



March 7, 2011

Dr. Patrick Gallagher
National Institute of Standards and Technology (NIST)
U.S. Department of Commerce
100 Bureau Drive, Stop 1070
Gaithersburg, MD 20899-1070

Sent Electronically to: SOS_RFI@nist.gov

Re: Request for Information Regarding the Effectiveness of Federal Agency Participation in Standardization in Select Technology Sectors for the National Science and Technology Council's Sub-Committee on Standardization.

Dear Dr. Gallagher:

On behalf of AMIA, I am pleased to submit these comments regarding NIST's recent request for information about the effectiveness of federal agency participation in standardization in select technology sectors for the National Science and Technology Council's Sub-Committee on Standardization.

Federal government standards activities in the health information technology (health IT) domain are of great interest to AMIA, the leading professional association for informatics professionals. AMIA serves as the voice of the nation's top biomedical and health informatics professionals and plays an important role in medicine, health care, and science, encouraging the use of data, information, and knowledge to improve both human health and the delivery of healthcare services. Our members are an interdisciplinary and diverse group of individuals and organizations that come from numerous countries, organizations, and backgrounds, working to support and leverage basic and applied informatics principles to help inform public policy issues, such as research and evaluation, patient safety, technology, change implementation, and quality of care.

AMIA thanks NIST and the Sub-Committee for providing this opportunity to comment on federal standards activities. As noted in a recent report from the National Research Council, "standards are not a new idea in health care IT—indeed, they are a critical element of 'plug-and-play' architectures that enable the infusion of new technologies when they are available (in contrast to monolithic architectures that make it difficult to take advantage of new technologies)."¹ AMIA believes that continued federal involvement is crucial for developing

¹ William W. Stead and Herbert S. Lin, eds., 2009, Computational Technology for Effective Health Care: Immediate Steps and Strategic Directions, National Research Council, available online at <http://www.nap.edu/catalog/12572.html>, p. 62.

and maintaining the standards that support the fast-growing health IT domain and, more broadly, the advancement of health care in the United States.

Below we provide AMIA's specific comments based on the areas specified in the original request for information.

Standards-Setting Processes, Reasons for Participation, and the Benefits of Standardization

A wide variety of people and organizations participate in standards development, including health care providers, payors (public and private), academics, software vendors, researchers, local, state, and federal agencies, and public health departments. Standards benefit all parties by decreasing the cost of developing interfaces and of sharing data across enterprises and institutions. Stakeholders typically participate because they have a business interest in better information exchange and sharing.

It is important for all stakeholders fully to understand and appreciate the magnitude of both the potential advantages and the challenges associated with standards development and implementation. AMIA is concerned that health IT "standards" can mean different things across the many different professional domains and stakeholders involved in the health IT development and implementation effort—from data architecture and data interchange standards, to hardware and software standards aimed at providing device or system interoperability, to communications standards aimed at assuring data transmission and receipt, to standards regarding terminologies, vocabularies, and classification systems. AMIA believes that further clarification and reconciliation of standards-related terms and terminology would be beneficial to all stakeholders. Further AMIA encourages additional federal efforts to foster interagency collaboration to help establish clearer coordination regarding standards development.

NIST is respected in the IT industry and has been deeply involved in health care standards guidance for some time. There are a number of other federal organizations involved in standards setting for health IT, including those noted below:

- The Department of Health and Human Services' (HHS's) National Committee on Vital and Health Statistics (NCVHS)² is the statutory advisory committee with primary responsibility for providing recommendations on health information policy and standards to the Secretary of HHS.
- The Office of the National Coordinator for Health IT is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health IT and the electronic exchange of health information. ONC oversees the Health IT Standards Committee, a federal advisory committee created by the American Recovery and Reinvestment Act of 2009³ (ARRA).

² See <http://www.ncvhs.hhs.gov/>.

³ See <http://www.recovery.gov/FAQ/Pages/ForCitizens.aspx#whatisrecoveryact>.

- The National Institutes of Health’s National Library of Medicine (NLM) is a key player in developing, maintaining, and providing access to standards for health IT—indeed, NLM is the central coordinating body for a number of crucial clinical terminology standards.

There are also a number of other non-governmental organizations working with the federal government and other private sector organizations in developing and promoting standards in health IT, including, among others, the American National Standards Institute (ANSI),⁴ Health Level Seven International (HL7),⁵ the Clinical Data Interchange Standards Consortium (CDISC),⁶ and the DICOM Standards Committee.⁷ These organizations bring together a wide range of stakeholders from industry, academia, and government to collaborate on standards development in a number of key areas.

Also notable has been the work of the Healthcare Information Technology Standards Panel (HITSP),⁸ a cooperative partnership between the public and private sectors that was established through a contract with HHS. HITSP was formed for the purpose of harmonizing and integrating standards that will meet clinical and business needs for sharing information among organizations and systems. In the fall of 2005, HHS awarded multiple contracts to advance the White House’s vision for widespread adoption of interoperable electronic health records (EHRs) within ten (10) years. The contracts targeted the creation of processes to harmonize standards, certify EHR applications, develop nationwide health information network prototypes and recommend necessary changes to standardized diverse security and privacy policies. ANSI was selected as a part of the Standards Harmonization Collaborative, a cooperative effort of eighteen (18) independent entities that resulted in the formation of HITSP. HITSP’s contract with HHS concluded on April 30, 2010.

Standards also exist regarding accessibility to health IT for people with disabilities (e.g., interoperability with assistive technologies to support those with hearing, visual, speech, or mobility impairments). These are in part addressed in section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d).^{9,10,11}

Taken together, all of these organizations and activities bring together a wide range of stakeholders from industry, academia, and government to collaborate on standards development in a number of critical areas. The health IT standards developed and maintained by these public and private organizations benefit all stakeholders by decreasing the cost of developing interfaces and of sharing data across enterprises and institutions. Data and terminology standards are critical for aggregating, analyzing, and exchanging data for improvements in patient safety and

⁴ See <http://www.ansi.org>.

⁵ See <http://www.hl7.org/>.

⁶ See <http://www.cdisc.org/>.

⁷ See <http://dicom.nema.org/>.

⁸ See <http://www.hitsp.org/>.

⁹ See <http://www.section508.gov/index.cfm>

¹⁰ See http://www.ada.gov/medicare_mobility_ta/medicare_ta.htm.

¹¹ See <https://www.disability.gov/technology> and <https://www.disability.gov/health>.

quality of care. Hardware and software standards help reduce errors of misinterpretation and facilitate broader and better communications, again for patient safety and quality of care.

Furthermore, health IT standards can drastically reduce the barriers to, and facilitate the development of, innovative approaches such as enhanced data visualization techniques and next-generation EHR systems with decision support functions. Another example is the development of standards for semantic interoperability between personal health records and other clinical information systems. AMIA believes that additional study, research and evaluation is required to develop standards related to the use of specific mobile technologies and devices and web-based portals and tools that collect or use personal health information (PHI).

Perspectives on Government's Approach to Standards Activities

AMIA believes that federal participation in health IT standards efforts is, on balance, extremely positive. However, additional participation by other Federal agencies would be beneficial. Furthermore, we believe that additional and targeted funding and other resources for standards development, implementation, and maintenance is also critical. NLM, for example, has been deeply involved in facilitating standards development and dissemination for a number of years, and, according to a recent report from NLM's Working Group on Health Data Standards, the organization supported standards in health IT to the tune of \$14 million and allocated 49 FTEs to standards activities in 2008.¹² NLM helps develop, maintain, and make available such crucial health IT standards as SNOMED CT,¹³ LOINC,¹⁴ and UMLS.¹⁵ NLM's standards activities support essential infrastructure for enabling EHR development and advanced decision support.

Meanwhile, ONC's Health IT Standards Committee,¹⁶ whose creation was provided for in the American Recovery and Reinvestment Act of 2009 (ARRA), has been instrumental in making recommendations on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information. The committee has created a number of distinct workgroups (Clinical Operations, Clinical Quality, Privacy & Security, Implementation, and Vocabulary) to address specific standards issues.

NCVHS's Subcommittee on Standards has also been an active participant in health IT standards development in recent years. Recently, the subcommittee issued guidance to HHS on electronic funds transfers (EFT) specific to health care use and health care payment and remittance advice, commonly referred to as electronic remittance advice (ERA).¹⁷

¹² NLM Working Group on Health Data Standards, 2009, *Interoperable Information: Enhancing NLM's Contribution to the Nation's Health IT Agenda* (Final Report to the NLM Board of Regents), available online at <http://www.nlm.nih.gov/od/bor/BORHDSWG-report.pdf>, p. 2.

¹³ See http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html.

¹⁴ See http://www.nlm.nih.gov/research/umls/loinc_main.html.

¹⁵ See <http://www.nlm.nih.gov/research/umls/>.

¹⁶ See http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_health_it_standards_committee/1271.

¹⁷ See the letter to Secretary Sebelius at <http://www.ncvhs.hhs.gov/110217lt2.pdf>.

Traditionally, federal agencies have also sent or designated representatives as regular participants to non-governmental standards efforts. Some federal agencies have had a major impact on standard groups because they provide knowledgeable and hard working individuals for the work of creating the standards. Federal agencies have also been extraordinarily effective in supporting the development of robust health terminology standards by directly funding their development or purchasing country-wide licenses.

However, government participation can vary from agency to agency, and overall government participation in standards efforts can often appear to have no overarching coordination. As a consequence, government activities may be perceived to demonstrate less leadership and be less efficient than they might otherwise be. The sheer volume and diverse nature of existing standards along with the dynamic nature of health IT and associated regulations (such as those related to meaningful use¹⁸ and HIPAA¹⁹) provides an opportunity for the federal government to assure their harmonization. As previously noted, we believe that differences in definition are likely to lead to variations in interpretation and implementation. It is also important to recognize that standards, once adopted become tightly integrated into commercial and private sector industry activities, so it is important to “get it right the first time” and to include in any standards adoption robust and well defined practices for how to maintain them. AMIA believes that improved efforts to communicate with and to inform the wide diversity of stakeholders in health IT are critical.

AMIA supports a coordinated and multidisciplinary standards development strategy to assure the successful adoption of interoperable EHRs and true health information exchange. AMIA also supports continued dialogue and communication with all stakeholders to help assure that EHR product development and refinement are responsive to regulations and requirements.²⁰

Indeed, beyond the development of health IT standards themselves, the federal government, through agencies like NLM, also has a key role to play maintaining, updating, and keeping standards available once they have been developed. AMIA believes that this continued federal role is a key to future progress in health IT development, adoption, implementation and use and should not be overlooked nor under resourced.

Issues Considered During the Standards Setting Process

Federal agencies vary widely in their perception of scope and role. For example, the Food and Drug Administration (FDA) has made extensive efforts for international standards. It is however, perceived that many government agencies typically ignore international standards and related activities.

¹⁸ See <http://healthit.hhs.gov/portal/server.pt?open=512&objID=2996&mode=2>.

¹⁹ See <http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html>.

²⁰ Goossen, W., Ozbolt, J., Coenen, A., Park, H., Mead, C., Ehnfors, M., Marin, H. (2004.) Development of a provisional domain model for the nursing process for use within the Health Level 7 RIM. *Journal of the American Medical Informatics Association*, 11(3), 186-194. Ozbolt, J. (2003). The Nursing Terminology Summit Conferences: a case study of successful collaboration for change. *Journal of Biomedical Informatics*, 36(4-5), 362-374.

Intellectual property has been the single greatest obstacle to broadly based standards specification and adoption. The most recent health IT example has been SNOMED, which without a site license for all U.S.-based users (brokered via the NLM) was doomed to irrelevancy. This problem still plagues the International Health Terminology Standards Development Organisation (IHTSDO)²¹ in many developed countries. Part of the problem arises from a disproportionate dependence on the private sector for standards funding and development, which oddly brings private interests and profit motives into the process. Much higher federal funding or leadership in the process would be hugely welcome.

With respect to foreign regulations affecting standards development, the European Commission and the United States Secretary of Health and Human Services have recently executed a Memorandum of Understanding²² in Washington to promote a common approach on the interoperability of electronic health records and on education programs for information technology and health professionals. Common standards and interoperability stand to create substantial growth opportunities for the industry as well as to have a positive impact on the safety and quality of care.

AMIA is encouraged by the level of recent international coordination and cooperation on health IT matters from both a technical and a policy perspective. Indeed, AMIA itself is a partner in an ongoing transatlantic collaborative effort known as the ARGOS eHealth Consortium,²³ a project funded by the European Commission with the overall goal of contributing to the formation of a “Transatlantic Observatory for Meeting Global Health Policy Challenges through ICT-Enabled Solutions” to develop and promote common methods for responding to global ehealth challenges in the E.U. and the U.S.

The project is promoting mutual understanding and learning among E.U. and U.S. policy researchers and policymakers on health IT challenges with a global dimension – issues such as semantic interoperability and certification. In November 2010, AMIA convened the only meeting of the consortium on U.S. soil, an event which had participation from numerous government agencies including the Agency for Healthcare Research and Quality (AHRQ), the Department of Defense (DOD), NIH, NLM, and ONC. In 2011, AMIA will be coordinating the project recommendations to support coordinated actions on eHealth policies in the E.U. and the U.S.

Meanwhile, as noted in a recent edition of AMIA’s *Standards Standard* newsletter,²⁴ a number of European initiatives have published information and proposals in relation to health, standardization and eHealth standardization, in particular. Once such initiative is CALLIOPE,²⁵ a project coordinating an open, stakeholder-driven process to identify key challenges and issues related to interoperability, and define priorities for a European eHealth Roadmap.

²¹ See <http://www.ihtsdo.org/>.

²² The full memorandum can be found at <http://www.state.gov/p/eur/rls/or/153422.htm>.

²³ For complete information, see <http://argos.eurorec.org/>.

²⁴ See <https://www.amia.org/standards-standard-no2-interoperability-reviews-2>.

²⁵ See <http://www.calliope-network.eu/>.

Adequacy of Resources

A great deal of resources are already dedicated to doing standards work within the public and private sectors. AMIA believes the primary issues surrounding resources are less about inadequate funding and more about how best to facilitate diverse groups toward reaching a common goal.

Most health IT standards development activities rely heavily on the work of volunteers. This reliance on volunteers has resulted in a dedicated and expert cadre of developers but has often slowed progress, as standards development must usually be undertaken in addition to an expert's primary employment responsibilities. As a result, these activities can often be put in difficult positions when specific federal regulations and policies call for large amounts of work in short periods of time.

Although federal funding has assisted in these efforts, completion, maintenance of, or access to critically needed standards could be facilitated by additional timely short-term bursts of federal support.

Process Review and Improvement Metrics

AMIA believes that standards development in any one component of health care affects all the other parts of health care. For this reason, federally facilitated collaboration and communication across key focus areas are essential. The most important metric of success will be the widespread adoption of standards that result in increased patient safety, quality and outcomes of care, information exchange, better allocation of health care resources, and control of costs.

Achieving the objectives implicit in these metrics will require ongoing incentives (e.g., such as the meaningful use incentives²⁶) to care providers, manufacturers, and vendors to incorporate the standards and associated functionality, as well as incentives to clinicians and healthcare managers to add the work of analyzing and improving care to their current routines.

Concluding Comments

AMIA encourages NIST and the Sub-Committee to recognize that the standards process specific to health IT is complex, dynamic, and continuous. Indeed, often the evolution of standards and the dissemination of information about them go on for many years after a given standard is established, and this work is often carried out by federal agencies (as is the case, for example, with NLM and SNOMED CT) or other organizations that were not the original developers. For these reasons, the federal government has an irreplaceable role to play in maintaining standards development and progress in health IT into the future. Again, AMIA thanks NIST and the Sub-

²⁶ See <https://www.cms.gov/ehrincentiveprograms/>.

Committee for soliciting input to help inform the future of standards development and the federal role in this key activity. Please feel free to contact me at shortliffe@amia.org or Meryl Bloomrosen, AMIA's Vice President for Policy, at Meryl@amia.org at any time for further discussion of any of the issues raised here.

Sincerely,

A handwritten signature in cursive script that reads "Edward H. Shortliffe".

Edward H. Shortliffe, MD, PhD
President and CEO, AMIA