AMERICAN ACADEMY OF FAMILY PHYSICIANS

STRONG MEDICINE FOR AMERICA

January 30, 2013

Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave. SW.
Washington, DC 20201

Re: Health IT Patient Safety Action and Surveillance Plan

Dear Dr. Mostashari:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 105,300 family physicians and medical students nationwide, I write in response to the Health IT Patient Safety Action and Surveillance Plan as issued by ONC for public comment on December 21, 2012.

According to the plan, it builds on HHS' overall commitment to patient safety, addresses recommendations made in the 2011 Institute of Medicine (IOM) Report, Health IT and Patient Safety: Building Safer Systems for Better Care, and leverages the shared responsibility among HHS and private organizations' existing programs that are focused on using health IT to improve patient safety to support a culture of safety.

The AAFP has a longstanding interest in and commitment to serving the needs of our members to improve the health of patients, families, and communities. As such, we offer the following comments and reactions to ONC's Health IT Patient Safety Strategies and Actions to assist in the development of the final plan.

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

The AAFP fully supports patient safety event and risk reporting, but reporting requirements must occur in a non-punitive environment and be compatible with the task and time constraints of ambulatory care delivery. Though evidence-based content and processes for adverse event reporting exist in the inpatient setting, the

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AAFP urges ONC to carefully consider how the outpatient setting presents a different set of workflows and potential event cascades leading to unique patient safety events and risk. Current Agency for Healthcare Research and Quality (AHRQ) Common Formats are inpatient specific and are more likely to be completed by support staff after the incident rather than by clinicians at the point of care. The AAFP calls for the adoption of a streamlined, clinical workflow compatible mechanism that provides consistency in reporting across multiple, independent end-user physicians who may not have deep domain knowledge of patient safety event and risk reporting. The AAFP remains concerned that protracted HIT product development cycles present a significant barrier to the application of knowledge collected by patient safety event and risk reporting, even when significant defects are identified. To enable the rapid development and implementation of software tools that decrease event reporting burden and improve patient safety, the AAFP calls on ONC to require EHR vendors to support the analysis of patient safety events and risks by allowing read-only access to their backend databases for independent evaluation and appropriate safety interventions.

The AAFP believes that developers, purchasers, implementers, clinical and administrative end-users, researchers, policymakers, physician, patients, and families all have a shared responsibility for patient safety. Though ONC currently has direct influence on HIT vendors participating in certification for the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, the AAFP believes a comprehensive approach that clarifies expectations and empowers appropriate action by all stakeholders must be adopted. Acknowledgment of and response to patient safety events and risks might be significantly shaped by an organization's financial concerns, legal issues, or ingrained business practices. Reports of patient safety events and risks therefore should flow directly from physicians to independent third parties in addition to being channeled to product vendors and implementing health care organizations for evaluation and remedial action as appropriate.

In the draft ONC document, Figure 1 graphically represents information flow from patient safety organizations (PSO) to the AHRQ. The AAFP believes that another layer should extend down to the level of the HIT end-users themselves. In solo practices, those end-users are the "Providers" in the figure, but in larger health care organizations or in more complex vendor environments, there are likely to be complex sociotechnical relationships among "Providers" that must also be addressed (and diagrammed) to ensure appropriate understanding of patient safety event reporting and risk mitigation. As more family physicians chose health system employed positions, their ability to independently identify and report patient safety events and risks must be clearly understood and preserved.

EHR technology certification attempts to address an array of issues much broader than HIT patient safety. To date, the AAFP is unaware of any post-market surveillance performed as part of certification, any user complaint monitoring and redress, or any censuring or revocation of certifications by ONC-authorized certifying bodies, leaving significant gaps in our understanding of the effectiveness of the

existing EHR certification process. Also, regarding the repurposing of existing evaluations, CMS surveyors audit only a small fraction of ambulatory practices annually. With a focus on fraud, they may not have the opportunity to interact with the practices that are in most need of patient safety evaluation and improvement.

The AAFP believes it will likely be several years before AHRQ's Quality & Safety Reporting System (QSRS) and its underlying Common Formats are applicable to the ambulatory care setting. The AAFP encourages more distributed efforts to more effectively bring the lessons learned from reported patient safety events and risk mitigation from the bench to all points of care, be it in the hospital room, exam room, bedroom, or living room. Similarly, the Manufacturer and User Device Experience (MAUDE) device reports will unlikely be pertinent for some time to primary care ambulatory practices.

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

It is posited, but not proven, that the EHR certification process has positively impacted clinical care and could be further focused to improve the safety of HIT products. Individual experiences of AAFP members, many using EHR technology for over a decade, have not shown improvements in clinical care through upgrades to meaningful use stage 1 certified EHR technology (CEHRT). Some members have identified instances where implemented MU requirements have interfered with their ability to focus on clinical care.

Privacy and security risk assessments have been a difficult aspect of meaningful use compliance for small practices even though the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules have been in place for over a decade. Small practices will require extensive guidance in conducting health IT safety risk assessments given the current lack of evidence and best practices, particularly in the ambulatory care setting.

Though the AAFP agrees with ONC that inaccurate, incomplete, and inaccessible clinical records are detriments to patient safety, we do not believe that improving the current process of bullet-based documentation for reimbursement will positively impact patient safety. Rather, the AAFP believes new reimbursement models and new clinical documentation expectations must be established to enhance a culture of patient safety and risk mitigation.

The AHRQ's existing portfolio of tools and reports apply predominantly to the inpatient setting. Though the outpatient setting presents significantly more variation in EHR systems and workflows, the ambulatory setting is a key target for research on patient safety issues and should be a focus of research funding, solutions development, and implementation efforts. Patient identity is a key element of patient safety - "right care for the right patient at the right time" - and continues to be a complex technical and political issue. Both technical and policy components must be

addressed in concert regarding the acceptable balance between patient safety and patient privacy.

The ability of a hospitals' independent medical staff organization to oversee quality and safety continues to erode as hospital systems increasingly adopt employed physician strategies. The AAFP is concerned that our members' ability to implement and assess quality and safety initiatives in their own practices is being eroded by expanding organizational structures and bureaucracy.

Entities that are divested from the business models of care delivery and can truly focus on patient safety - rather than organizational fraud - are essential to care quality and patient safety improvements. As health IT and its expanding functionality are more broadly adopted across inpatient and ambulatory health care settings, it will become increasingly difficult to disambiguate health IT patient safety issues from general patient safety issues. An integrated approach to patient safety improvement that holistically evaluates products, processes, and people is imperative to sustained success.

The AAFP welcomes the opportunity to provide its members with resources to increase awareness of HIT safety issues and their successful mitigation. We appreciate ONC's offer of collaboration in turning best evidence into impactful educational experiences for practicing family physicians, residents, and students in ambulatory, primary care settings.

Lead: Promote a culture of safety related to health IT

Although initial activity in new programs may require a theory-based approach, the AAFP believes that rapid evaluation, operationalization of lessons learns, and conversion to an evidence-based approach is essential for optimizing outcomes. Not all health IT products or applications bear the same level of patient risks. Regulation must promote the public welfare, but must do so with minimized burden on the regulators and the regulated, allowing for optimal growth and improvement. A spectrum of caution and regulation must emerge to align with the spectrum of likelihood and degree of harm.

The AAFP applauds ONC's proposed coordination of state patient safety efforts and aggregation of data for national representation and regional comparisons. Standardizing existing patient safety efforts, where appropriate, will increase our knowledge of and ability to improve patient safety related to HIT use. The AAFP is committed to improving patient safety through the appropriate application of health IT solutions and to continuously improving the safety, functionality, and usability of health IT in primary care.

As strong supporters of HIT, we thank ONC for the opportunity to offer these recommendations. We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have or clarifications you

might need. Please contact Jason Mitchell, MD, the AAFP's Director of the Center for Health IT, at 913-906-6000 ext. 4102 or jmitchell@aafp.org.

Sincerely,

Glen Stream, MD, MBI, FAAFP
Board Chair