

Legal Protection of Patient Safety Information Submitted to ISMP Patient Safety Organization

Healthcare practitioners and organizations often send patient safety information to ISMP in the form of hazard reports, error reports, survey data, and self-assessment data. In addition to the usual high standards of confidentiality associated with any patient safety information submitted to ISMP, we would like to remind practitioners and organizations that ISMP is a federally certified Patient Safety Organization (PSO). This certification offers federal legal protection of patient safety information submitted to ISMP as a PSO if the following criteria, described in detail in the Federal Patient Safety Act,¹ are met: The patient safety information was collected within a **patient safety evaluation system** for the purpose of reporting to the ISMP PSO; the patient safety information is reported to ISMP by a healthcare **provider**; the patient safety information is documented by the healthcare provider as being collected for reporting to a PSO; and the patient safety information is documented by the healthcare provider as being **patient safety work product**.

Simply stated, any patient safety information that has been collected within an organization's **patient safety evaluation system** and prepared for submission to ISMP as a certified PSO is granted federal protection of that data. This means that the information cannot be used against the healthcare provider or any of its employees during a disciplinary action or civil lawsuit. The information is protected from legal discovery, and neither ISMP nor the healthcare provider will be required to disclose the data.

Information submitted to ISMP as **patient safety work product** is not restricted regarding its use for quality and safety improvement purposes within the healthcare **providers'** system. There is no restriction for **providers** who want to share **patient safety work product** with their workforce for the purposes of improvement. However, **providers** should inform staff with whom **patient safety work product** is shared of the need for careful handling, labeling, and discussion so an unauthorized disclosure of the information is not made.

A contractual agreement between the healthcare provider and ISMP is NOT required for protection of the patient safety information submitted to, or shared with, ISMP. All patient safety information received by ISMP from a **provider** will be considered protected **patient safety work product** unless otherwise directed by the **provider**, and, thus afforded the highest degree of security and non-disclosure required by law. **Patient safety work product** will only be disclosed if it can be reasonably and contextually de-identified.

Please feel free to contact ISMP (ismpinfo@ismp.org, 215-947-7797) to discuss any concerns or questions you have regarding the submission of patient safety information to ISMP under the provisions of the Patient Safety Act.¹

Definitions

A. Patient Safety Organization (PSO) – an entity or a component of an organization that is listed by the Agency for Healthcare Research and Quality based upon a self-attestation that

it meets certain criteria established in the Patient Safety Act.¹ The primary activity of a PSO is to improve patient safety and health care quality.

B. Patient Safety Work Product (PSWP) – is the information protected by the privilege and confidentiality protections of the Patient Safety Act.¹ PSWP includes any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements which are gathered for the purpose of reporting to a PSO, or developed by a PSO in the conduct of defined patient safety activities. A provider’s business records and a patient’s original medical record or billing and discharge information cannot be considered PSWP. External reporting obligations also cannot be satisfied with PSWP. Thus, information that is collected to comply with external reporting obligations, such as reporting obligations to state regulatory agencies and the National Practitioner Data Bank, cannot be considered PSWP.

C. Provider - an individual or entity licensed or otherwise authorized under State law to provide healthcare services.

D. Patient Safety Evaluation System (PSES) – is the mechanism by which the provider collects, manages, and analyzes information; it is the protected space in which PSWP is assembled or developed for reporting to or from a PSO.

Reference

1) Department of Health and Human Services. Patient Safety and Quality Improvement; final rule (42 CFR Part 3). November 21, 2008. In: Federal Register. 2008;73(226):70731-70814. Accessed on April 20, 2011 at: <http://www.pso.ahrq.gov/regulations/fnlrule01.pdf>.