosis of a particular disease becomes less sensitive once treatment is available and commonly prescribed.

      If privacy requirements are embedded in a message in the form of metadata tags, those requirements are therefore static and cannot be updated. Instead, what should be embedded in the message is a pointer to a web-based server that implements the requirements in a dynamically updatable manner. In that way, even once a message has been created and distributed there still is an opportunity to change its privacy constraints should the patient desire to do so.

      Or, instead, tags could be dynamically applied at the time of information exchange and not statically held with the data. This would allow them to reflect the context.

    - An integral part of the PCAST effort must be to establish minimum standards for expressing patient privacy preferences. These standards must include how to capture patient privacy wishes; how to embody these wishes in a standardized, machine-processable form, and how vendors can apply these requirements in a consistent manner to the messages they generate for information exchange using the PCAST UHDEL. There has been a lot of work in the last decade on specifying privacy preferences. We can build on work on P3P, EPAL, S4P, etc.

- A method for capturing patient privacy wishes must be easily updated by the patient and some action (some level of exchange) must be allowed when patients fail to express their preferences or fail to keep them current.

- We must find a way to reconcile the plethora of inconsistent privacy regulations across the country at the national and state level. In addition, if we desire to tag all data elements, there might be an assumption to include behavioral health, drug and alcohol treatment protocols, genetic information and/or sexual health information that may currently be protected under state or federal statutes. In hearings held by the ONC in 2010, they determined healthcare is not currently prepared to filter such sensitive data. Will tagging solve this issue and will changes to regulations be necessary to share the information?

- Standards and solutions around consent management would be critical to the success of this project.

- **All patient information should always be encrypted either when stored or transmitted. An encryption key for patient information should be stored on the computer system that holds its corresponding patient data.**

  - HIMSS agrees with these statements and supports the implementation of encryption technology with healthcare data.

  - Use of a data-tagging scheme as described in the PCAST report is indeed feasible. The question is how to execute it securely. Encrypting all data at-rest is going to be quite a shift from what the current implementation in healthcare. If each data element was encrypted separately and only deciphered when access is required, this would allow data to be protected, of course. And, it would absolutely provide an audit trail that could not be questioned since the decryption activity would be tied to the user trying to access the data and with the smart card and a password; it would be unique to an individual every time. This kind of two-factor approach would also go a long way towards identifying the person taking the action uniquely and therefore support things like Accounting of Disclosures. The issues associated with such an approach include cost, work flow and the complexity/sophistication of such an approach, which might be out-of-reach for the typical healthcare entity.

- **The PCAST report states, "Identity is also a crucial aspect of security. Determining the identity of a principal is commonly called authentication."**

  - This section of the PCAST report ("The Health IT Architecture for 21st Century Privacy and Security", page 49) confuses the terms/concepts of identity and authentication.

    HIMSS believes that the key issue requiring discussion in the context of the architecture discussed in this report is *identity* and *patient identity integrity.* See next set of comments.

- **The PCAST report states, "The health IT ecosystem <PCAST> envisions does not require the existence of a uniform patient identifier. Instead, it could use associations of intrinsic patient-related information to link the appropriate data to specific patients. This method is**

used now to create patient record locators within local closed systems and regional health exchanges, but as employed today, it can be plagued by human error."

- HIMSS is concerned that the PCAST report continually states that there is no role for universal patient identifiers, but does not offer a detailed approach as to how the healthcare community will achieve error-free patient identification across healthcare organizations.

- In December 2009, HIMSS published the results of a HIMSS member Workgroup in a white paper entitled, "Patient Identity Integrity." This paper makes observations regarding the manifestation of patient matching issues for healthcare organizations, documents examples, describes barriers and proposes action items for the industry. Patient identification/matching errors are:

  - Frequent
  - Serious
  - Difficult to eliminate
  - Costly (administrative, duplicative/unnecessary procedures, etc.)
  - Patient safety issue
  - Quality of care issue

HIMSS has concerns that the PCAST project will indeed exacerbate patient identification problems because it will involve searching larger patient populations and communications across environments that have no ability to coordinate their automation systems nor common techniques for patient identification unless such capabilities are made available. Therefore, if the effort outlined in the PCAST Report is going to succeed, it must find ways to improve the accuracy of patient identification over current methods or risk failure just on the basis of inadequate patient identification. HIMSS encourages a study of available technologies and techniques in this regard.

The assertion that "unique patient identification is not necessary because multi-factor or algorithm solutions can be leveraged to identify a patient" is not technically correct. The PCAST report seems to confuse the intended purpose of UPI and MF++. UPI is intended to ensure that multiples records for the same person across multiple silos can be combined with 100% accuracy. MF++ is intended to ensure that a single person is correctly authenticated. Current algorithms for medical record/identity resolution leverage matching across multiple fields (which may contain errors) and normally never achieve 100% accuracy, which means that false positives and false negatives are possible when joining multiple records for the same person.

Finally, with respect to the patient matching issue, HHS/ONC needs to take into account integrated health systems (e.g. the MHS, the VA, Kaiser Permanente) that already have elaborate EHR systems and established patient identifiers for large populations. In addition, HHS/ONC must take into account patient populations (e.g. active duty service members in the military) whose stated privacy wishes might be treated differently than those of other patient populations. See 45 CFR 164.512(k)(1) (permitting disclosure of protected health information to appropriate military command authorities for certain purposes).

ONC Question #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?

HIMSS concurs with the PCAST that the data element access services would not see plaintext or raw patient data; this is critical for acceptance by the privacy community and also simplifies the operation of the DEAS. The logical place for the DEAS to reside is the health information exchange network that is part of the Nationwide Health Information Network. The government should make DEAS software available to each HIE, perhaps in the form of an open source repository. The DEAS may need to be hosted by a trusted authority.

To achieve more rapid success, the federal government could initially provide the starting momentum, work closely with the open community, and provide an open source reference implementation that encourages industry / commercial development of other implementations, artifacts and certification.

Finally, HIMSS also encourages the federal government to leverage existing work efforts associated with open source technology.

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

HIMSS appreciates the opportunity to respond to the question, and suggests to HHS/ONC that Meaningful Use Stage 2 requirements 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/AHRQ sponsored HIEs to implement an agreed-to HIE to EHR interface.

We are all aware the outlined timeline for achieving Stage 2 is especially tight. 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 is going to be extremely difficult.

HIMSS members suggest for HHS/ONC 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 standards do achieve the stated goal of moving to a standards approach for clinical summaries. To achieve this effort, HIMSS strongly encourages HHS/ONC to identify a single patient record summary standard for Stage 2.

In addition, since it will not be feasible to require full UHDEL capability of all healthcare organization for stage 2 and probably not for stage 3 of Meaningful Use, it should be implemented as a 'bonus' target with associated financial rewards and incentives.

ONC Question #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?

HIMSS appreciates the opportunity to respond to the question. HIMSS sees multiple areas for dialogue between the healthcare community and ONC/HHS.

- HHS/ONC, CMS, PCAST and standards organizations should collaborate regarding the various HIT programs and activities in effect and in future consideration to complement and progress national healthcare standards and to create a set of mutually agreeable initiatives and mandates versus additive and potentially conflicting initiatives.

- Since the healthcare community is still in the process of determining the best approach to achieving sustainability for health information organizations, it is difficult to predict the number of models that will be available to the healthcare community.

- The PCAST report also raises awareness that the data sent to clinicians needs to be timely and accurate. Workflow changes in the clinical setting need to occur. This is 80% of the time, money, expense and frustration. 20% is the hardware/software. Thus, resources need to be for workflow changes for a successful implementation.

In addition, HIMSS suggests to HHS/ONC that there is significant experience with metadata data tagging and the specification of DEAS-like services in other national programs, which are critical to improve the PCAST solution design and not repeat errors identified by others. Some of the major references are:

- The English Spine Care Record Service was in its two initial designs, operating as an atomic data element query (like the PCAST DEAS). This design had to be abandoned after three years of investment and piloting for the reason explained below. The current design, now operational, relies on the grouping of data elements in HL7 CDA templated documents. In a study conducted in 2009, the NHS concluded that its document sharing design was aligned with the XDS design (and its metadata).
- The European NHIN, called epSOS has made the same design choice to rely on sharing CDA documents along with the use of the IHE XCA and XCPD profiles (same as those used by NHIN exchange)
- 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.

Finally, there are three issues that need to be addressed in order to advance the likelihood for success of the solutions being espoused in the PCAST Report.

- Clinical Data Collection: PCAST is correct in stating that **meta-data tagged health 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 convey much more semantics than the individual elements do. Such implicit context setting is especially critical with human captured information. By discounting such a safety critical grouping of such data elements, the PCAST report is missing a vital point.

Such a grouping by a clinical source of a set of data elements (whether called a document or not) is critical for health information exchange within an organization, as well as across multiple organizations, where such a context is not provided by a single PHR or EHR in a hospital or practice.

- Data and Program Complexity: The proposed PCAST implementation is complex and will have difficulty scaling to widely-distributed sources of data elements for one patient and induces significant risks of undetected and undetectable software/clinical errors (e.g. in patient identity matching, singular clinical data etc.).

  Therefore, HIMSS recommends that data elements remain grouped in document or data sets, as they have been issued by a source, and that the needed filtering/aggregation is 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, as suggested by the PCAST Report.

- Meta-data tagging: PCAST is correct in proposing that the metadata-tagging be associated to individual data elements. But the "association" should remain virtual and not become "physical" as suggested by the report. This results from three important facts. 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). 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. Third, there are some metadata-tags, especially those related to privacy that should not be attached to the data element, but should reference it, so that patient preferences are allowed simply to be changed over time, without engaging 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 meta-data should be factored at three levels: (1) like data elements (e.g. a medication list) should be tagged at the 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; (3) group of documents to be shared together should be tagged at the highest level. This level is critical for searches, but should be minimized to be kept as clinically non-specific to minimize privacy issues.

Finally, a great deal of time and effort has gone into supporting the initial efforts of HITSP, FHA Connect, the Nationwide Health Information Network, HL7 and IHE. The private sector and government agencies have created a momentum for interoperability adoption. HIMSS encourages HHS/ONC to work closely with healthcare community colleagues in the U.S. and abroad to understand the analyses that have occurred. We look forward to working with HHS/ONC on this important topic and to outlining how some of these issues have already been specified in IHE profiles such as XDS and XCA.

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

HIMSS suggests that the healthcare community has significant resources and research that can be made available to HHS/ONC. We encourage HHS/ONC to learn from and leverage work in ontology and information sharing in healthcare (both by medical informaticians and computer scientists).

In addition, look to the banking and energy communities as two areas where ONC can learn more about metadata tagging.

ONC Question #9: Are there lessons learned from initiatives to establish information sharing languages (''universal languages'') in other sectors?

HIMSS members have limited experience analyzing the establishment of a universal language in other sectors. We defer to other public and private sector organizations on the relative successes of establishing universal languages in non-health care settings.

Key Findings:

Healthcare in the United States is too large and too complex to be fixed by any single 'magic bullet' solution. The Universal Healthcare Data Exchange Language proposed in the PCAST document can be of significant benefit to the practice of healthcare, but only if it is coordinated with a variety of other standards and capabilities to form a well-integrated and standardized total system. We urge the HHS to incorporate this work as an integral component of a larger integrated plan for services and capabilities that extends across the entire spectrum of healthcare functions and activities. In order to provide maximum benefit, the UHDEL must become a key component of a carefully-considered, tightly-integrated, flexible and functional infrastructure that can be used by the healthcare IT community as a stable platform upon which to construct applications that progressively add value to the practice of healthcare in the United States.

We appreciate PCAST's recognition of the importance of health care data and of robust liquidity for and exchange of such data, especially the ability of providers and others with authorized access to query across time and space for relevant clinical information on specific patients and patient populations. We agree with PCAST that exchange of healthcare data should be at a substantially more robust level for Stages 2 and 3 of Meaningful Use relative to either the current Stage 1 levels or what seem to be initial plans for Stage 2. We also agree with PCAST on the importance of semantically interoperable data elements.

We also agree that it is important to more explicitly address data transport methods and standards. We urge ONC build upon work that has already been done in the FHA Connect and Exchange projects to implement a bi-direction, publish/query-based approach to HIE in Stages 2 and 3 of Meaningful Use, utilizing such proven IHE profiles as XCA and XDS.

We wish to emphasize strongly that virtually all PCAST use cases and specific technical requirements, such as the use of meta-tagged and searchable and indexable XML, can be met with existing and under-development 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 such areas as making CDA documents accessible via web-type indexing, crawling, and browsers.

Key elements of this progress, notably the ability to generate and receive CCD clinical document summaries have been included in meaningful use associated EHR certification requirements for Stage 1 of Meaningful Use. In essence, these various interlinked standards 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 understanding .

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 focuses 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 experts, 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. This approach imposes substantial unwarranted overhead and 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 a sufficiently accurate or complete clinical picture.

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 such as clinical impressions. It creates a very material risk that virtual records created by the use of 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 PCAST, patient identification and matching across health care data is made 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 supporting a highly granular meta-tagging approach could disrupt the patient care process. Overall, we believe that the specific approach called for by PCAST poses substantial and entirely unwarranted patient safety risks.

Finally, we believe that the PCAST approach could lead to substantial and negative disruptions that will impose clinical and financial costs that are not offset by reasonably foreseeable benefits. Not only are we unaware of any industry that that has adopted this approach to the extent envisioned in the PCAST report, but we must also recognize that healthcare has unique characteristics. Clearly, healthcare technologists and standards experts draw on work from broader informatics domains, but the risks associated with inaccurate or misleading healthcare data simply dwarf those that would be felt in almost any other sector.

Moreover, although we are pleased that PCAST recognizes the negative implications of a "rip and replace" approach to current health care systems, we believe that the report is entirely too 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 additional strain on a healthcare system already facing the challenges of meaningful use, ICD-10 and SNOMED-CT implementation, value-based payment, quality reporting, and accountable care organizations, to just name a few. It could also be highly disruptive of the carefully laid out plans of ONC regarding meaningful use and the S&I Framework. The reality is that the substantial changes associated with implementation of HITECH have already delayed what had been planned implementation of key aspects of standards-based HIE; the industry simply does not need further and in this instance, non-productive, disruption.

This timing issue is especially acute regarding Stage 2 of Meaningful Use. 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, as well as ensuring that the Stage 2 standards 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.

We also recognize that challenges faced by health information exchange 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 meaningful use incentives, progress on the S&I Framework, and appropriate resourcing via state HIE funding, further progress on privacy policy and NW-HIN governance, that major and sufficient progress can be in the areas or HIE policies, governance, and sustainability.
PCAST appropriately emphasizes the importance of innovation in healthcare and healthcare data.

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 five or ten years and ago and roadmaps for the near-term future portend even more innovative, patient-centric change. The PCAST report's critique of EHRs as being primarily billing focused is hopelessly out-of–date; it does not reflect newer technologies and standards that are already widely deployed across healthcare.

In summary, the access and sharing of metadata-tagged data element can be best performed and implemented by sharing metadata-tagged data packaged in documents, but with access to individual data elements, performing filtering and aggregation at the requesting IT system. This approach has several impressive advantages:

- Enhances the ability to ensure patient safety
- Consistent with provider workflow and cognitive processes
- Consistent with the current Nationwide Health Information Network Exchange design
- Fully leverages the MU Stage 1 investment in CCD/HITSP C32
- Provides a ready "on ramp" for providers and HIT developers and vendors
- Easily coexists with the Direct Project transport
- Has been implemented by close to 200 IT systems around the world, many of those being available in the USA
- The test tools have already been developed by NIST and are widely used in IHE Connectathons around the world
- Most HIE and EHR vendors in the USA are familiar with these profiles, and this strategy can be rolled out rapidly
- Consistent with several other national and regional HIT projects around the world including (EU-Level epSOS, Austria, France, Japan, China, Switzerland, Luxemburg, Wales, etc.).

Finally, HIMSS appreciates the opportunity to provide public comments to the Office of the National Coordinator on this important Request for Public Comment. We look forward to continued dialogue between HIMSS members and the Department, in order to achieve the benefits of an interoperable healthcare system. If you have any additional questions please contact Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN, Vice President, Informatics. or Thomas M. Leary, Senior Director, Federal Affairs, 703.562.8814.

Sincerely,

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