



Physicians Caring for Texans

February 4, 2013

Farzad Mostashari, MD, ScM  
Office of the National Coordinator for HIT  
Patriots Plaza III  
355 E. Street, SW  
Washington, DC 20201

RE: HIT Patient Safety Action and Surveillance Plan

Dear Dr. Mostashari:

The Texas Medical Association (TMA) is a private, voluntary, nonprofit association of Texas physicians and medical students. TMA was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health. Today, our maxim continues in the same direction: "Physicians Caring for Texans." TMA's diverse physician members practice in all fields of medicine.

TMA is strongly committed to improving patient safety in all aspects of Health Information Technology (HIT), not just Electronic Medical Records. We have worked closely with multiple organizations in Texas and nationally, most recently hosting a HIT Patient Safety Summit where physicians, PSO, liability carriers and vendor representatives exchanged ideas, TMA is grateful for the thought that your Office has put into this complex subject.

TMA believes that significant patient safety risks exist now and new ones will emerge in the next one to two years as many EHR and other HIT vendors merge or go out of business. Therefore it is imperative to set mandatory deadlines and have a robust reporting and learning system in place now, not later. We are extremely concerned that the proposed Plan is lacks the specificity necessary for success. For example, in several cases the Appendix C timeline contains the words "should" or "can require" rather than "will". To address this, TMA recommends that ONC revise Appendix C to make the tasks listed in it required rather than optional.

TMA feels that responsibility for the Plan lacks focus. We recommend the appointment of a highly-visible "HIT Safety Czar" to oversee, coordinate *and market* health IT patient safety across the multiple organizations, programs, developers and end users.

TMA is also concerned that the document contains fundamental weaknesses that will cripple the effectiveness of the programs, such as reliance on voluntary reporting and funding.

TMA is glad to see that patient safety organizations (PSOs) are proposed as the recipients of event reports. However, the capabilities, strategy and funding of PSOs vary widely, making it unrealistic to think that a strong safety reporting system can be built from the current PSOs without significant additional funding, technology, and programmatic re-direction. TMA believes strongly that a single or at a maximum two PSOs financed to focus on HIT Patient Safety reporting would probably be the most efficient and effective way of managing this process rather than a federation of PSOs.

The TMA Committee on HIT recently previewed the SAFER guides developed by Dean Sittig, PhD and Hardeep Singh, MD and are very impressed by their work. TMA recommends that ONC work with medical and other professional societies to gain endorsement of these guides to ensure widespread dissemination and education.

Finally, TMA believes strongly that reporting by physicians needs to be done in workflow-friendly ways. For example, reporting tools need to be developed such as a “green button” within EMRs/other HIT products that captures standardized background system-level information with a single click and sends it to the appropriate reporting body (e.g. the PSO or the organization’s safety officer).

On behalf of our more than 47,000 member physicians, the TMA appreciates this opportunity to review these and the specific comments and recommendations on the following pages regarding the above- referenced document. We look forward to helping you create the real plan of action that will truly support the “Culture of Safety” that we all desire.

Should you have any additional questions or need any further information, please do not hesitate to contact me directly or contact Shannon Vogel of the TMA at 512-370-1411.

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph H. Schneider". The signature is fluid and cursive, with a large initial "J" and "S".

Joseph H. Schneider, MD, MBA  
Chair, *ad hoc* Committee on Health Information Technology

## **Additional Comments and Recommendations**

Page 8 talks about continuously improving the safety of health IT, but seems to focus on CPOE and CDS. While these are vital parts of the process and have great potential to improve safety, TMA would like to emphasize that they are not the only factors affecting care and safety. Other examples of HIT that impact safety include barcoding of medications, the accessibility and usability of nursing documentation, the integration of HIE data into workflow and even concepts such as how safety is assured after downtimes.

Page 9 mentions the importance of establishing mechanisms that facilitate reporting among users and developers. TMA believes that patients increasingly will be using HIT and finding a way for them to report incidents is important to keep in mind. Also, HIT safety should be inclusive of all health technologies, such as PHRs and HIEs, not just EHRs.

Page 11 and page 30 refer to developers and professional groups establishing a code of conduct that “ensures vendors work with safety organizations to aggregate and analyze events and promote adverse event reporting among providers”. TMA is concerned that this will not materially affect industry accountability and generate the changes that are needed. For example, what if a developer does not comply with said code of conduct? There is no penalty or impetus for change. We recommend that the ONC look to the FDA Good Manufacturing Practices as a model; these are not voluntary but yet they are general enough that innovation is not stifled.

Page 11 has a recommendation that developers should work with PSOs. Without legal protection for reporting, TMA has grave concerns that this will not happen. We feel that immediate action to remedy this is needed for a PSO-centered program to work

Page 13 refers to ONC working with ONC-ACBs to track and document complaints and then take appropriate action. TMA is concerned that there is insufficient detail as to how “appropriate action” will be determined. Example questions include:

- What kind of action may be taken against the offending developer?
- How will users of the product be notified?
- Is there consideration of requiring compensation for remedying problems caused by external developers?
- Who will assist users with data migration strategies if the product offenses are so egregious that use of the product use must cease immediately?

Page 13 states that “CMS plans to align its health and safety standards for providers and suppliers and its interpretive guidance, as needed, related to the safety of health IT with this Health IT Safety Plan. Working with ONC, CMS plans to also develop training for surveyors that enhances their ability to identify safe and unsafe practices associated with health IT”. TMA is eager to know how we and others might participate in the development of these.

Page 15 states that “ONC will monitor health IT adverse event reports to the FDA MAUDE database<sup>21</sup> to identify potential trends of health IT patient safety risks.” TMA is generally supportive of this, but further specificity is needed.

Page 19 states that “ONC will work with developers to request voluntary corrective action when HHS becomes aware of a potential serious safety risks through the programs described in this Health IT Safety Plan”. TMA is very concerned with this statement, because logically if developers do not take action, serious safety risks will continue to exist. We find this to be unacceptable.

Page 22 refers to the use of the Common Format tools. TMA supports this, but the tools need to be rapidly enhanced to include the ability to handle images, including screen shots, photos and videos, as these often are the only way to communicate HIT issues effectively.

Page 25, Recommendation 1.b. TMA recommends that SHARP-C or the equivalent usability testing and evaluation should be mandatory for all certified EHR vendors.

Page 27, Recommendation 2. The action does not address the recommendation.

Page 27 Recommendation 2 states that “ONC will engage developers and facilitate the development of a voluntary code of conduct that ensures business practices are in place that promote adverse event reporting.” There are many disincentives to adverse event reporting, so allowing this to be voluntary will bias reporting and analysis, with the net result being probable failure of the program to achieve its objectives.

Page 28, Recommendation 3. TMA supports wider communication of user experiences and recommends that ONC consider support for EHR rating systems already in place such as those developed by American EHR Partners and the American Academy of Pediatrics.