February 4, 2013

Dr. Farzad Mostashari, M.D., ScM
National Coordinator for Health IT
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Mostashari:

On behalf of the Healthcare Information and Management Systems Society (HIMSS), we are pleased to provide written comments to the Office of the National Coordinator (ONC) on the Health Information Technology Patient Safety Action & Surveillance Plan for Public Comment, released on December 21, 2012. We appreciate the opportunity to contribute to this dialogue as we continue to support efforts aimed at improving patient safety through use of health information technology.

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 52 years ago, HIMSS and its related organizations are headquartered in Chicago with additional offices in the United States, Europe and Asia. HIMSS represents nearly 50,000 individual members, of which more than two thirds work in healthcare provider, governmental and not-for-profit organizations. HIMSS also includes over 570 corporate members and more than 225 not-for-profit partner 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, research initiatives, and media vehicles designed to promote information and management systems' contributions to improving the quality, safety, access, and cost-effectiveness of patient care.

In December of 2012, the HIMSS Board of Directors approved its updated Public Policy Principles that serve as guidance for proposed health IT-related legislation and regulatory activity. Several principles directly mention patient safety concerns and directives, and these Principles are referenced throughout our comments on this Action & Surveillance Plan.

For each of the three components that the ONC references in its Plan—Learn, Improve and Lead—we have provided specific comments. As a general note, we appreciate ONC’s emphasis that health information technology facilitates potentially significant improvements in health care quality and safety as compared to paper records, and for recognizing this throughout the proposed Plan.

Learn:
Increase the quantity and quality of data and knowledge about health IT safety.
Engage health IT developers to embrace their shared responsibility for patient safety and promote reporting of patient safety events and risks.

HIMSS recognizes that health IT systems must be safe, should support optimal user workflow, follow usability guidelines, and help technology-enabled delivery systems evolve toward a “Learning Health System” in which the culture is team-based, patients and the public are engaged, and a trust fabric is strong, protected and actively nurtured.¹ HIMSS supports the acknowledgement by ONC that health IT can also be a significant enabler of safety. We also note that health IT is just one part of shifting the patient safety paradigm. We encourage ONC to emphasize this point and also highlight that health IT can be a tool to facilitate broader patient safety reporting.

HIMSS supports ONCs proposed engagement with multiple stakeholders in developing a code of conduct, and acknowledges that this initiative should be private-sector based and led. HIMSS has experience in developing professional practice standards, and we are committed to engaging in the development of an agreement through collaborative efforts with the EHR Association and other stakeholders. We recognize that codes of conduct can be powerful and valuable tools, and should be developed with diverse external stakeholders at the outset.

In particular, ONC recommends that a code of conduct “ensure business practices are in place to promote the usability and safety (safe design) of health IT products and adverse event reporting.”² We note that often there are significant customizations that occur in a provider organization that can impact usability and we support providers and vendors working in tandem to address issues of usability. The ONC Plan references emerging tools for comparing user experience across different EHR systems. HIMSS notes that this is appropriate, but such tools should be one of several market-driven choices available to providers for comparing products.

Finally, HIMSS notes that our EHR Usability Task Force developed a Usability Maturity Model in order to help healthcare leaders, organizations and individuals assess their current level of Health IT usability, and then helps build toward more advanced levels. The various phases of the model, which range from “unrecognized” integration of usability to “strategic,” correlate with the level of maturity achieved when user-centered design becomes fully integrated within an organization. The Model provides a systematic approach that can lead to increased attention to usability and its benefits. Despite perceptions that invoking usability principles inhibits the development process, the Model provides evidence of value to healthcare organizations, and outlines where and how ROI related to usability is evaluated.

Additionally, in recognizing that implementing health IT and creating a culture of safety requires organizational management that extends beyond the project level, the HIMSS Change Management Task Force created a Change Management Framework that can be applied to organizational development of new workflows, communication models and cultural change brought about by the implementation of health IT.

The attached Framework identifies project management and change management activities across three phases—Present state, Transition state, and Transformed state—that organizations should follow to achieve impactful change through technology adoption.

**Provide support to Patient Safety Organizations (PSOs) to identify, aggregate, and analyze health IT safety event and hazard reports.**

HIMSS supports voluntary reporting using the AHRQ Common Data Format, with refinements as appropriate to meet the needs of health IT users, including those in ambulatory settings. We note that much of event report aggregation happens too late to allow for adequate response time to immediate issues, and therefore emphasize the importance of two key activities that ONC should emphasize in the final report:

- Recognition of the critical importance of direct provider reporting to, and consulting with, their EHR developer when conducting root cause investigations.
- Inclusion of IT developers in the PSO primary work with reporting providers, and other components of the protected PSO process.

We also appreciate ONC’s recognition of the complex issues around the legal protection framework of the PSO system in the Patient Safety and Quality Improvement Act of 2003, and the general sensitivity of all parties to the legal ramifications around patient privacy, legal medical records and court processes for discovery of electronic documents. Finally, we note that voluntary provider reporting to PSOs on safety issues should be the primary focus, given that safety events generally happen in a provider context, and that health IT is likely to only be one element of any safety event.

**Incorporate health IT safety in post-market surveillance of certified EHR technology through ONC-Authorized Certification Bodies (ONC-ACBs).**

HIMSS is concerned that this envisioned role for ACBs may be too broad, and that ACBs do not have the core competencies to focus on patient safety. Given ONC’s intent to leverage the PSO reporting system and the AHRQ common format, we are concerned that adding an ACB component may not serve ONC’s overall goal of efficacy. We note that an ACB appendage for reporting may create an unnecessary level of complexity due to the potential for generating unfiltered reports in the absence of an analytic or response mechanism that fits into the overall reporting system.

**Align CMS health and safety standards with the safety of health IT, and train surveyors.**

HIMSS supports achieving the promotion and reporting of improvements in patient safety achievable from broad use of EHRs. We need to strike a balance between the importance of innovation associated with the development and implementation of EHR technology with dissemination and incorporation or sharing of lessons learned from unintended consequences into education and training of health IT implementation. This balance should minimize the risks
of inappropriate information disclosure and the negative impact on innovation while enhancing patient safety.\(^3\)

HIMSS has also actively contributed best practice guidance for improving patient safety through health IT for providers. HIMSS has developed *Electronic Prescribing for the Medical Practice: Everything You Wanted to Know But Were Afraid to Ask* to provide concise step-by-step guidance on planning, choosing, and implementing electronic prescribing for practicing physicians and their office staff; extensive clinical decision support best practice guidance through HIMSS CDS101 and CDS Guidebook series; and the HIMSS CPOE Wiki to assist in CPOE implementation and optimization for hospitals. HIMSS is currently developing best practice guidance for mitigating e-iatrogenesis (defined in the Journal of the American Medical Informatics Association as patient harm caused, at least in part, by health IT) that is scheduled to be released in spring 2013.

**Collect data on health IT safety events through the Quality & Safety Review System (QSRS).**

HIMSS emphasizes our commitment to the issue of nationwide patient data matching, and the patient safety risks that occur with not having a nationwide strategy. Stemming from our work on the *Patient Identity Integrity White Paper*, HIMSS convened a multiple stakeholder organization group on the issue which included the College of Healthcare Information Management Executives, American Health Information Management Association, American Medical Informatics Association, HIT Now Coalition, Association of Medical Directors of Information Systems and the National Association of Healthcare Access Management.

HIMSS has led the charge in educating Congress on this issue, including three official Congressional Asks in 2010, 2011 and 2012. In our most recent “Ask,” we asked that Congress should direct a study of patient data matching issues and best approaches to identify an appropriate nationwide patient data matching strategy. This study of a nationwide patient data matching strategy, would include: the prevalence and costs of patient-data mismatches nationwide, the costs of correcting these errors, the patient safety risks of *not* having a nationwide strategy, the benefits and implications of applying a nationwide strategy, the impact on privacy, security, and safety of a nationwide strategy, current and near-term available technologies, the costs/benefits and practicality of adopting a nationwide strategy, and best industry practices currently employed to ensure acceptably reliable patient data matching across systems while enhancing patient privacy, security, and safety.\(^4\)

The HIMSS Patient Identity Integrity (PII) Toolkit provides resources detailing the complexities of patient identity management, and we encourage its utilization as a resource, and was a collaborative effort among HIMSS volunteers and committees. In an April 2012 HIMSS blog entry on this topic, we note that if Health Information Exchange (HIE) connects us to better healthcare, “PII is a concept and process that we must address and for which we must find viable solutions” and notes that HIMSS and coalition partners had briefed over 40 Congressional

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offices on the concept. Through our work, HIMSS is a demonstrated leader in advocating for an
effective patient matching solution

Finally, HIMSS suggests aligning data collection initiatives with the Standards &
Interoperability (S&I) Framework, and other S&I initiatives such as Query Health to expedite
creation and receipt of de-identified reports that are population based.

**Improve:**
Target resources and corrective actions to improve health IT safety and patient
safety

**Use Meaningful Use of EHR technology to improve patient safety.**

HIMSS agrees that it makes sense to prioritize items for Meaningful Use that exhibit a patient
safety benefit (e.g. CPOE, med lists, etc.). We continue to encourage alignment of the EHR
Incentive Program’s quality reporting requirements with other federal reporting/incentive
programs. In terms of the requirement for a safety risk assessment, we suggest that this could be
a premature step—in lieu of standards, this may be burdensome to providers.

**Support research and development of testing, user tools, and best practices related to health IT
safety and its safe use.**

HIMSS supports funding for research on human factors related to the use of EHRs, such as
ordering, documentation, usability, organizational change, ergonomics, device utilization and
preference, and decision support. Such research can identify user acceptance issues and
implementation barriers, predict success and failure factors, and inform the development of
evidence-based usability guidelines for EHRs and improve patient safety.\(^5\)

HIMSS has an extensive background through our EHR Usability Task Force, including the
Usability Maturity Model referenced above. The various phases of the model, which range from
“unrecognized” integration of usability to “strategic,” correlate with the level of maturity
achieved when user-centered design becomes fully integrated within an organization. The Model
provides a systematic approach that can lead to increased attention to usability and its benefits.
Despite perceptions that invoking usability principles inhibits the development process, the
Model provides evidence of value to healthcare organizations, and outlines where and how ROI
related to usability is evaluated

**Incorporate health IT safety into medical education and training for all health care providers.**

HIMSS strongly supports the inclusion of health IT safety into clinical education and training.
We note that a root cause of unintended consequences is often due to a lack of education or
inadequate training, and we support the addition of health informatics education in accredited
schools, developing competency-based continuing education programs, and improving specialty
training programs. HIMSS Policy Principles outline clear support for the credentialing of health

IT professionals affirming ongoing development and acquisition of needed competencies. We also continue to support critical steps to support a component and proficient workforce including Clinical and Business Intelligence, EHR Usability, Clinical Decision Support and Privacy and Security.

Investigate and take corrective action, when necessary, to address serious adverse events or unsafe conditions involving EHR technology.

HIMSS supports ONC's approach of building on existing federal authorities rather than creating a new federal entity. We also support ONC's proposal for working with developers to request voluntary corrective action when HHS becomes aware of a potential serious safety risks. We point out that clinical and business intelligence may play a larger role in this component by potentially helping to mitigate risks and predict potential events. Finally, we suggest inclusion of references to automated transactional clinical decision support (CDS) and the requirement for data standards—vocabulary, data type and information model standards—so that alerts can be done in a way that does not penalize clinicians.

Lead:
Promote a culture of safety related to Health IT

Develop health IT safety priority areas, measures, and targets.

HIMSS supports this public-private collaboration, and also appreciates the inclusion of ambulatory settings by ONC.

Publish a report on a strategy and recommendations for an appropriate, risk-based regulatory framework for health IT.

HIMSS supports the need for widespread stakeholder involvement in the investigation and potential development of a risk-based regulatory framework for health IT. We are very interested in participating in the expected discussions and public-private action to develop a framework that supports innovations that improve patient safety and quality improvements.

Establish an ONC Safety Program to coordinate the implementation the Health IT Safety Plan.

HIMSS supports this multi-agency approach outlined in the proposed Plan with federal partners including AHRQ, CMS, FDA, and OCR to accomplish goals, and encourage participation by state governments to incorporate health IT into their patient safety oversight programs. We are very interested in participating in the expected discussions and public-private action to develop a framework that supports innovations that improve patient safety and quality improvements.

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Encourage private sector leadership and shared responsibility for health IT patient safety.

HIMSS supports this initiative. As outlined, we have a long history of supporting a balanced approach to patient safety, through our work in advancing patient matching for benefits that include enhanced patient safety, our work on usability, our Committee work around enhanced quality of care, and our multi-stakeholder initiative to develop patient safety-geared materials.

These and other HIMSS initiatives serve to illustrate our deep commitment to retaining patient safety as a top priority and consideration for future health IT initiatives. We are very interested in participating in the expected discussions and public-private action to develop a framework that supports innovations that improve patient safety and quality improvements. We look forward to continued engagement with the federal government and the healthcare community to achieve a balanced approach that supports patient safety and health IT leverages to improve healthcare outcomes.

HIMSS appreciates this opportunity to provide public comment on this proposed Plan. We look forward to continued dialogue with ONC, and welcome any questions you may have. For more information, please contact Thomas M. Leary, 703.562.8814, Vice President of Government Relations, or Stephanie Jamison, 703.562.8844, Director of Government Services.

Sincerely,

Willa Fields, DNSc, RN, FHIMSS
Chair, HIMSS Board of Directors
Professor, School of Nursing,
San Diego State University

H. Stephen Lieber, CAE
President/CEO
HIMSS

Enclosure:
PDF Document – HIMSS Change Management Framework