Institute for Safe Medication Practices
200 Lakeside Drive, Suite 200
Horsham, PA 19044
www.ismp.org

April 14, 2008

Agency for Healthcare Research and Quality
Office of Civil Rights
HHS
Federal eRulemaking Portal: http://www.regulations.gov

RE: RIN 0919-AA01 - Patient Safety and Quality Improvement Act of 2005

To Whom It May Concern:

The Institute for Safe Medication Practices (ISMP) is the nation's only nonprofit organization devoted entirely to medication error prevention and safe medication use. ISMP strongly supports voluntary reporting by providers as essential to improving the medication-use process, and appreciates the opportunity to offer written comments about the proposed regulations to implement the Patient Safety and Quality Improvement Act of 2005 (PSA).

The national Medication Errors Reporting Program (MERP), operated by ISMP in cooperation with the United States Pharmacopoeia (USP), uniquely receives voluntary reports of errors directly from healthcare professionals. The information derived from investigation and analysis of these reports is communicated back to healthcare practitioners and their organizations (providers) through ISMP's initiatives to improve the medication use process, directly impacting product and practice changes.

ISMP's productive experience working in collaborative relationships with providers and other patient safety organizations has convinced ISMP that the free flow of information among and between all relevant parties is critical to improving the quality and safety of health care services. The proposed PSO regulations, which encourage broad reporting, are compatible with this experience, and raise several issues in this regard:

1. ISMP often conducts national medication safety self assessments that health care providers complete and provide their results anonymously to ISMP, e.g., some providers may not provide their name or location when completing these forms. Still, the information provided is sufficient to confirm that the reporting facility is a provider as defined in the Notice of Public Rulemaking (NPRM) (§3.20, p. 8173). These anonymous reports provide critical aggregate comparison data, and are also often used by the facilities as a benchmark for evaluation and re-evaluation of the effectiveness of their own safety performance improvement efforts. Please clarify that anonymous reports will be considered PSWP as long

as the information contained therein is sufficient to identify the reporter as a "provider" under the Act.

2. As noted in the NPRM (p. 8121), self-assessments and other reports often require a reasonable time period to complete, occasionally as long as several weeks. Please clarify whether such reports, while under preparation in accordance with a clearly defined patient safety evaluation system for reporting to a PSO, will be afforded protection under the PSA during this preparation period.

The USP-ISMP MERP is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and widely disseminates recommendations for prevention through various means including journal columns and articles, frequent newsletter publications, media releases, electronic communication, etc. The program is operated by the U.S. Pharmacopoeia (USP) in cooperation with ISMP. This program generates issues for consideration:

3. Under the agreement between ISMP and USP, reports may be made to either organization by telephone, mail, or, most commonly, through the ISMP and USP websites. In all circumstances, reporters are advised that all reports are shared reciprocally between ISMP and USP. ISMP uses these reports to follow up with the reporter to analyze the underlying incident and develop recommendations for prevention, and, therefore, the identity and contact information for the reporter is essential. Likewise, USP may use the reports in the same manner. Please confirm that disclosures made pursuant to 1.) a contract between PSOs that 2.) calls for sharing of PSWP back and forth between the PSO's for the purpose of undertaking patient safety activities by each PSO on behalf of the other is a permitted disclosure under §3.206(b)(4)(ii).

4. Consider and advise whether multiple PSO's, with different and complementary specialties and interests, may, with clear and appropriate notice to the reporting provider, develop a single reporting portal.

5. Please consider expanding the definition of "provider" (§3.20) to include pharmaceutical companies and medical device manufacturers, thus enabling these entities to share adverse drug events with PSOs in accordance with the requirements and protections of the Act.6.

6. When safety is of concern, information developed from the MERP reports is sent to third parties such as the **Food and Drug Administration** (FDA) MedWatch reporting program so that needed changes may be made as soon as possible. Reporters are advised, prior to reporting, that the information they provide will be sent to the FDA, and that they have the option of including their identity and location on these reports. Please consider expanding §3.206(b)(7) to allow a PSO to report PSWP to the FDA and/or to an entity required to report to the **FDA**.

7. Similarly, when safety is of concern, information developed from the MERP reports is sent to third parties such as to the **manufacturer/labeler** so that needed changes may be made as soon as possible. Reporters are advised, prior to reporting, that the information they provide will be sent to **third parties**, and that they have the option of including their identity and location on these reports. Please consider expanding §3.206(b)(7) to allow a PSO to report PSWP to **an entity required to report to the FDA.**

Confidentiality of information is a stated concern of the PSA, and comparability of information has been articulated as one of the long-range goals of the PSA. Both issues impact the format in which PSWP is reported and the manner in which it is stored. These considerations give rise to additional questions:

8. We believe that the nonidentification requirements of §3.212 are too stringent and will actually work in opposition to the purpose of the NPRM by making it impossible to provide to the public needed information regarding certain medical safety issues. For example, a PSO that receives reports from the sole provider of a particular service, or the single provider in a particular geographic region, may remove all of the listed identifiers and yet the provider or reporter may still be identifiable. In this circumstance, contextual nonidentification would be virtually impossible to achieve, yet the severity of the risk to health and safety may compel immediate public notification of the event. ISMP publications are a source of timely information on medication error prevention that is relied upon by practitioners and the industry to effect change. This would present an intolerable dilemma for a PSO. We strongly urge the elimination of the nonidentification standard and suggest that it be replaced with the clearer, more workable anonymization standard set forth in §3.206(b)(4)(iii).

9. Safety-minded organizations impacted by diminishing resources, ever-changing technology, complex therapies, and newly marketed pharmaceutical products are being challenged to implement high-leverage medication error prevention strategies to reduce the possibility of patient harm. These organizations see the value of learning as much as they can about their current state of medication use in order to begin the process of organizational change and process improvement. The ability of ISMP consulting staff to work confidentially and objectively is fundamental to the willingness of all types of practitioners and organizations to engage in these evaluations. Please clarify that the disclosure of information regarding contractual relationships required by §3.102(d)(2) may be made in such a way so as not to breach obligations of confidentiality imposed outside of the Act (e.g., as contractually agreed, other statutory obligations, etc.), and so as not to contravene the purposes of the Act by discouraging providers from requesting assistance or services from PSOs.

10. Reports from "non-providers" are often the earliest and best source of information regarding medication safety issues. Indeed, in certain situations consumer-use may be the only nexus at which an incident might occur. Handling these "non-provider" reports in the same process as reports received from providers can result in early identification and correction, often averting serious errors much more quickly than would otherwise occur. For example, ISMP recently received a report from a parent informing us the death of a child due to an overdose of Cerebyx. We quickly investigated the matter, advised the FDA (which resulted in the issuance of an FDA advisory) and publicized the issue with recommendations in the ISMP April 10, 2008 Newsletter. Please consider modifying §3.106(b)(2)(i), regarding Separation of Systems, to permit all reports obtained by a PSO to be kept together, rather than segregated by type of reporter (e.g., reports from consumers, international providers), as long as 1.) all information is kept protected in accordance with the security and confidentiality requirements of the Act, and 2.) PSWP is readily identifiable and retrievable.

11. ISMP analyzes medication error reports as the foundation for its suggestion of credible recommendations on how to prevent medication errors. ISMP established a wholly-owned subsidiary that works with manufacturers to reduce risk related to medications before they reach the market. This subsidiary learns about potential errors, actual errors and error-reduction strategies through its relationship with ISMP and, informed by this knowledge *and without disclosing PSWP*, analyzes the potential for confusion and/or medication errors presented by a proposed trademark, package or label. Please clarify that a wholly-owned subsidiary of a PSO, engaged in patient safety activities under the direct control of the PSO, will be considered a workforce member of the PSO and that, in this context, the sharing of PSWP between a PSO and its wholly-owned subsidiary will constitute a use of the information within the entity and will not be a disclosure regulated or prohibited under the Act (pp. 8117-8118).

We appreciate AHRQ's consideration of these matters, and its willingness to engage in thoughtful dialogue with the organizations and individuals impacted by these regulations. The opportunity to discuss these issues with representatives from AHRQ has been very helpful as we have developed our comments. We would be happy to discuss these or any other aspects of the NPRM further if that would be useful to AHRQ or any of the other interested parties.

Very truly yours,

Michael R. Cohen
President