



May 6, 2011

Dr. Farzad Mostashari
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Suite 729-D
Washington, DC 20201

RE: AMIA Comments on the Federal Health IT Strategic Plan: 2011-2015. Submitted online at
ONC Blog and via email to onc.request@hhs.gov.

Dear Dr. Mostashari:

On behalf of AMIA (the American Medical Informatics Association), I am pleased to submit these comments to help inform your important discussions regarding the Federal Health IT Strategic Plan: 2011-2015 (the Plan). AMIA is an unbiased, authoritative source within the informatics community and the healthcare industry. AMIA and its members are transforming health care through trusted science, education, and practice in biomedical and health informatics. AMIA members – 4,000 informatics professionals from more than 65 countries – belong to a world-class informatics community where they actively share best practices and research for the advancement of the field. Members are subject matter experts dedicated to expanding the role that informaticians play in patient care, public health, teaching, research, administration, and related policy. As the voice of the nation's top biomedical and health informatics professionals, AMIA plays a leading role in moving basic research findings from bench to bedside, evaluating interventions across communities, assessing the effects of health innovations on public policy, and advancing the field of informatics.

AMIA thanks ONC for providing an open comment period on this vital topic. AMIA applauds ONC for updating the HIT strategic plan and for addressing important issues regarding health IT, electronic health records (EHRs), interoperability, and quality improvement. We believe that the Plan would benefit from additional details and specificity to support the proposed goals, objectives, and activities. We have noted that the Plan emphasizes several current efforts (such as those related to health information exchange and meaningful use (MU)) and suggest that the Plan depict mechanisms for incremental changes/enhancements as ONC and the industry gain experience with these policy initiatives.

AMIA invites and encourages ONC to consider AMIA as a resource. We represent national and international experts and dedicated professionals who have invested considerable time and effort

exploring these complex matters and we would be delighted to share our knowledge, resources, and counsel.

These comments are organized according to the specific goals addressed in the Plan:

- Goal I: Achieve Adoption and Information Exchange through Meaningful Use of Health IT
- Goal II: Improve Care, Improve Population Health, and Reduce Health Care Costs through the Use of Health IT
- Goal III: Inspire Confidence and Trust in Health IT
- Goal IV: Empower Individuals with Health IT to Improve their Health and the Health Care System
- Goal V: Achieve Rapid Learning and Technological Advancement

Goal I: Achieve Adoption and Information Exchange through Meaningful Use of Health IT

AMIA believes that several elements of this goal are laudable, including the creation of standards, certification of systems, and the incorporation of these issues into medical education. However, we are concerned that there are ongoing usability challenges with current health IT systems (Strategy I.A.9) that have the potential to affect workflow negatively. Thus, rather than responding exclusively to market forces to support workflow, AMIA believes that ONC should move cautiously with the pace of adoption and monetary penalties until health IT products clearly demonstrate that they are more effectively meeting users' needs.

We believe that ONC should develop a clearer plan to evaluate and assure systems' usability and integration into clinical workflow and should encourage those in the vendor community to take such considerations especially seriously as they evolve their products. The current state of usability and workflow-sensitive informatics research and the clinical reality of available systems do not concur consistently, especially as we move from early adopters to implementations by small institutions and providers. While previous studies have provided sufficient evidence to conclude that having an EHR is better than having none, there needs to be a greater emphasis on evaluating the impact of EHR-related innovations at the point of care under real-time conditions before the release of new tools into the market.

We offer the following additional comments on the individual sections within Goal I:

On page 9 in the "Spotlight on Health Outcomes" box, we suggest that "computerized physician order entry" be changed to "computerized provider order entry".

I.A.1 – AMIA is concerned that the role of the incentives and penalties related to MU in managing physicians' and other providers' implementation and adoption of health information technology may be overemphasized. It is not clear to what extent MU will continue to be an

adequate lever to encourage adoption rather than other or additional ongoing policy. For example, the plan does not adequately describe a strategy to incentivize those providers who are not currently included in the MU regulations to adopt EHRs. Additionally, we encourage ONC to harmonize MU requirements with existing regulations (such as the HIPAA privacy, security, and confidentiality requirements) before seeking to refine or extend HIPAA or other regulations.

In many instances, the cost to implement an EHR will be greater than the level of incentive payments being offered. It has also been shown that given the current payment structure the vast majority of financial benefits accrue to the health plans, not the provider, although this could change with health reform depending on the pace of ACO development. The Centers for Medicare & Medicaid Services (CMS) has stepped forward to contribute its portion of this cost, but no coordinated approach exists to have private health plans pay for their portion of the financial benefit. AMIA suggests that it should be part of the ONC strategy to develop a coordinated plan with private health plans to increase the available incentives for EHR adoption so that the cost of implementation is reduced as a barrier to participation (perhaps an extension of the OPM plan in I.A.7 and in suggested change to I.A.8 below).

I.A.2 – AMIA believes that some of the challenges facing the regional extension centers (RECs) relate to scale, workforce, and funding. The recent extension of REC funding for four years is a strong sign of support by ONC. However, we believe that there will be an ongoing need to support building the necessary workforce (in I.A.3) and implementing the reduction of the financial burdens to providers (in I.A.1 comments above). The plan should describe ONC’s strategy for supporting the RECs after the end of ARRA funding or otherwise helping to assure their long-term sustainability.

I.A.3 – We believe strongly that ongoing support for workforce development is needed. This involves facilitating the education and training of future leaders (many of whom will have masters or doctoral degrees in informatics), as well as supporting the current programs to help train workers through the university-based training and community college programs. The strategies for insuring an adequate supply of trained clinical and health informatics workers and scientists beyond ARRA funding should be delineated. We applaud ONC for initiating a number of significant workforce-related grants, yet we believe that even more effort is needed in this area. AMIA has consistently cautioned that there is a pressing need to increase and broaden the pool of workers who can help health and healthcare organizations and practitioners to maximize the effectiveness of their investments in technology, and the supply of scientists who can perform the research that will lead to the health IT innovations of tomorrow. Strengthening the breadth and depth of the biomedical and health informatics workforce is a critical component in the transformation of the American healthcare system through deployment and use of health IT. In an innovative, competitive health IT market, we believe that the value of biomedical and health informatics will be readily apparent through the increased speed and wider impact that

advancements and innovations will have as they incorporate, and are guided by, biomedical and health informatics knowledge and expertise.

I.A.4 – We believe that it is important for professional education and training to focus on knowledge, skills, and abilities in clinical and health informatics and quality improvement rather than on any specific federal rule-making effort (such as MU certification). AMIA is concerned that the proposed strategy (i.e., encouraging the inclusion of MU as part of direct professional certification) may prove to be counterproductive. We are unaware of any comparable example in which federal rule-making becomes the focus of professional certification or competency.

Regardless, we believe that ONC's strategy needs to be inclusive of additional health professionals (including nurses), not just physicians. AMIA believes that it is critical for all medical and clinical specialties and professional societies to take steps to assist and encourage their members in the adoption and meaningful use of EHRs, with the ultimate goal that such EHR use and competencies will become an element of professional training, education, and continuing education. Another purpose of these efforts should be to identify information/knowledge management best practices and effective technology capabilities for the health workforce.

I.A.5 - We believe that the role of health IT system certification has been confused by the process of certifying modules separate from systems and by the proliferation of certification bodies. ONC should describe a strategy that ensures that purchase of a certified system includes all the capabilities needed for meaningful use, while explicitly stating (so that it is better understood by purchasers) that some elements of meaningful use will depend on actions by the providers, and by the implementation itself – they will not simply be guaranteed by buying the right product. RECs might be a good source of data on the extent to which this type of confusion currently exists in the market.

I.A.6 – *Communicate the value of EHRs and the benefits of achieving meaningful use.*

We offer the following potential revisions to the proposed wording: “Promote the benefits that EHRs can bring to patient outcomes while acknowledging and working to mitigate or resolve risks as they become known.”

I.A.8 – *Work with private sector payers and provider groups to encourage providers to achieve meaningful use.*

We believe that the strategy should be to encourage health plans to pay additional incentives for adoption and that the language used should be much more explicit than the present wording. We suggest the following wording: "Work with private sector payers to assure that they fund additional incentive payments for EHR adoption and demonstration of meaningful use." These payments might occur through pooled resources or partial payments based on network participation. ONC should clarify what it means by working with private payers for MU

certification. Institutionalization of MU should be avoided and the burden of reporting for smaller practices limited.

I.B.1 – The strategic plan details a de facto shift in the enterprise architecture of the Nationwide Health Information Network (NHIN) from community-based networks and regional health information exchanges to direct exchange and private networks. It appears that the rationale for this change has not been publically discussed or debated. We are concerned that the decision to make this change has not been subject to rigorous and careful peer review, and there is little evidence that direct exchange will work.

There are significant trade-offs in the move to private exchanges. The motivation for the move seems to be focused primarily on meeting the tight timelines for MU rather than development of the most robust systems. The proposed change in architecture of the NHIN is something that deserves full hearings, perhaps within the Policy and Standards Committees, prior to incorporation into any strategic plan. A careful review of the security considerations of the change in architecture is also warranted. A network is only as secure as its weakest entry point.

I.B.2 – This strategy argues for a public utility model. If states have to subsidize ongoing connectivity for remote regions, this could result in yet another unfunded mandate. Developing a long-term model for how states will fund activities such as master patient indices (MPIs) and facility and provider indices is not a part of the plan. We feel that it is also premature for the report by the President's Council of Advisors on Science and Technology (PCAST) to be a cornerstone of ONC's strategic plan, as there is substantial doubt regarding whether the approach promoted for data exchange will be effective. We believe that pilots are needed first.

I.B.3 - AMIA is very concerned with the recent purchases of HIE vendors by health plans and insurers. We suggest that ONC consider prohibiting exchange networks from blocking exchange for reasons other than patient privacy. For example, it is not clear what the ramifications would be if participation in a specific exchange required that providers or patients participate in a health plan's network in some way. Potential additional language might read: "Ensure that, unless explicitly prohibited by a patient's request, no information exchange network will refuse to transmit patient information to another exchange network."

We are also concerned about inadequate attention to health information exchange efforts specifically related to public health priorities. It appears that there are no systematic elements within the Plan that are designed to enhance national public health capabilities. We believe that efforts to address ongoing health disparities require a community-wide view, and we wonder if the ONC focus on private networks precludes a community-wide view of data. We also believe that the role of the NHIN efforts in preparedness for disasters and/or bioterrorism needs to be expanded.

I.C.1 - Ensure public health agencies are able to receive and share information with providers using certified EHR technology.

This strategy as written implies that public health agencies will communicate with providers via certified EHR technology. We believe that the wording should be revised as follows: “Ensure public health agencies are able to receive and share information electronically with providers who are using certified EHR technology.”

I.C.2 – Track health disparities and promote health IT that reduces them.

We offer the following revised wording: “Track health disparities, identify and promote technology where it can be beneficial, and minimize any negative impact of health IT.”

Goal II: Improve Care, Improve Population Health, and Reduce Health Care Costs through the Use of Health IT

II.A.1 – It appears that this goal is based on the assumption that useable and practical clinical decision support (CDS) tools exist and will be adopted. This goal also seems to assume that the adoption of health IT will result in improved care and reduced costs. We believe that best practices regarding health IT implementation in general and CDS in particular should be “evidence based.” Further, it is not clear how ONC will assure that research funding will be available to help the ongoing development, implementation, and evaluation of new and better integrated approaches to health IT and CDS. It is not clear how the NHIN development is being advanced to facilitate improved population and public health.

The Plan does not discuss or acknowledge the extent to which ongoing MU certification will create an administrative burden for providers. We believe that the Plan should include a discussion of ONC’s strategy for managing the complexity of e-measures and the denominator definition problem. We propose that ONC target compliance with best practices toward an agreed upon goal, but also carefully review the reasons why best practices were not implemented so that we can actually return to the practice guidelines and manage them in a more granular fashion.

II.C.1 – Fund and administer demonstration communities to show how the advanced use of health IT can achieve measurable improvements in care, efficiency, and population health.

We offer the following additional language: “Learn from the challenges and failures and share those findings widely.”

Goal III: Inspire Confidence and Trust in Health IT

This goal deals with education and penalties for security breaches and HIPAA violations. However, it does not address how security will be achieved. The fundamentals of this objective rest with convincing the public that the NHIN has a rational design, uniform principles for security, and is built to be as secure as we know how to make it. Given the current evolutionary approach to the enterprise architecture of the NHIN (i.e., we press ahead to data exchange even as the architecture for the security of that exchange is being defined), inspiring confidence seems a difficult task. As the NHIN moves to a more Internet-like design, the approach to validation of entities on the network becomes more important, as well as having secure and robust approaches for authentication of individual patients, providers, and facilities.

III.A.1 - We suggest that the Plan address the potential for interstate privacy discrepancies or inconsistencies. As each state determines how it wishes to manage the patient consent process, the federal role of ensuring minimal privacy should also be used to ensure that some states do not make privacy rules so tight as to make sharing information with neighboring states overly difficult. Many communities (or medical service areas) cross state lines and have already seen the challenges of trying to harmonize different privacy and security requirements.

III.A.4 - AMIA believes that ONC may need to consider ongoing and future efforts in the private sector and open source community.

III.C.1 – AMIA suggests that further clarification is needed. While many of the described tools may exist, AMIA believes that ONC should leverage existing efforts rather than begin again.

III.C.2 – *Evaluate safety concerns and update approach to health IT safety.*

AMIA cautions that evaluation is not a one-time event; rather, it is an ongoing process. These efforts require a culture shift, as identified in I.A.6 above. We suggest the potential revised wording: “Support a culture of vigilance in rapidly identifying and addressing health IT risks, whether technical, process, organizational, or personnel, and work with the healthcare community to resolve or mitigate these risks.”

AMIA supports a coordinated and multidisciplinary 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. AMIA believes that improved efforts to communicate with and inform the wide diversity of stakeholders about the all proposed policy and processes are critical.

In addition, many of the issues regarding safety relate to implementation, not simply to the vendor systems themselves. Ongoing testing of these systems as implemented would be helpful.

III.C.3 – *Monitor patient safety issues related to health IT and address concerns.*

We are concerned that the proposed strategy and the explanation do not match. Patient safety is much broader than data integrity and is addressed in the revised versions of I.A.6 and III.C.2. We suggest that revised wording here could be as follows: “Identify risks to patient data integrity and work to resolve or mitigate those risks.”

AMIA has previously submitted comments to ONC that describe our position regarding how the use of health information technologies and informatics science principles, tools, and practices will, ultimately, enable clinicians to make health care safer, more effective, efficient, patient-centered, timely, and equitable. This goal can be achieved only if such concepts and technologies are fully integrated into clinical practice and education. In addition to a substantial investment in capital, technology, and resources, the successful implementation of a safe electronic platform to improve healthcare delivery and quality will require an investment in people across a broad range of expertise levels. That is, we must ensure that healthcare providers not only invest in EHR systems, but obtain the competencies required to work with electronic records, including basic computer skills, information literacy, and an understanding of informatics and information management capabilities. In brief, achieving “meaningful use” will be a matter not only of providing financial assistance to eligible providers and hospitals to purchase qualified systems and then expecting technology vendors to provide adequate training and support for the use of those systems, but also to assist providers in obtaining the competencies necessary to select and use EHR systems effectively. It will also mean developing the clerical, administrative, and technical staff necessary to support a healthcare enterprise built on electronic platforms. Importantly, developing a real “meaningful use” pathway for EHRs will also require supporting the basic and applied informatics science needed to address issues of design safety, change implementation, error monitoring and reduction, and other innovative methods and systems that will define the world of health IT in the mid-term and beyond.

Goal IV: Empower Individuals with Health IT to Improve their Health and the Health Care System

AMIA has previously submitted comments to ONC about Stage 2 Meaningful Use and we direct your attention to those comments.¹ In general, we support the meaningful use efforts that are being designed and promoted by ONC, but we have made clear our concerns about the pace of change and certain other details that could have unintended consequences.

¹ See <https://www.amia.org/files/AMIA-HITPC-Meaningful-Use-02252011.pdf>.

IV.A.1 – Listen to individuals and implement health IT policies and programs to meet their interests.

We suggest that the current wording would benefit from additional explanation and clarification. We offer the following revised wording: “Engage healthcare consumers and their caregivers in discussions about how HIT policies and programs affect them.”

IV.B.1 – Through Medicare and Medicaid EHR Incentive Programs, encourage providers to give patients access to their health information in an electronic format.

It is not clear if providers would be required to provide the data in a specific electronic format. We offer the following additional wording: “supported by the provider and for a reasonable fee.”

IV.B.2 - We believe that there needs to be a mechanism to ensure that certain data are not shared immediately without a provider discussion. We question how ONC proposes to allow for instances where certain values might be incorrect and are subsequently changed (e.g., lab errors).

IV.C.2 – We question if this strategy is perhaps premature. It is reasonable to solicit patient participation, but we believe this is more appropriate when IV.C.1 is accomplished and not just a strategic goal.

Goal V: Achieve Rapid Learning and Technological Advancement

AMIA believes that ONC should ensure that agencies with a proven and strong history and existing infrastructure to support health IT research, such as the Agency for Healthcare Research and Quality (AHRQ) and the National Library of Medicine (NLM), have adequate funding to continue their efforts. AMIA is also concerned about the potential for fragmenting health IT research, or on making the research portfolio so applied that more fundamental issues that will lead to future innovations are being neglected and are accordingly underrepresented. We encourage ONC to leverage existing federal programs and to continue to support research in the private sector. The strategic plan also emphasizes work in government healthcare settings to enhance the effectiveness. The generalizability of research conducted in government settings may be limited; thus we recommend ongoing funding to support research in non-government settings and/or to explore how to adapt research findings from the public sector to the private sector.

As we have stated in other comments submitted to ONC, AMIA believes that **interoperability** is critical to safe and effective transmission of patient-centered data and that without criteria and certification, long-term meaningful use (e.g., a learning health system) cannot be realized.

Under the current certification process, providers or hospital systems may invest in a complement of certified products, assuming that the products will be successful in addressing meaningful use and will result in a well-rounded EHR system, only to learn after implementation

that the certified products are not interoperable. AMIA supports and encourages heightened discussions with a targeted focus on interoperability criteria and certification; we support accelerating the timeline to develop and implement interoperability criteria as part of EHR certification. AMIA believes that the lack of attention to interoperability criteria within the current certification process is a key deficiency and will likely pose significant challenges and impediments to long term health information exchange.

V.A.1 – Establish an initial group of learning health system participants.

We caution that what is learned from large systems or early adopters is not necessarily applicable in other organizations or settings, especially those in resource constrained environments. We ask that ONC consider insertion of additional wording such as the following: "that represent systems in dispersed geographies and of varying resources and sizes."

V.B.1 – Liberate health data to enable health IT innovation.

We offer refined wording to achieve greater clarification: "Encourage patients to permit their deidentified data to be available to promote health innovation."

V.B.2 - We suggest that ONC describe what to target in the strategy – for example, user interfaces, workflow, improving outcomes, and connectivity.

V.B.5 – Provide clear direction to the health IT industry regarding government roles and policies for protecting individuals while not stifling innovation.

We offer the following refined language: "Collaborate with the HIT industry to develop government roles and policies that protect patient safety while promoting innovation." AMIA encourages ONC to help assure that the Health IT Strategic Plan fosters a culture of health IT and health informatics innovation.

Concluding Remarks

AMIA appreciates this opportunity to submit comments and participate in ONC's development of a federal health IT strategic plan, and we thank the ONC for soliciting public input. We serve as a source of informed, unbiased opinions on issues relating to the national health information infrastructure, the uses and protection of clinical and personal health information, and a variety of public health considerations, and we accordingly appreciate the opportunity to contribute to your deliberations.

Finally, AMIA again wishes to thank ONC for inviting public comments. Please contact us at any time for further discussion of the issues we have raised.

Sincerely,

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