American Hospital Association

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 638-1100 Phone
www.aha.org

January 19, 2011

David Blumenthal, M.D., M.P.P.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services

Filed electronically

Dear Dr. Blumenthal:

On behalf of our 5,000 member hospitals, health systems and other health care organizations and nearly 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Request for Information (RFI) published in the December 10, 2010 *Federal Register* regarding the President's Council of Advisors on Science and Technology (PCAST) report, *Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward.* America's hospitals are working intently to implement health information technology (HIT) solutions to support the safest, best possible care, improved efficiency, engaged patients and improved public health.

PCAST REPORT

The PCAST report recommends that the United States pursue health information exchange based on adoption of a "universal exchange language for healthcare information and an infrastructure for locating patient records, while rigorously protecting privacy and security." This approach would rely on tagged metadata that would identify component data elements held in individual health records that could then be pulled from the record and shared with others over a network. For example, records could be tagged to identify individual laboratory test results to be shared upon request. According to the PCAST report, this approach would allow individuals (patients, providers, researchers, payers and others) to conduct secure, network-based searches for needed pieces of the records pertaining to an individual. According to the report, one or more "Data Element Access Services" (DEAS) would provide the infrastructure to locate and assemble individual elements of patients' records and deliver likely matches to requesters. PCAST also promotes the ability of individuals to outline individual patient preferences to be attached to different kinds of information and use of data-level encryption.

OVERALL COMMENTS

America's hospitals share the council's goal to move toward a health information exchange approach that supports the best possible care across the continuum of care settings and informs and engages patients. A robust health information infrastructure will support patients and providers to improve health in America. Further, we support an environment where health information follows the patient so that the right information is available to the right caregiver at the right time to support the best possible care.

While the PCAST report provides a vision for the future state, it also raises significant concerns and questions that must be addressed. First and foremost, the report states that "ONC should move rapidly to ensure the development" of the recommended approach and incorporate it into meaningful use guidelines for 2013 and 2015. This is an overly aggressive timeline that would add significant stress for hospitals that are already stretched to their limits as they transform their information systems to accommodate existing obligations and new initiatives, including, but not limited to, meaningful use of electronic health records (EHR). Change in the health information sector is already fast and accelerating, moving toward what some have termed a "perfect storm." To clearly depict the numerous IT initiatives the health care field is facing, we have attached a timeline. As outlined in our attachment, hospitals and physicians are already overhauling their IT systems to meet:

- Introduction of new versions of the *Health Insurance Portability and Accountability Act* (HIPAA) transactions standards (5010) and associated business rules;
- A transition to the new ICD-10 coding standard;
- Stage 1 of meaningful use of electronic health records for clinical care;
- Changes to support myriad reporting requirements and information transfers for the current quality reporting program under Medicare as well as numerous initiatives introduced through the *Patient Protection and Affordable Care Act* (ACA), such as reductions in readmissions, value-based purchasing, accountable care organizations, bundling of payments; and
- Participation in state-level health information exchange initiatives funded by ONC.

The timeline implied by the report and repeated in the RFI – that this could be part of Stage 2 meaningful use – is unrealistic and would result in halting national progress toward implementation of EHR technology. Taken together, hospitals are currently investing billions of dollars in HIT solutions to meet Stage 1 meaningful use and the other initiatives outlined above. They are not in a position to immediately replace that technology to pursue a new approach for health information exchange. Given this reality, the AHA is very concerned that if this approach were incorporated into Stage 2 of meaningful use, few hospitals would actually be able to comply. In that scenario, not only would they miss out on incentive payments, but they could easily be subject to the payment penalties that begin in 2015.

In addition, the PCAST report does not adequately recognize the existing framework of law and regulation, most notably state medical records laws, HIPAA privacy and security requirements and state/local privacy laws. Consequently, the report raises, but does not answer, many

technical and policy questions, such as how records would be tagged with the required metadata and indexed; how the DEAS would accurately match individual data elements to individual patients without a unique patient identifier; how to ensure proper levels of security for protected health information (PHI) shared over the network; and how to ensure compliance with existing laws and regulations (including HIPAA) under this new scenario.

The AHA recommends that ONC devote considerable resources and time to thoroughly examine the approach recommended by the PCAST report and develop, in consultation with providers, consumers, other stakeholders, other federal agencies, and the HIT Standards Committee, a detailed plan with reasonable timelines to transition to this approach. The plan should fully identify and address the policy issues (detailed below) that must be resolved before this approach can be taken. Such a plan cannot be developed in a rushed manner with artificial deadlines, but must take a deliberative approach that acknowledges competing initiatives and requirements already at play.

COMMENTS ON SPECIFIC QUESTIONS

The remainder of our letter addresses several, but not all, of the specific questions noted in the RFI. The technical approach outlined by PCAST is appealing and has merits, but is not ready for nationwide adoption. Considerable, consultative effort is needed to develop a map of how the health care sector can reasonably – and responsibly – get from the current state of health information to the vision promoted by PCAST and to legitimately answer the questions posed in the RFI.

Question 1. What standards, implementation specifications, certification criteria and certification processes for 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;
b. That ONC facilitate the rapid mapping of existing semantic taxonomies into tagged data elements;
c. That certification of EHR technology and other HIT should focus on interoperability with reference implementations developed by ONC.

ONC should first look to existing standards work, such as that done through the ONC's own clinical document architecture (CDA) standards and the standards developed as part of the use cases considered by the American Health Information Community (AHIC). The HIT standards community has developed a solid base of standards that outlines specific data elements, including, for example, those developed for the continuity-of-care document (CCD), the HL7 CDA discharge summary and other CDA templates. While these efforts offer a solid starting point, ONC also will need to fund a new national modeling effort to establish detailed clinical models that can map to both document-based provider records and to consumer-oriented disaggregated models, such as personal health records (PHR). In addition, universal language for health information has already been established in ONC-adopted standards (such as

SNOMED, LOINC and RxNorm) that should be promoted and used in the new disaggregated environment envisioned in the report.

The PCAST approach rests on the development of a metadata standard, but the report does not identify the entity that would establish and maintain the metadata standard. Consistent with the general federal approach to standards development and maintenance, development of a metadata standard should be done through an open, ISO-compliant standards development organization. Such a standard should not be developed and maintained by the federal government. Other questions that remain unanswered in the report, but must be addressed before moving forward, include:

- Who decides what metadata is required?
- Who decides where data are stored?
- Who decides how the DEAS works?
- Who decides what the standards are?

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

As noted in the answer to Question 1, a full study of the implications of the PCAST report is needed before specific questions can be answered. As a general rule, however, existing standards processes should be used provided they are open, transparent, inclusive, and result in ISO or ANSI-accredited standards. As discussed more fully in our response to Question 6, inclusion of this approach as a requirement in Stage 2 of meaningful use, beginning as early as 2013, is an unrealistic expectation. ONC should take a more measured approach.

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

A number of issues must be resolved before implementation of the PCAST approach can be contemplated.

First, it is unclear how data elements in provider-held records would be "tagged," or labeled with metadata and how indexing of records to enable queries would take place. The report indicates tagging would be done in provider workflows; this is unrealistic. The PCAST approach would only work if tagging is automated and embedded in vendor technologies, and providers do not have expertise or resources to do this. Even if the tagging is automated, many steps are needed to build the provider capacity to administer this approach, which takes time and resources. Standards and technology only get you a short way toward operations. Health care information

is generated from individual care providers and patients, all of whom must be educated and trained to use new systems. Provider training is already a major cost factor in EHR implementation. Furthermore, even with widespread training, there will be errors in tagging, necessitating deployment of review and correction processes to identify and correct errors. The approach outlined in the report is a fundamental shift in how health records are documented, therefore it is difficult to estimate the resource requirement, other than to say that it would be substantial and involves technology costs, data security costs, training costs, and expenses to monitor and ensure compliance.

Second, it is unclear how the PCAST approach could be implemented without first developing solid record matching processes, using either a national patient ID or a single, national approach to probabilistic matching that has a very low error rate. Previous discussions of health information exchange have noted that scaling up to national information exchange means that even with low error rates, many individual errors occur. If medical records are disaggregated into individual data elements, the number of opportunities for error increases exponentially. These errors also will compound over time. What is a provider to do if, after a period of time, 5 percent of the data elements in their records are wrong? How would they know which elements or for which patients? Every mismatch of a patient to a piece of health information creates opportunity for clinical error, potentially harming patients and raising liability questions for physicians that act on data provided through a DEAS.

Third, the PCAST report implies that individuals would be given the opportunity to set their own preferences for which data can and cannot be shared. It does not, however, indicate what entities would be tasked with collecting and sharing that information. Providers do not have a process or capacity to conduct that data collection without specific additional resources. Variation in state medical records and privacy laws further complicates this task.

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?

The approach outlined by PCAST raises many policy and operational questions that must be answered through further study and consultation. The Department of Health and Human Services would need to develop policies to address many issues, including:

Access to Data. PCAST assumes that data will be available through a DEAS. It does not address fundamental policy questions, such as:

- Who has access to data from the DEAS? For what uses?
- How would the DEAS differentiate levels of access for providers versus health plans, patients or researchers? What happens if an individual has more than one role (such as a clinician who treats patients and also conducts research)? What rights will those accessing data from a DEAS have for further use?
- How would authentication and authorization of individuals seeking data work?

- If, as implied by PCAST, patients also could access records through the DEAS, how would millions of patients be authenticated? How would that authentication be maintained? What entities would be responsible if authentication were handled improperly, leading to breaches of PHI?

Impact on Provider Systems. The PCAST report seems to envision a number of scenarios that would significantly impact provider systems. In addition to the question of data-tagging noted above, other questions include:

- How would the queries for information affect the performance of provider systems?
- What enhanced security efforts would be needed to protect PHI that can potentially be accessed via the Internet? AHA members have found that public cloud technology is not consistent with HIPAA requirements for storage of PHI. In addition, some of the security measures mentioned in the PCAST report, such as two-factor authentication and encryption of data at rest, are not currently standard of practice, except in specific circumstances (such as two-factor authentication for remote access). These security measures impose significant costs in both dollars and system performance, and are often inconvenient for clinicians to use, resulting in decreased productivity.

Impact of Patient Ability to Withhold Data. The PCAST report suggests that patients would be able to selectively restrict access to specific data elements in their records. While such limitations may be appropriate outside of clinical care, for clinical decision-making, selective redaction is medically unsafe. Furthermore, it is not possible to redact all references to a condition from physician or nursing notes and other text files. As noted previously, the PCAST report does not make clear who would collect patient preferences, and who would bear the costs of that collection. Finally, what are the implications for professional liability if decisions made in the absence of information withheld at the patient's request result in harm?

Interactions with HIPAA Requirements (privacy, security, breach, business associate agreements). ONC must work **through** the Office of Civil Rights (OCR) and with all affected stakeholders to understand how the existing obligations under HIPAA would apply under the approach embodied in the PCAST report, including for those contributing and accessing data, and for the DEAS. New methods of health information exchange do not convey to ONC jurisdiction over privacy and security regulations. OCR is charged with developing and enforcing the HIPAA privacy and security rules.

Question 5. How might a system of 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?

All of the governance and other questions raised in the context of health information exchanges and the nationwide health information network also would apply to the DEAS.

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?

The changes envisioned by the PCAST report are premature, at best, for inclusion in Stage 2 of meaningful use. They represent a significant change in direction from all signals previously received, which have focused on exchange of specific documents using adopted standards, not individual data elements. As outlined above, many policy questions must be addressed before the country can move toward the vision embodied by the PCAST report.

The AHA strongly recommends against integrating the recommendations of the PCAST into Stage 2 of meaningful use. Instead, ONC should:

- Devote resources to accelerate development of data models and standards to support future adoption of this kind of approach, drawing from the existing body of standards work;
- Work toward providing a single, national, accurate method for matching patients across providers, potentially to include a unique national patient identifier;
- Develop, in consultation with affected stakeholders, the HIT Standards Committee, and other federal agencies, a detailed plan with reasonable timelines, to transition toward this approach;
- Work with stakeholders and other federal agencies to fully identify and address the policy issues that must be resolved before this approach can be taken; and
- Devote resources to develop the technical security mechanisms that will be needed to operationalize this kind of approach.

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?

We look to ONC to clarify how the agency envisions its current programs, including state-based health insurance exchanges and the nationwide health information network, aligning with this approach.

CLOSING COMMENTS

Finally, given the vast number of HIT activities underway in America's hospitals and within the federal government, we are disappointed in the short comment period provided in this RFI. Given the significance of the recommendations in the PCAST report, a comment period of approximately five weeks is insufficient to provide fully informed comments.

We understand that the tight timelines needed to initially implement the certification and incentives programs previously required truncated public comment timeframes. Now that those deadlines have been met, resuming a measured approach with sufficient time for stakeholders to fully evaluate proposals and develop comments is essential.

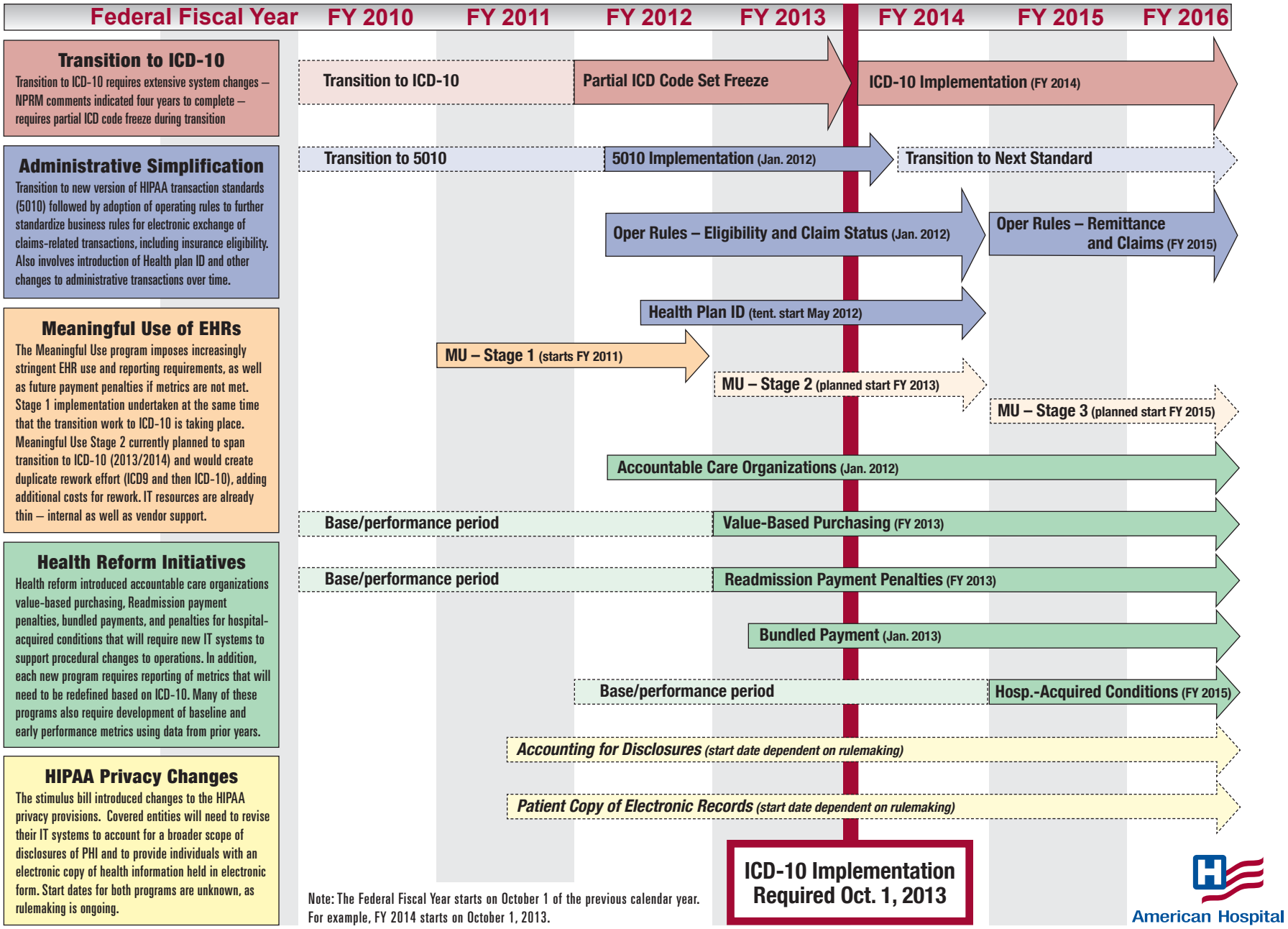
In conclusion, the AHA appreciates the opportunity to provide comment on these issues. If you have questions or need additional information, please contact me or Chantal Worzala, director of policy at cworzala@aha.org.

Sincerely,

Linda E. Fishman
Senior Vice President
Public Policy Analysis & Development

Attachment

Overlapping Timelines of ICD-10, Meaningful Use of EHRs, and Health Reform Initiatives



Note: The Federal Fiscal Year starts on October 1 of the previous calendar year. For example, FY 2014 starts on October 1, 2013.

American Hospital Association