AMA
AMERICAN MEDICAL ASSOCIATION

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October 31, 2012

Carolyn M. Clancy, MD
Director
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road, Suite 2000
Rockville, MD 20850

Re: Prototype Consumer Reporting System for Patient Safety Events

Dear Dr. Clancy:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the Agency for Healthcare Research and Quality's (AHRQ) proposed prototype consumer reporting system for patient safety events. According to AHRQ, the purpose of this prototype is to enable patients to report on patient safety events that they perceive to be caused by medical errors that resulted or nearly resulted in patient harm or injury. The AMA strongly supports patient engagement in systems to enhance patient safety and improve quality of care. We also strongly support patient privacy rights and the need to scrupulously protect sensitive medical information. Patient Safety Organizations (PSOs) are the mechanism under federal law to ensure that information about errors that are submitted for purposes of evaluating and improving patient safety are legally protected and confidential, along with the identity of the reporter. **We are extremely concerned that a new, parallel reporting system for patients being considered by AHRQ might not have these protections, and would not be a covered entity under the Health Insurance Portability and Accountability Act (HIPAA), leaving both patients and the subjects of their reports in extremely vulnerable positions.**

AHRQ's Technical Expert Panel's (TEP) concerns about the ability of consumer reporting systems to keep information confidential and protected from legal proceedings were highlighted in AHRQ's July 2011 report, "The Designing Consumer Reporting Systems for Patient Safety Events:"

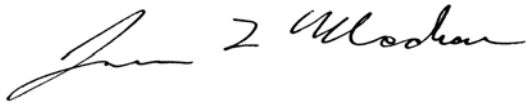
> Private individuals or government agencies could obtain legal orders (e.g., subpoenas) requiring the release of information from consumer reporting systems despite assurances of such information's confidentiality. In addition to discouraging future confidential consumer reports of patient safety events, release of confidential information could jeopardize the future medical care for involved individuals and potentially even result in legal challenges (e.g., defamation suits) with associated economic damages. For whistleblowers (individuals who submit reports on patient safety events at health care facilities where they work), the release of confidential information could result in loss of employment and substantial damage to future career options. PSOs have been granted protections related to such legal actions.

Absent clear privacy and security protections at a minimum, we believe information submitted to the proposed prototype system must be de-identified to protect highly identifiable incidences, individuals involved, and sites where the incident may have occurred. In addition, **we urge AHRQ to form an expert advisory panel comprising representatives from consumer, hospital, and physician organizations, including the AMA and other patient safety experts, to help design and monitor implementation of the proposed prototype.** This advisory panel would help ensure that any potential prototype systems for consumer reporting of patient safety events are thoroughly assessed and adequate legal protections are incorporated to protect the confidentiality of this type of reporting. **The AMA believes that these steps are necessary before any such system can be implemented.**

The AMA agrees that more and better information is needed for health care professionals and systems to determine how to avoid medical errors. If we want to prevent incidences of patient safety events, we will need to learn from everyone involved in health care, including patients. Patients have a unique and valuable perspective, and so it is especially important to include patients in the learning process. Not only should patients have the ability to confidentially report on patient safety events, but the system should include a mechanism to follow-up with health care practitioners and organizations that may have been involved in the event, so that further information about what happened is collected and analyzed. Even if a patient perceives that an error occurred that did not, it would be valuable to know, so that we are able to better address incorrect perceptions and patient concerns about misperceived errors in their care. **Feedback to patients and health care providers in a confidential, legally protected manner will also help to ensure that the ultimate goal of the Patient Safety Act is met—to advance culture, process, and system changes that ultimately enhance patient safety in the delivery of quality health care.**

The AMA is committed to providing feedback to AHRQ on a continuous basis to improve patient safety event reporting. If you have any questions or need additional information, please do not hesitate to contact Carol Vargo, Division of Federal Affairs, at 202-789-7492, or by email at carol.vargo@ama-assn.org.

Sincerely,



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