November 9, 2012

Ms. Doris Lefkowitz
Reports Clearance Officer
Agency for Healthcare Research and Quality
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Rockville, MD 20850

Submitted electronically to: doris.lefkowitz@ahrq.hhs.gov

RE: **A Prototype Consumer Reporting System for Patient Safety Events, Published September 10, 2012**

Dear Ms. Lefkowitz:

The American Nurses Association (ANA), which is the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses, appreciates the opportunity to respond to the Agency for Healthcare Research and Quality (AHRQ) request for funding the pilot project entitled, *A Prototype Consumer Reporting System for Patient Safety Events*. The project cites three goals: 1) To develop and design a prototype system to collect information about patient safety events; 2) To develop and test Web and telephone modes of a prototype questionnaire; and 3) To develop and test protocols for a follow-up survey of health care providers.

This project appears to have the best intentions; however, for the reasons presented below the ANA recommends that AHRQ complete additional improvement work prior to implementing a pilot project. Further, the ANA recommends that AHRQ invest in improving patient use of existing quality-related public reporting systems, such as Hospital Compare, Nursing Home Compare, and Home Health Compare, as well as improving self-reporting systems, such as health care organizations' advocacy or ombudsman programs, and Medicare Quality Improvement Organizations (QIOs), before engaging in pilots of new consumer reporting systems.

There are several effective methods in use for reporting patient safety events. For instance, many hospitals and health care systems employ patient representatives or ombudsmen. Medicare beneficiaries could report to QIOs. The AHRQ report does not mention the former and gives little discussion to the latter, even though these services facilitate collection of consumer and patient safety events and empower patients to present concerns and report events in a non-threatening and effective manner. Individuals knowledgeable of these and other extant methods to capture and mitigate error could provide AHRQ with valuable knowledge that could be used to improve and maximize the effectiveness of these resources before AHRQ resorts to development and testing of new methods.

The ANA suggests that AHRQ review the challenge promoted by the Office of the National Coordinator for Health Information Technology (ONC) to develop a handheld computer application (app) for reporting patient safety events[1]. The ONC notice cites several important criteria required for an app to win the challenge. Those criteria, while developed by another office within the Department

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[1] Challenge.gov. Reporting Patient Safety Events (http://challenge.gov/ONC/349-reporting-patient-safety-events).

of Health and Human Services and for a different purpose, are sufficiently broad and integral to the success of any patient safety reporting system that AHRQ might benefit from including them in its own project. In the text of the challenge document, the ONC states, "…it is important to innovate beyond the existing tools so that a new system will:

1) Collect and analyze information that characterizes patient safety events in a standardized, discrete, measurable way
2) Increase the rate of reporting of patient safety events and improve the quality of the reported data
3) Leverage existing health information technology (HIT) to eliminate duplicate data entry, as well as transcription and transposition errors
4) Analyze patient safety event data to provide useful reports and actionable information to providers and PSOs"

As they currently read, neither the report nor the subsequent funding request sufficiently address or clarify how the pilot system might meet those criteria.

Other issues could limit the effectiveness of a pilot. First, AHRQ mentions, but does not specify, methods for patient engagement, data sharing, interoperability among systems, confidentiality of data, or public reporting of results. Further, the report does not address the potential for high costs associated with matching the reported error with the health care record. This matching could be particularly challenging and costly in paper-based or disparate electronic systems. Additionally, the report wisely recommends confidential data collection; however, the technical expert panel (TEP) also recommends an option to report anonymously. The TEP does not clarify how anonymous reports might contribute to error mitigation or reduction. Finally, AHRQ does not address protections that might need to be placed to prevent negative repercussions to individual clinicians named in any error reports.

In addition to overlooking the several existing methods of patient reporting, the report does not acknowledge or address the role of legal remedies. The ANA certainly does not endorse legal remedies for this purpose. However, ANA recognizes that many lawsuits arise from claims regarding medical errors. These can involve claims of malpractice, personal injury, and product liability contributing to personal injury or death. It could benefit AHRQ to acknowledge the presence of legal remedies and determine methods to mitigate errors before victims resort to legal remedies to effect changes. For example, AHRQ could investigate whether the proposed pilot would increase, decrease, or have no effect on the frequency of legal remedies. Moreover, the report should address how to protect the information collected by the system from improper usage in legal actions.

Most troubling is the fact that the survey questions or drafts of such questions are not included in the report. In a recent New York Times interview[2], Director Clancy gave some clues as to the content of several questions. The article reports one draft question that directs respondents to, "Tell us the name and address of the doctor, nurse or other health care provider involved in the mistake," indicating that this information and permission to share it with clinicians could improve safety. The article lists a series of possible responses to answer why an event occurred. These include:

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[2] New System for Patients to Report Medical Mistakes (2012, September 22). New York Times. (http://www.nytimes.com/2012/09/23/health/new-system-for-patients-to-report-medical-mistakes.html?_r=0).
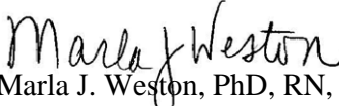
- "A doctor, nurse or other health care provider did not communicate well with the patient or the patient's family."
- "A health care provider didn't respect the patient's race, language or culture."
- "A health care provider didn't seem to care about the patient."
- "A health care provider was too busy."
- "A health care provider didn't spend enough time with the patient."
- "Health care providers failed to work together."
- "Health care providers were not aware of care received someplace else."

Unfortunately, these types of subjective and judgmental statements could misdirect respondents away from actually helping to solve the problem, but instead promote blaming an individual for the event. Additionally, none of the questions or answers cited adds valuable information from the reported incident that could inform a root cause analysis. Further, the questions and answers cited do not reflect the systems approach to error prevention and remediation effectively promoted by such organizations as The Institute of Medicine.

The ANA supports the idea of developing a method to improve consumer and patient access to an effective and non-judgmental method of detecting, reporting, and mitigating health care errors. As a profession, registered nurses are the most proximal and, therefore, most available clinicians providing for the health care needs of patients and their families. Registered nurses strongly advocate for the reduction of error and improvement of care structures, processes, and outcomes. In this case, the ANA does not believe that the current project is ready for piloting until it addresses the multiple issues cited above.

If we can be of further assistance, or if you have any questions or comments, please feel free to contact Darryl Roberts, Senior Policy Fellow, National Center for Nursing Quality at Darryl.roberts@ana.org or 301-628-5081.

Sincerely,

Marla J. Weston, PhD, RN, FAAN
Chief Executive Officer
American Nurses Association

cc: ANA President Karen A. Daley, PhD, MPH, RN, FAAN