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October 14, 2015

Karen DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Acting Assistant Secretary for Health
U.S. Department of Health and Human Services

Dear Dr. DeSalvo,

On behalf of the Electronic Health Record Association (EHRA), we would like to provide comments on the Office of the National Coordinator for Health IT's (ONC's) Health IT Safety Center Roadmap. We represent over 30 companies that develop and support operational electronic health record systems and other health IT solutions to the majority of hospitals and ambulatory practices across the country. These comments are informed by our collective experiences working with our customers to ensure that our products and services enhance patient safety as important tools in their risk management and quality improvement programs.

First, we agree with the Roadmap's emphasis on culture, rather than prescriptive solutions to the complex questions around health IT and patient safety. We believe that the Roadmap report is well balanced across all stakeholders and issues. The Roadmap aligns with our positions that there are shared responsibilities among all stakeholders and that an open dialog is essential to a learning healthcare system.

The proposed Health IT Patient Safety Center, or Collaboratory as it was recently named by ONC leadership, could be a national asset that is appropriately developed through initial government funding, with a well-thought-out plan to transition to a private/public partnership at a reasonable pace (i.e., five years). We agree that the Collaboratory should be non-regulatory and non-punitive, consistent with the goal of building a national learning healthcare system that EHRA has long supported.

EHRA also supports leveraging existing structures (e.g., patient safety organizations (PSOs) and the Medicare 5-Star programs for [Medicare Advantage](#), [Hospital Compare](#) and [Nursing Home](#) ratings) rather than superseding or replacing them. The models and experiences of these organizations will support the Collaboratory's emphasis on evidence-based decisions and non-punitive processes that encourage constructive dialog among stakeholders.

As stated above, leveraging PSOs is a positive concept and one we've supported for some time, but there are potential risks and limitations to this approach that will need to be addressed as part of the establishment of any HIT Safety Collaboratory:

- There are numerous disparate PSOs and, realistically, EHR vendors would only be able to effectively work with a subset. Working with one or two PSOs could not cover the needs of any vendor's entire customer base.
- A national aggregation of PSO data is in the process of rolling out, but value to date has not been established.
- Very few ambulatory and smaller institutional provider organizations have experience with this reporting or analysis process.
- PSO reporting and the Common Data Formats still need refinement for meaningful health IT reporting.
- The Patient Safety Act of 2005 does not afford vendors the confidentiality protections that it does to PSOs and providers, which makes vendor participation in PSOs problematic. This issue must be addressed in an effective manner to provide confidentiality for all who participate in Collaboratory activities and discussions, and to avoid removing the software developer from the review and analysis of any areas of concern.

In the current environment, where healthcare stakeholders are frequently being approached by new organizations with an interest in health information technology development, deployment, and use, the EHRA is cautiously supportive of the idea that the Collaboratory can add value by bringing stakeholders together to address the siloed nature of many existing safety initiatives and programs. However, we have some concern that the Collaboratory could become "just another new bureaucracy" that duplicates existing private sector and/or government initiatives rather than harmonizing them. What is in the structure to ensure it remains a value-added collaborative and not just an administrative burden? Despite strong positive statements in the Roadmap, we worry that the Collaboratory could create a "slippery slope" that could push vendors and providers into more certification and regulatory requirements for health IT development and implementation, rather than providing the learning environment that is intended.

Fundamentally, EHRA believes that a key requisite for the success of the Patient Safety Collaboratory is that, from the outset, ONC, CMS, HHS and other federal programs commit to supporting it programmatically – i.e., applicable Collaboratory recommendations would be incorporated into Medicare and Medicaid programs and provider efforts toward safety improvement recognized in the reimbursement formulas in both fee-for-service and risk-sharing programs. We also expect that if CMS commits to programmatically recognizing provider implementation efforts, then the private payers would follow CMS' lead as they often do for payment programs.

Further, although the Roadmap concept is a good start, it lacks specific and tangible objectives or the identification of where value can be derived by participating stakeholders in the event that they choose to do so. This value proposition is something that is going to need to be addressed proactively at the outset for the nation to move forward with any level of broad involvement.

We are also concerned with the funding range in the proposal. If this is intended to be a global program with benefit to society at large, the burden of ongoing costs to maintain the Center needs to be distributed to all deriving benefit, and not placed solely onto vendors and providers. Beyond those stakeholders referenced in Section 3.3 of the Roadmap, potential stakeholders should also include pharmaceutical companies, provider and medical associations, and specialty societies. We also point

out that representation of the “patients and family caregivers” category is key to the Collaboratory, and for that sector it is appropriate that funding come from taxpayers.

We appreciate and concur with the necessity of the concept of a “safe space” (i.e., protections for stakeholders who might report, respond, or investigate/study suspected health IT-related patient safety incidents), but we believe that stakeholders must have a good understanding about what such a “safe space” is and is not. We also believe that the concept of “safe space” must be defined prior to the creation of the Collaboratory, and may ultimately involve regulatory or Congressional action to enable those protections.

Finally, EHRA strongly suggests that the Collaboratory should be structured to ensure that no single stakeholder category, or even a subset of categories, is able to unilaterally impose policy on any other stakeholder category.

We will continue to monitor ONC’s progress on this important initiative and welcome any questions on the comments submitted.

Sincerely,

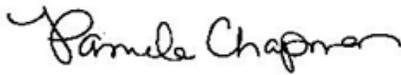


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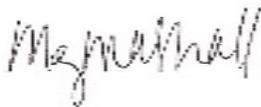
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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 30 companies that supply the vast majority of EHRs to physicians’ practices and hospitals across the United States. The EHR Association operates on the

premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

CC:

Andrew Gettinger, M.D., Chief Medical Information Officer, Acting Director, Office of Clinical Quality and Safety, ONC