February 4, 2013

Office of the National Coordinator for Health Information Technology
Attn: Farzad Mostashari, MD, ScM
U.S. Department of Health and Human Services
200 Independence Avenue SW
Suite 729D
Washington, D.C. 20201

RE: Health Information Technology Patient Safety Action & Surveillance Plan for Public
Comment

[Submitted Electronically]

Dear Dr. Mostashari,

eHealth Initiative (eHI) welcomes this opportunity to comment on the Office of the National
Coordinator for Health Information Technology (ONC) Health Information Technology Patient
Safety Action & Surveillance Plan (the Plan) for Public Comment. eHI is an independent, non-
profit, multi-stakeholder organization. Its mission is to drive improvements in the quality,
safety, and efficiency of healthcare through information and information technology (IT). eHI
advocates for the use of health IT that is practical, sustainable, and advances high quality patient
care. The comments below were developed through our multi-stakeholder consensus process.

eHI appreciates your efforts in reaching out to stakeholders to provide input as you continue to
finalize the Plan. Below you will find our general comments followed by detailed comments
regarding the following sections outlined within the Plan: increase the quantity and quality of
data and knowledge about health IT safety; target resources and corrective actions to improve
health IT safety and patient safety; and promote a culture of safety related to health IT.

General Comments

eHI supports the development of a patient safety plan and we encourage the timely and
appropriate integration of current activities, such as the findings from the 18-month study as
required by the Food and Drug Administration (FDA) Safety and Innovation Act of 2012. We
applaud ONC for the careful approach with which it integrated patient safety issues into the 2014

818 Connecticut Avenue NW Suite 500 Washington, D.C. 20006
Tel: 202.624-3270   Fax: 202.429.5553
www.ehealthinitiative.org

1

Edition Standards and Certification Criteria and recommend additional research and analysis to better inform how ONC can successfully develop and integrate a balanced approach toward patient safety initiatives. As ONC begins advancing the health IT patient safety program, we encourage emphasis on the fact that health IT as just one element of the overall patient safety effort.

eHI supports ONC's commitment to fostering a culture of patient safety and confidential and/or non-punitive reporting. Collaborating with and leveraging the current patient safety program infrastructure developed by the Agency for Healthcare Research and Quality (AHRQ) will provide invaluable resources as ONC navigates the Meaningful Use program through health IT patient safety initiatives. Through collaboration with AHRQ and other public/private organizations, this will enable the development of a consistent approach toward reporting at the national level, as well as the local level.

As ONC continues developing the final Plan, we strongly recommend addressing the critical role health information exchange plays in the successful implementation and use of health IT. As the adoption of health information exchange accelerates, it is critical to ensure a robust exchange infrastructure exists to support accurate patient matching, timely access and exchange of information for patient care.

Detailed Comments

Increase the quantity and quality of data and knowledge about health IT safety

1. Make it easier for clinicians to report patient safety events and risks using EHR technology.

eHI applauds AHRQ for taking steps to promote increased reporting of adverse events and integrating health IT safety events into the latest version of the Patient Safety Organization (PSO) Common Formats. We encourage the Department of Health and Human Services (HHS) and its agencies such as the AHRQ and ONC to conduct further study and analysis to seek broad stakeholder input on how to improve the Common Formats for improved usability. We also recommend ONC commit to coordinating a balanced approach toward addressing health IT and patient safety, including its focus on the positive health IT contributions to patient safety that avoids a siloed approach. This is a complex issue and requires a broader perspective that can be supported through the engagement of all stakeholders to address multiple areas of potential concern such as interoperability (technical and data), workflow and processes, implementation and training, accurate and timely capture of patient information, etc.

2. Engage health IT developers to embrace their shared responsibility for patient safety and promote reporting of patient safety events and risks.

818 Connecticut Avenue NW Suite 500 Washington, D.C. 20006
Tel: 202.624-3270   Fax: 202.429.5553
www.ehealthinitiative.org

2

eHI supports the need to engage health IT stakeholders and foster a culture of shared responsibility for patient safety. Industry-based codes of conduct that consider the issues highlighted in the Plan could be one useful tool as we address this complex issue. At the same time, we emphasize that codes of conduct should be developed by the applicable industry stakeholder and their organizations, with appropriate broader input and that ONC should avoid applying a regulatory, enforcement approach to such voluntary codes. As mentioned previously, it is critical to ensure ONC's efforts take a balanced approach to ensuring safety, where all stakeholders take responsibility for the aspects of health IT design, production, implementation and use that they control.

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

eHI supports AHRQ's commitment to collecting data regarding health IT patient safety events, including the aggregation of data for widespread learning. More routine reporting of patient safety events to the National Patient Safety Database (NPSD) could serve as an important foundation from which common data elements have been selected to enable the collection, aggregation, and analysis to assist in determining the root cause of events. We believe this approach will serve ONC well by leveraging an existing program and collaborating with AHRQ to continue integrating health IT adverse events.

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

We agree with ONC's consideration of post-market surveillance but believe that such surveillance can best be accomplished through a learning system and we also question the proposed role of ONC-Authorized Certification Bodies (ONC-ACB) in this process. Such a new role, if that is what is envisioned, extends beyond the core competency of the ACBs and could compromise their core mission. We request further clarity on the proposed role of ONC-ACBs in this process and whether ONC will be creating an additional functional area or current ONC-ACBs will assume these new responsibilities.

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

eHI supports ONC's intent to work with the Centers for Medicare and Medicaid Services (CMS) to align the health and safety standards for providers and suppliers as they relate to health IT safety. We note that all changes to the Medicare Conditions of Participation must go through rulemaking, and surveyors must be adequately trained and supervised, especially when expanding into new areas.

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

818 Connecticut Avenue NW Suite 500 Washington, D.C. 20006
Tel: 202.624-3270   Fax: 202.429.5553
www.ehealthinitiative.org

3

eHI supports the collection of data on health IT safety events and the improvement of the AHRQ Common Formats to support comparability of data across health care organizations and ongoing surveillance. The move toward use of consistent data elements must be balanced against the need for narrative to support root cause analysis, and the challenges of collapsing complex analyses into structured data formats. We are also pleased to note AHRQ's intent to support patient safety research as it relates to health IT while the QSRS is being developed with the expected completion in 2014.

7. *Monitor health IT adverse event reports to the Manufacturer and User Facility Device Experience (MAUDE) database.*

eHI supports ONC's intent to monitor the Manufacturer and User Facility Device Experience (MAUDE) database; however, since most health IT is not currently regulated by the FDA and thus does not require reporting, we are concerned this recommendation could imply the need for duplicative patient safety event reporting and processes. Therefore we urge ONC to provide clarification regarding MAUDE reports for health IT in its final plan.

Target resources and corrective actions to improve health IT safety and patient safety

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

eHI supports ONC's conclusion that health IT products have inherent safety advantages over paper records in that the patient record is rarely physically lost, is legible, has the ability to be available in multiple locations, and can provide clinical decision support. In this regard, we agree with ONC's continued focus on prioritizing capabilities for meaningful use that have a documented positive relationship to patient safety. We also support ONC's plan to collaborate with its federal advisory committees on health IT-related documentation issues. We believe a critical component needs to be added to the e statement referenced, "to determine ways to improve clinical documentation, thereby, reducing the risk that records will be inaccessible or their accuracy or completeness compromised." Improving clinical documentation has been a long time struggle and continues to be a complex challenge. Improving clinical documentation and leveraging health IT applications must be addressed in tandem through sufficient training and education to enable modification of workflows and processes to maximize health IT utilization.

We support ONC's effort of integrating important steps in the developing safety structure for health IT as demonstrated by the examples listed in the plan. We believe the addition of a safety risk assessment is premature, given that industry stakeholders have just begun Meaningful Use Stage 1.

818 Connecticut Avenue NW Suite 500 Washington, D.C. 20006
Tel: 202.624.3270   Fax: 202.429.5553
www.ehealthinitiative.org

4

2. Incorporate safety into certification criteria for health IT products.

eHI commends ONC's general approach towards addressing health IT safety in Stage 2 of the Meaningful Use program as described in the draft Plan. At the same time, we believe plans for incorporating patient safety standards and certification criteria and program rulemaking is premature and that, in general, these issues should remain separate from the ONC certification program. As ONC continues developing plans for addressing health IT patient safety related events we urge the review and consideration of how workflow and processes impact patient care while enabling the use of health IT. We believe there continues to be opportunity for a learning environment that informs the appropriate and accurate use of health IT in reducing patient safety events.

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

eHI supports ONC's intent to collaborate with the National Institute of Standards and Technology (NIST), AHRQ, and National Library of Medicine (NLM) to address and improve health IT usability to improve patient safety. Collaborating with AHRQ and helping to build upon the portfolio of excellent work to address potential safety issues will enable conducting further analysis to determine areas of vulnerability, and address those gap areas through the implementation of best practices or by the development of different interventions and tools aimed at improving patient safety.

eHI strongly supports ONC's intent to further improve patient matching with their health information, as this is a critical patient safety issue and is a complex and challenging issue to resolve once a patient has been mismatched. As the growth of health information exchange continues to accelerate nationwide, this will become more challenging to address as more providers and health care organizations contribute to a patient's record. We believe addressing workflow and process issues, data quality, functional and technical requirements, data standards and policy to support these efforts will further enhance the ability to accurately match patients with their health information. We look forward to learning more about this initiative and the opportunity to provide input during the development of this process.

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

eHI supports ONC's effort to work with organizations, as identified within the Plan, to foster a culture of safety and the dissemination of best – in -class tools and strategies to effectively reduce health IT related adverse events. We believe an emphasis on workflow and processes in using health IT for patient care is critical to a better understanding of how this is an enabler to support the capture, use, and dissemination of patients' health information.

818 Connecticut Avenue NW Suite 500 Washington, D.C. 20006
Tel: 202.624.3270   Fax: 202.429.5553
www.ehealthinitiative.org

5

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

eHI supports ONC's intent to investigate and take corrective actions. We strongly encourage the development and use of formal protocols and processes that support this effort that have been developed through an open, transparent and consistent approach. We applaud HHS' approach to leverage existing Federal authorities and programs in conducting these actions.

Promote a culture of safety related to health IT

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

eHI supports ONC's intent to identify health IT safety priorities through the implementation of a public – private process. We encourage the evaluation of vulnerable areas for patient safety and the development of measures through a harmonization process that will assist in reducing health IT related adverse events.

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

eHI supports this step as a requirement of the FDA Safety and Innovation Act of 2012. We believe ONC's active engagement in this effort will enable the inclusion of stakeholder and expert input in developing a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications that promote innovation, protects patient safety, and avoids regulatory duplication.

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

eHI supports this plan and encourage the timely and appropriate integration of the findings from the 18-month study as required by the FDA Safety and Innovation Act of 2012. We applaud ONC's alignment with other agencies in the development of the ONC Safety Program.

4. Encourage state governments to incorporate health IT into their patient safety oversight programs.

eHI supports the approach of encouraging states to leverage and integrate into existing patient safety efforts to reduce duplication and overlap, and encourage consistency in patient safety data for comparability.

5. Encourage private sector leadership and shared responsibility for health IT patient safety. (IOM Report, Chapter 6, "Shared Responsibility for Improving Health IT Safety")

818 Connecticut Avenue NW Suite 500 Washington, D.C. 20006
Tel: 202.624-3270   Fax: 202.429.5553
www.ehealthinitiative.org

6

eHI applauds ONC for acknowledging the need for all stakeholders to have a shared interest in leadership and responsibility for health IT patient safety. We agree with ONC's effort to collaborate with federal agencies and build upon the work and resources that have been developed to address patient safety issues. We strongly believe this approach will help in reducing duplication and administrative burden.

Conclusion

eHI is pleased with the proposals outlined within the Plan and support ONC's effort in reaching out to health care stakeholders for solicitation of input as the ONC health IT Patient Safety Program begins to take shape. We anticipate through this effort significant improvements shall be made. eHI appreciates the opportunity to provide comments on the Health Information Technology Patient Safety Action & Surveillance Plan and we look forward to providing further information in support of your efforts. If you have any questions, please contact me at Jennifer.Covich@ehealthinitiative.org.

Sincerely,

Jennifer Covich Bordenick
Chief Executive Officer
eHealth Initiative

818 Connecticut Avenue NW Suite 500 Washington, D.C. 20006
Tel: 202.624-3270   Fax: 202.429.5553
www.ehealthinitiative.org

7