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May 6, 2011

Farzad Mostashari, MD, ScM
National Coordinator for Health IT
U.S. Department of Health and Human Services
200 Independence Avenue, SW
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Dear Dr. Mostashari:

On behalf of the Board of Directors and members of HIMSS, we are pleased to submit written comments to the Office of the National Coordinator for Health IT (ONC) regarding the Federal Health IT Strategic Plan for 2011-2015, as published on the ONC website on March 25, 2011.

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 35,000 individual members, of which two-thirds work in healthcare provider, governmental and not-for-profit organizations. HIMSS membership also includes over 500 corporate members and more than 120 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 recognizes the significance of the fact that this Strategic Plan is the first official strategic plan since ONC was codified in the American Recovery and Reinvestment Act of 2009. The process of leveraging health IT as the foundation for healthcare transformation is an incredibly challenging opportunity for ONC and our nation. The new Strategic Plan provides a roadmap for how ONC intends to coordinate with your federal colleagues, the healthcare community, and the public to optimize cross-agency resources that can support improving the quality and cost effectiveness of care delivery in all care settings that receive federal funding.

We appreciate ONCs attempt to document the health IT goals and milestones associated with a number of laws and regulations that are laying the groundwork for our nation to transform our healthcare system using IT, including the Patient Protection and Affordable Care Act of 2010 (ACA), the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), the Medicaid Information Technology Architecture (MITA) modernization effort, the National Health Care Quality Strategy and Plan, and the CMS administrative requirements to convert to the X-12 5010 Standard and implement ICD-10 coding.

Each year, HIMSS creates public policy principles for all stakeholders to consider for inclusion as provisions in legislation proposed by the U.S. Congress or state legislatures, or for inclusion in federal and state regulations, to foster enhanced healthcare using IT. In reviewing our 2011-2012 Policy Principles against the Strategic Plan, we are pleased to note a considerable number of synergies between the two documents in such areas as Funding and Incentives, Quality and Outcomes, Safety, Standards, Infrastructure, and Innovation, Patient Empowerment, Population Health, Workforce Development, and Privacy and Security.

Among the areas of synergy, we appreciate the opportunity to provide comments on the Strategic Plan's goals, objectives, and strategies, including the following observations:

Goal #1: Achieve Adoption and Information Exchange through Meaningful Use of Health IT

Consistent and Consolidated Source of Information

HIMSS members have expressed concern that preparation for Meaningful Use has created real issues with Eligible Professionals and Eligible Hospitals understanding the Certification and Meaningful Use requirements. Although the information may be available in various locations on the ONC, HHS, and CMS websites, it's hard to find, is sometimes conflicting between sites, and difficult to understand. While integration of the comments received subsequent to publication of the NPRM and the responses from CMS adds value, it also potentially contributes to confusion and lack of clarity, conciseness and readability. Most clinicians don't have the time and not all will have the expertise to read and correctly interpret the nuanced points and make connections between various sites and pages within sites. Information needs to be conveyed in clear and concise language so that it can be operationalized by Eligible Professionals and Eligible Hospitals. HIMSS suggests ONC and CMS create a single, consolidated, readable, and easily understood "source of truth" from the government that is focused on the "bottom line", and serves the public function similar to recovery.gov.

In an effort to assist provider education on health IT, HIMSS has developed the Meaningful Use OneSource to equip our members and other interested organizations to prepare for the Meaningful Use and Certification Criteria and Standards regulations. The Meaningful Use OneSource is a repository of hundreds of documents, tools, and links to other knowledge available on the Internet.

Best Practice

We would like to highlight exemplars in the healthcare IT community, most notable, 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.

In addition, given the expanding level of information available through the EMRAM, to include data on Meaningful Use preparedness for non-government hospitals and affiliated clinics in the U.S., we are confident that the EMRAM data can assist ONC achieve the performance measure "Better performance in hospitals: Increase the percentage of hospitals that have adopted electronic health records," as outlined in Appendix A of the Strategic Plan.

Finally, with respect to a federal focus on innovation and usability, we support the effort, but also caution the federal government against creating policies that hinder innovation or create federal requirements for EHR interfaces or architecture and urge that any usability initiatives use valid and reliable measures that enhance and do not interfere with the EHR technology market.

Integration, Interoperability, and Standards

HIMSS appreciates that these issues are complex and that rapid progress is necessary to achieve a nationwide health IT infrastructure. Success requires a vision for the future and laying out a roadmap. It is encouraging to the healthcare community to know that the Strategic Plan will continue the federal government's commitment to promoting a standards-based approach to sharing electronic health information.

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

[2] Information on HIMSS Analytics Stage 7 available online

The ability to integrate electronic health information about a patient and exchange it among clinical providers remains the exception rather than the rule, although change is happening as a result of standards maturity, technology availability, and federal and private sector initiatives. 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.

The healthcare community has taken great strides over the past decade to work 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 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.

Privacy and security remain key issues for patient trust as we move towards widespread information exchange of patient data within and external to the healthcare community. 2010 demonstrated that we have a long way to go in earning and maintaining patient trust, especially when we consider the data breach statistics released by HHS. The ONC FACA groups are doing excellent work "shining a spotlight" on the industry's most pressing security implementation challenges and looking for policy levers to help guide healthcare organizations. Adoption of a standards-based approach to security, defining best practice and providing guidance on minimum controls will help promote and build confidence in sharing electronic health information.

In addition, regarding the Strategic Plan's reference to fulfilling the recommendations in the President's Council of Advisors on Science and Technology (PCAST) Report, we reiterate our January 2011 comments to ONC on the PCAST Report on standards and tagged metadata

> 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.

Workforce Development

The automation of the nation's healthcare system requires sufficient numbers of educated and experienced professionals in a variety of roles. HIMSS supports efforts to promote the development and perpetuation of a well-trained, diverse workforce that understands the knowledge, data and wisdom of technology and informatics and is competent to deliver high quality healthcare using health IT. Thus to achieve and sustain the meaningful use of health IT, which holds promise for transforming healthcare, HIMSS realizes the strategic importance of creating a trusted, go-to source for all talent management needs for both job seekers and employers. This source is the HIMSS Career Services Center. HIMSS provides a tremendous focus on providing education and training for those interested in a career in health IT, and is the cornerstone for the expansion of health IT career services. HIMSS is a trusted, go-to source for all to accomplish their health IT career aspirations.

Administrative Simplification

HIMSS concurs with the Strategic Plan's attempt to address the administrative requirements in the Affordable Care Act. The health IT community has solutions that can support the establishment of efficient business practices that take advantage of automation. We strongly encourage the federal government to align federal policy in order to facilitate the electronic business processes that can markedly reduce inefficiency in the healthcare financial infrastructure and support real time information management that can impact quality of care.

Among the initiatives that are targeted towards electronic business transformation is the creation of operating rules for health data transactions (ACA, Section 1104). HIMSS actively participates in creating an educational and industry action platform around this critical topic as one of the founding advisors for the CAQH CORE initiative, (selected by NCVHS for creation of operating rules) and offers its educational programming to speed adoption of the new operating rules for healthcare that the Department of Health and Human Services is mandating for adoption commencing July 2011 and going forward (under the Affordable Care Act, Section 1104). Within this initiative is the creation of new operating rules to spur the adoption of Electronic Funds Transfer (EFT) and Electronic Remittance Advice (ERA). The adoption of these transactions alone will move the paper chase for healthcare payments towards a digital platform

and provide a substantial benefit to the industry (estimated to be between $11 billion to $35 billion annually by the US Healthcare Efficiency Index® and the HIMSS Medical Banking Project.)

In addition to operating rules, migration to ASC X12's version 5010 of the HIPAA transactions is a key provider initiative that will prepare the way for ICD-10 transformation. HIMSS hosted a cross-industry webinar series jointly created with WEDI, AHIMA, HBMA and AMA entitled "GetReady5010.org" (also a website) that had over 16,000 registrants over three days (and a follow-on webinar series with some 10,000 registrations).

A key global healthcare issue that requires rigorous enterprise-wide assessment and alignment is the implementation of the ICD-10-CM/PCS coding scheme. This initiative will enable stronger support for implementing quality measures in healthcare by markedly increasing the granularity of data around healthcare treatments with concomitant support for understanding outcomes. The current coding scheme (ICD-9) uses some 15,000 codes while the new ICD-10 matrix will implement some 155,000 codes in total (ICD-10-CM and ICD-10-PCS). Achieving transformation will require the active and persistent involvement of many of the healthcare stakeholders, including financial institutions for purposes of risk mitigation and cash flow impact.

To enable electronic business transformation, HIMSS has created two initiatives: the new **HIMSS G7** thought leadership platform that invites seven healthcare stakeholders (government, health providers, health plans, consumers, financial institutions, employers and technology firms) to discuss critical path industry issues in the evolution of digital processing of health data as we collaboratively design the healthcare financial network of the future; and, the creation a broad industry collaborative – **The ICD-10 PlayBook** – that is a robust reference tool that aggregates industry-wide educational resources and tools primarily targeting providers (yet with content for health plans, banks and others), and which offers a time-driven format/strategy for staging electronic business transformation around ICD-10 implementation.

Finally, with respect to Goal 1 Objective C, HIMSS applauds the fact that ONC is working with the Substance Abuse and Mental Health Services Administration (SAMHSA) to determine if there are existing programs beyond the Medicare and Medicaid EHRs Incentive Programs that can create EHRs incentives for behavioral health care settings. We strongly encourage ONC to explore similar incentive arrangements in areas to include rural, long-term, rehabilitation, community-based, home care, pharmacies and public health based settings.

Goal #2: Improve Care, Improve Population Health, and Reduce Health Care Costs through the Use of Health IT

HIMSS supports the efforts to encourage the use of health information facilitated by EHRs and HIEs and secondary use services inside and outside of direct healthcare delivery to enable rapid detection and on-going characterization and monitoring of public health events for the purpose of triggering appropriate early response, including syndromic surveillance, resource management,

facilities planning and modeling, and improvement of public health, while protecting patient privacy.

We support initiatives that facilitate the flow of reliable health information (such as vaccine administration data) among population health and clinical care systems necessary to protect and improve public health while ensuring patient privacy.

Goal #3: Inspire Confidence and Trust in Health IT

Overall, HIMSS is supportive of the development of a strategy which facilitates the innovative development and ongoing operation of private and secure interoperable systems that allow patients to view and appropriately contribute patient notes to their complete clinical record, including individual controlled personal health technologies, and make determinations regarding how the information is shared and/or used for secondary purposes.

Putting health information into the hands of patients promotes health literacy, supports individual responsibility for health care decisions, and helps activate patients as participants in their care delivery. HIMSS encourages ONC to pursue programs that provide public and private incentives that encourage and educate patients' and providers' utilization of electronic health information with respect for the privacy and security of personal health information.

HIMSS supports a number of health IT initiatives, including engaging portable technology, and social media to facilitate appropriate and timely consumer awareness and to facilitate and aid decision making in privacy decisions; increase patient/provider communications; reduce medical errors; increase patient safety; manage advance directives; improve the transparency of price, cost and quality; foster trustworthiness among stakeholders; and positively impact the health and quality of life for all individuals residing in the U.S.

In addition, confidence in health IT is enhanced by appropriate strategies to address patient safety, as well as the privacy and security of personal health information. HIMSS agrees with the government that patient safety initiatives for health IT are essential to the overall trust in the healthcare system. As ONC continues working with the Institute of Medicine on this important issue, we suggest the program have parameters that (1) take into account the importance of innovation through the development and implementation of EHR technology and (2) support the dissemination and incorporation of lessons learned on unintended consequences (e-iatrogenesis) into education and training of health IT implementation and use, to enable enhanced patient safety and to minimize adverse events.

Notably, leading the dialogue on privacy and security of personal health information is critically important to HIMSS members. For example, in December 2009, HIMSS published the results of a HIMSS member Work Group analysis 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.), a patient safety issue, a quality of care issue, and a patient/provider trust issue.

HIMSS believes more work is needed in the areas of Privacy and Security guidance and communications as evidenced by the number and types of breaches reported to HHS in 2009/10. Patient confidence and adoption of technology associated with the National Health IT Network will be directly affected by the trust equation with those managing their data. For healthcare organizations, clearer, more focused guidance with respect to ongoing risk management, technical controls and oversight/enforcement is still needed to help organizations meet these requirements and continue to foster trust. HHS must also continue to find ways to directly address patient concerns to demonstrate the community's commitment to patient privacy.

HIMSS continues its 10-year history of producing privacy and security tools that have helped shape the discussion and prepare the healthcare community for regulatory compliance and today's most pressing security implementation challenges. Featured tools include the HIMSS Privacy and Security Toolkit and the recently released HIMSS Privacy and Security Toolkit for Small Provider Organizations, published in partnership with the Medical Group Management Association (MGMA). HIMSS is currently working with the REC Community of Practice for Security to provide toolkit resources to RECs around the country.

HIMSS, working with HIMSS Analytics, also conducts an annual survey of healthcare organizations regarding security implementation practices and technology uses. Currently in its third year, the 2010 HIMSS Security Survey, sponsored by Intel, reported the opinions of IT and security professionals from healthcare provider organizations across the U.S. regarding key issues surrounding the tools and policies in place to secure electronic patient data at healthcare organizations.

For 2010, the study was supported by MGMA to encourage additional representation in the medical group and ambulatory space. The study was designed to collect information on a multitude of security-related items, including organizations' general security environment, access to patient data, access tracking and audit logs, security in a networked environment and technology tools in place. This year, we also added a series of questions to evaluate how healthcare organizations are handling patient identity issues.

Goal #4: Empower Individuals with Health IT to Improve their Health and the Health Care System

Patient involvement in their care coordination and inclusion of patient-entered data should be included in the process, as long as it is properly labeled and reviewable by the clinician. The general notion that patient self-entered data can be useful to the clinical decision making is valid. HIMSS encourages an ongoing dialogue on what should be considered useful data and the logic for incorporation into the chart if MU criteria are to be applied. For example, consideration needs to be given to the amount of time typically available for an encounter, and how the time needed for the provider to digest the patient-supplied data may impact clinical assessment time with the patient.

In addition, there are real-world examples of portals that have the ability to send patient-reported data, patient-requested corrections, etc. to EHRs. This data is transmitted as patient-entered data to be reviewed by the provider organizations prior to incorporating into an EHR. Data is clearly marked as 'patient-entered data' so that the provider and staff users clearly see that information

was provided by the patient. This allows the patient supplied data to be reviewed and approved by the clinician before it is incorporated in the patient's medical record.

Although an important component of data-sharing, we recommend ONC and the federal government look beyond the "Blue Button" model of securely sharing data with patients, recognizing that this is one approach to provide patient access to EHR data. EHR data can also be enhanced by sharing CCD formatted data, along with human readable data, which will provide a higher level of shareable, clinically relevant, comprehensive health data patient profiles to enhance continuity of care.

We are mindful that our membership and others in the healthcare community are keenly aware of the importance of accessible accommodations in the healthcare setting. We recognize that the awareness needs to expand to the health IT components of care delivery, particularly as we move to engage the patient as a consumer of the healthcare. Issues that will be important to address include patient health literacy, physical and mental capability, cultural competency, and patient education between provider visits. One of the many benefits of health IT is that the cost of producing information in variable languages and in a culturally appropriate manner is less than in the current paper environment. This provides opportunities for variations of consistent messages through culturally-appropriate mechanisms. We look forward to working with the Department and the U.S. Access Board to further educate our membership on this important topic.

Finally, the issue of variable languages goes beyond accessibility and beyond regulation of U.S. providers. Like economic exchange, health information exchange may become increasingly globalized. International workforces, military and government personnel stationed abroad, students studying abroad, immigrants/emigrants, and "medical tourists" all potentially have needs for interoperable health information exchange among different countries and languages. ONC's current draft of its Strategic Plan (p. 18) briefly notes its international activities, including a Memorandum of Understanding with the European Commission on EHR interoperability standards. However, HIMSS believes that these issues need further attention in the Strategic Plan.

Goal #5: Achieve Rapid Learning and Technological Advancement

HIMSS supports the Strategic Plan's commitment to lead the creation of a learning health system to support quality, research, and public and population health.

We strongly encourage ONC to continue working with the healthcare community and federal agencies like AHRQ, CMS, and CDC to seek continuous improvement in the quality of both medical care and the health of the nation's citizens is supported by a scientific approach to the development and reporting of electronic clinical quality measures. Performance improvement results from leveraging health IT to capture data and apply changes to workflow processes to improve efficiencies and quality outcomes. We all have a stake in the development of a learning health system, and should work together to realize its success.

Conclusion

HIMSS appreciates the opportunity to provide public comments on the Federal Health IT Strategic Plan for 2011-2015. The roadmap it creates is critically important to the overall success of the many challenges inherent in transforming healthcare using IT. We look forward to continued dialogue between HIMSS and the Department, in order to achieve the benefits of an interoperable healthcare system. If you have any additional questions, please contact Thomas M. Leary, Senior Director, Federal Affairs, at 703.562.8814.

Sincerely,

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