January 19, 2010

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: Steven Posnack
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Information Regarding the President's Council of Advisors on Science and Technology (PCAST) Report Entitled "Realizing the Full Potential of Health Information Technology To Improve Healthcare for Americans: The Path Forward"

Dear Mr. Posnack:

The American Clinical Laboratory Association (ACLA) is pleased to have this opportunity to submit our comments on the President's Council of Advisors on Science and Technology (PCAST) Report entitled, "Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: the Path Forward." ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As the primary providers of clinical laboratory services throughout the country, our members would be impacted provided PCAST's policy recommendations were ultimately implemented. The following comments represent our latest thinking on a few of the issues raised in the PCAST report.

The implementation of metadata-tagged data elements incorporating patient privacy preferences may be problematic for clinical laboratories. First, as indirect providers, clinical laboratories typically do not have contact with patients. To the extent that clinical laboratories would be required to tag data elements with patient privacy preferences, they are generally not in a position to do so. Second, even if metadata tagging is accomplished through middleware or some other methodology not involving intervention by the clinical laboratory, it is possible, depending on how patient privacy preferences are expressed and implemented, that data exchanges to and from clinical laboratories that are legally permissible or required could be blocked. Many unintended and harmful consequences could potentially result.

The Federal government needs to coordinate and sequence its health IT and Health Insurance Portability and Accountability Act (HIPAA) initiatives to reduce the burdens (including cost) on providers facing multiple such initiatives at the same time. Meaningful use of electronic health records (EHRs), a transition to the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10), and conversion to a universal exchange language with metadata tagged data elements cannot be achieved simultaneously. Furthermore, PCAST has not adequately addressed the cost of making the changes it is proposing, and does not appear to appreciate the implications of such costs for providers such as clinical laboratories.

As outlined above, we have a few concerns with the PCAST report's policy recommendations. However, if the Office of the National Coordinator (ONC) decides to move forward and implement these policy changes, ACLA provides the following recommendations. An American National Standards Institute (ANSI) accredited standards organization, Health Level Seven (HL7), has already established the version 3.0 standard that utilizes XML and the capability to tag data elements. Rather than working on a separate standards implementation, PCAST should provide input to HL7 to ensure that HL7 considers the views of PCAST as well as all of the affected industry stakeholders. The changes contemplated by HL7 version 3.0 are material, will require virtually complete system rewrites, will be extremely costly to test and implement, and will not be entirely backwardly convertible with previous standards versions. Therefore, an appropriate time frame of at least 5 years from adoption of the standard by ONC would be necessary for implementation, clarification of the obligations of indirect providers such as laboratories with regard to the use of the metadata, and to enable all stakeholders (including EHR vendors) to transition to this new standard. In order to ensure adoption, it's critical that any new standard become a component of Meaningful Use Certification Criteria.

In closing, we appreciate the opportunity to submit our comments on the PCAST report. If you have any questions or need any further information, please do not hesitate to contact us.

Sincerely,

Jason DuBois
Vice President, Government Relations

"ONC seeks comment on the questions below."

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:	
1a. That ONC establish minimal standards for the metadata associated with tagged data elements;	We strongly believe that a single standard (with tracked version number) should be established through a Standards Development Organization to include the input of all stakeholders on such key issues as defining what metadata to acquire and transmit, standards with version number / date; defining patient privacy choices, including revision date for any changes; and identifying data source for metadata.
1b. That ONC facilitate the rapid mapping of existing semantic taxonomies into tagged data elements;	We believe that PCAST should address the cost and burden of making the changes it is proposing, and should take into account the impact on providers, including clinical laboratories, that have other priorities such as ICD-10 conversion, etc..
1c. That certification of EHR technology and other HIT should focus on interoperability with reference implementations developed by ONC	We take this question to mean that ONC would develop pilots to test interoperability of standards. Because laboratory results impact as much as 70% of medical decisions about the patient, we believe that certification requirements with regard to interoperability should specifically include a focus on laboratory results and orders and finding ways to defray the laboratory's cost to and support such interoperability and maintain networks.
2. What processes and approaches would facilitate the rapid development and use of these standards, implementation specifications, certification criteria and certification processes?	
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?	We do not concur with the PCAST report assertion (Pg. 40): "In a sector as fragmented and rapidly evolving as healthcare, we believe it is impossible to build a national implementation of SOA solutions and directories that could be used and scaled indefinitely into the future." In fact, prominent vendors such as Amazon and Google have implemented Service Oriented Architecture (SOA) on a national basis. Similarly, Quest Diagnostics has experience implementing broad-scale national solutions and believes SOA is a viable and scalable solution. Of course, the scalability of SOA is dependent on the implementation approach and internal architectural decisions.
3a 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?	To ensure quality patient care and successfully implement PCAST's recommendations, it would be necessary to ensure that all parties in the data flow are able to and will concurrently implement the metadata tagged data elements and universal language. We raise our concern about the technological capability of providers to keep metadata current, particularly metadata

	that may be subject to repeated changes, such as patient privacy choices.
3b Alternatively, what are proposed solutions, or best practices from other industries, that could be leveraged to expedite these transitions?	No comment
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?	Notwithstanding the potential existence of metadata reflecting the patient's privacy choices, providers receiving a request for PHI still must authenticate the inquirer, identify the patient, and evaluate the authority for the request in order to determine whether the release of PHI is permissible under HIPAA. This is a highly manual process. PCAST's vision and recommendations should take into account the HIPAA requirements and patient privacy protections.
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?	We believe that at minimum, private sector DEAS products should be subject to a certification process.
6. How might ONC best integrate the changes envisioned by the PCAST report into its work in preparation for Stage 2 of Meaningful Use?	Vendors are already implementing proposed Stage 2 Meaningful Use standards. Rather than disrupting industry's forward progress, it would be preferable for PCAST recommendations to be considered for Stage 3 Meaningful Use and to ensure there are no conflicts between PCAST recommendations and the meaningful use and the certification criteria requirements.
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 propose that ONC take the lead for coordinating scheduling for <u>all</u> Federal agency initiatives related to health information exchange, and logically sequence activities, allowing sufficient time for education, development, testing, certification, testing, and deployment. This includes HIPAA and other CMS initiatives, such as HIPAA V5010 and ICD-10 implementations. The industry cannot simultaneously implement standards to achieve Meaningful Use of EHRs, ICD-10, HIPAA V5010, and conversion to a universal language recommendation with metadata tagged data elements.
8. Are there lessons learned regarding metadata tagging in other industries that ONC should be aware of?	No comment
9. Are there lessons learned from initiatives to establish information sharing languages (''universal languages'') in other sectors?	No comment