



April 14, 2008

Center for Quality Improvement and Patient Safety
Attention: Patient Safety Act NPRM Comments
AHRQ
540 Gaither Road
Rockville, MD 20850

Re: RIN: 0919-0AA01, Patient Safety and Quality Improvement Notice of Proposed Rulemaking

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the Patient Safety and Quality Improvement Notice of Proposed Rulemaking. ASHP represents pharmacists who practice in hospitals and health systems. The Society's more than 30,000 members include pharmacists and pharmacy technicians who practice in a variety of health-system settings, including inpatient, outpatient, home care, and long-term-care settings.

ASHP policy calls for statutory protection for medication error reporting. It is the Society's policy to collaborate with other health care providers, professions, and stakeholders to advocate and support federal legislative and regulatory initiatives that provide liability protection for the reporting of actual and potential medication errors by individuals and health care providers, and to seek federal liability protection for medication error reporting.

In 2005, in accordance with this policy, ASHP worked with other organizations to urge Congress to pass a patient safety bill that creates an environment for safety, confidentiality, and information sharing. ASHP was pleased when the Patient Safety Act (Act) was passed, and applauds the Agency for Healthcare Research and Quality (AHRQ) for publishing its notice of proposed rulemaking implementing the patient safety legislation. ASHP does, however, have some concerns relating to the proposed rule. These concerns are listed below, labeled with a citation to the section of the proposed rule being discussed, as requested by AHRQ in its proposed rule.

Section 3.20 (Identifiable Patient Safety Work Product)

Some health care providers submit anonymous safety self-assessments. These providers may not provide their name or location, however the information they provide is sufficient to demonstrate the reporting facility is a provider. ASHP recommends that AHRQ clarify that anonymous reports are patient safety work product (PSWP), provided there is enough information to identify the reporter as a "provider" as defined under the Act.

Section 3.20 (Patient Safety Evaluation System)

ASHP agrees with AHRQ that documentation of a patient safety evaluation system would be a prudent business practice. ASHP further agrees that, as part of the enforcement program, AHRQ should expect entities to follow sound business practices in maintaining adequate documentation regarding their patient safety evaluation systems to demonstrate their compliance with the confidentiality provisions. However, the Society recommends that AHRQ require a patient safety evaluation system to be documented in order to ensure it has met and is in compliance with confidentiality obligations.

Section 3.20 (Patient Safety Work Product)

ASHP believes that information assembled or developed by a provider should have a short period of protection for information assembled but not yet reported prior to its transmittal to a PSO. Additionally, ASHP recommends that reports, while being assembled, should be protected under the Act.

Section 3.20 (Provider)

ASHP commends AHRQ for including pharmacists as providers in the proposed rule. ASHP recommends that AHRQ also include medical product vendors in the list of providers. These companies should be protected under the Act so they are able to share error reports and other quality data with PSOs. Additionally, the Society recommends that AHRQ include pharmaceutical companies under the definition of “provider” so these companies may share adverse drug event reports with PSOs.

Section 3.101

ASHP recommends that AHRQ require PSOs to notify providers (similar to the HIPAA Privacy Rule business associate notification requirement) when PSWP is impermissibly disclosed or a security breach occurs. The Society believes that current standards for managing sensitive health care data between providers, payers, and regulators should apply to PSOs.

Section 3.104(d)

ASHP recommends that the Secretary consider posting the following materials on the AHRQ PSO website to assist PSOs and providers: The final rule implementing the Act, individuals at AHRQ who can be contacted for information, and a list of PSOs with links to their websites.

Section 3.104(e)

ASHP believes the AHRQ PSO website should indicate if the 3-year period of a PSO’s listing is about to expire and whether the PSO has not sought continued listing. There should be a deadline to relist so that providers do not engage a PSO if their listing is about to expire.

Section 3.206(b)(4)(iii)

The Food and Drug Administration's (FDA) MedWatch program and manufacturers should be able to receive PSWP, including near misses, from the PSOs so that any need for product labeling changes is communicated quickly, and any necessary labeling changes can be made. ASHP recommends that AHRQ allow a PSO to report PSWP, including near misses, to an entity that is required to report to the FDA. These reports should maintain their legal protections under the Act.

ASHP appreciates this opportunity to present its written comments on the Patient Safety and Quality Improvement Notice of Proposed Rulemaking. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,

A handwritten signature in cursive script that reads "Justine Coffey".

Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs