

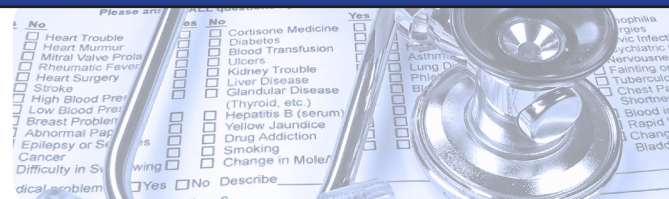
Suggested Guidelines

*Establishing a Patient Safety Evaluation System (PSES) and
Defining Patient Safety Work Produce (PSWP)
for PSO Participation*



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Establishing a Patient Safety Evaluation System (PSES) and Defining Patient Safety Work Product (PSWP) for PSO Participation



INTRODUCTION

The Patient Safety and Quality Improvement Act of 2005 and its implementing regulations, 42 CFR, Part 3, establish a framework for healthcare providers to voluntarily report information regarding medical errors to a federally listed Patient Safety Organization (PSO). Such reporting is on a privileged and confidential basis, for the purpose of aggregation and analysis of patient safety events. Information shared within the PSO system that qualifies as Patient Safety Work Product (PSWP), with limited exceptions, is not subject to subpoena, discovery or admission into evidence in federal, state or local civil, criminal or administrative proceedings, including disciplinary proceedings against a provider.

Information becomes PSWP when the provider develops or assembles the information as part of a Patient Safety Evaluation System (PSES), and the information is either reported to a PSO or identifies or constitutes the deliberations or analysis of the PSES. Clear identification of what information is PSWP and when such information becomes PSWP is an essential step in creating an environment to maintain the privilege and confidentiality requirements intended by the Act. Establishing a PSES, although not required by the Act and accompanying Rule, is encouraged by the Department of Health and Human Services as a best practice to support the identification and protection for PSWP. The Missouri Center for Patient Safety (MOCPS), as a PSO, also encourages development of a PSES for its PSO participants.

A PSES defines the processes within an organization for the collection, management and reporting of PSWP to a PSO. It can likely be established as a component of an organization's current risk management, patient safety and/or quality improvement program. A PSO may also establish a PSES to define processes for collection, management, and reporting of data and information submitted to the PSO. The MOCPS has established a PSES.

SUGGESTED GUIDELINES

The following suggested guidelines are provided to assist your organization in developing a PSES to clearly identify when information becomes PSWP. You may use these guidelines as you prepare for participation with the MOCPS as your PSO.

Suggested First Steps:

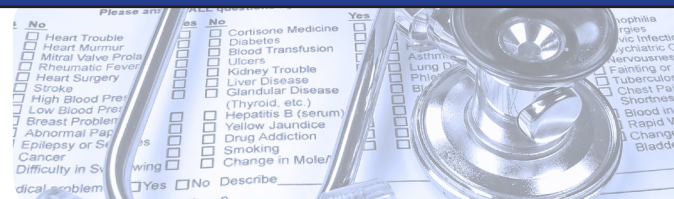
_____ Assign an individual or team to review the Patient Safety & Quality Improvement Act of 2005, the Act's Final Rule and current applicable quality, risk, medical staff and safety policies, procedures, and practices.

The individual(s) should be familiar with:

- The organization's safety reporting system;
- Peer review/credentialing processes;
- HIPAA;
- Risk management;
- Claims activities, including reporting and disclosure practices.

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_____ Identify and assess current reporting systems and information flow for patient safety activities and events.

Consider:

- How patient safety events are currently identified, reported and managed through risk management/patient safety/quality improvement/customer services/credentialing processes;
- How such data is being shared, processed and documented;
- Developing a flowchart of these processes.

Establishing a Patient Safety Evaluation System (PSES)

_____ Develop new or amend current applicable policies to identify and define the scope and function of your PSES.

- Assess data and information currently collected for patient safety/risk management/quality purposes to determine what should and should not be included in the PSES;
- Address how PSWP and non-PSWP will be managed within the PSES related policies. (See PSWP Guidelines below)

_____ Determine where and how data and information to be included within the PSES will be maintained, including in what equipment/systems it will be maintained, the physical location where it will be maintained at and who will have access to it.

- Store information within the PSES in a secure physical or electronic space designated for the conduct of patient safety activities;
- Identify individuals who are authorized to report to the PSO within your organization's PSES.

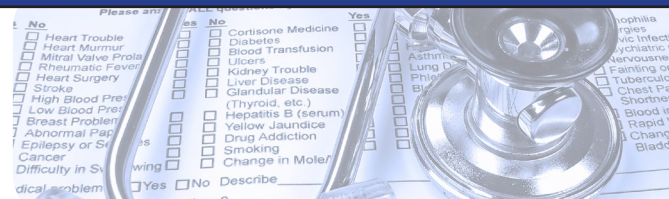
_____ Define procedures for how your PSES will report data to the PSO. Data and information reported to the MOCPS PSO will be entered into an electronic reporting system.

- Identify what reporting mechanism will be used (direct entry, interface with current electronic system, seamless submission using the Quantros™ SRM system);
- Identify who will be authorized to have access to the PSO reporting system to enter data and information;
- Identify who will be authorized to determine when data entered into the system will be officially "submitted to the PSO" – data will be maintained within the electronic system and available only to the participating provider, until action is taken by designated individual(s) to "submit to the PSO";
- Identify who will be authorized to have access to the PSO reporting system to retrieve and review reports.

_____ Consider using standard language on all documents submitted to the Center PSO from the organization's PSES, such as *"This information has been collected within the (name of organization) PSES for the purpose of reporting to the Missouri Center for Patient Safety Patient Safety Organization, (date of collection)."*

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Defining and Managing Patient Safety Work Product (PSWP)

Accurately defining and managing PSWP is one of the most important requirements to access the available privilege and confidentiality protections when working with a PSO.

The PSWP is what is considered privileged and confidential under the Act and Final Rule. PSWP may include data, reports, records, memoranda, deliberations, analysis, written or oral statements and other information collected, maintained, developed or assembled by the organization for the purpose of reporting to a PSO.

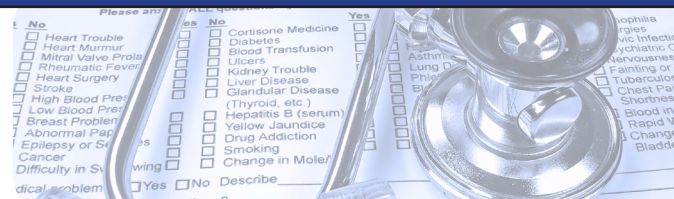
- _____ Identify and assess what patient safety related documents, data and information are currently developed by the organization. These may include:
 - Safety reports, quality reports, written and verbal reports;
 - Committee minutes, notes, checklists, tally sheets, transcripts, recordings peer review documents, incident reports, root cause analyses;
 - Any discussions or documentation used for quality and patient safety improvement.

- _____ Determine how these documents and discussions are being used, documented and maintained within your organization. Consider:
 - Who is collecting, reviewing and maintaining the data and information;
 - How, where and when the information is being filed;
 - How the information is being maintained;
 - Whether the information is for activities that would not allow the information to be defined as PSWP.

- _____ Determine what documentation can and cannot be considered PSWP, and how each type of documentation will be managed and separated within your PSES.
 - **What is not considered PSWP:**
 - Original source documents such as the patient's medical record, billing and discharge information and any other original patient or provider record;
 - Mandated reports for compliance with federal, state or accreditation requirements.
 - **What may be considered PSWP:**
 - Data, reports, records, memoranda, deliberations, analysis, written or oral statements and other information collected, maintained, developed or assembled by the organization for the purpose of reporting to a PSO;
 - Other documents developed for the purpose of analysis, review, quality improvement, risk management and patient safety improvement;
 - A *copy* of information included on mandated reports;
 - Analyses, deliberations and recommendations for improvements to be made related to events resulting in a mandated report.

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From time to time, it may be necessary to remove PSWP from your PSES. PSWP that has not been reported to the PSO may be removed from your PSES.

- Consider the following scenario: An event may initially enter the organization's PSES and be defined as PSWP, but then, for example:
 - Result in initiation of a peer review process leading to a report to the Board of Healing Arts;
 - Determined to be a Sentinel Event for reporting to the Joint Commission;
 - A health-care acquired infection that must be reported to the Missouri Department of Health and Senior Services.

Such reports would need to be removed from the organization's PSES and reported as required. The reports themselves cannot be submitted as PSWP to a PSO and receive the protections. However, the following data elements contained within the organization's PSES reporting system may be reported to the PSO as PSWP and could be eligible for the privilege and confidentiality protections afforded PSWP.

- Facts of the event;
- Analyses, deliberations and recommended improvements resulting from the event.

In developing a process to remove PSWP from your PSES prior to submission to the Center PSO, consider:

- Maintaining a log of PSWP that is removed from the PSES, including the date of removal and a statement that the provider no longer intends to report the information to a PSO;
- Identifying which personnel, or categories of personnel, are authorized to remove PSWP from the PSES.

Include within policies and procedures measures to comply with Missouri Regulation 13 CSR 70-15.200. See "Overview of MO HealthNet Regulation 13 CSR 70-15.200, Patient Safety Organization Provisions". Reports of defined events within this regulation and their root cause are to be reported to a PSO. For purposes of the regulation:

- The report, PSO defined elements, analyses and deliberations may be considered PSWP within the participant provider's PSES and reported to the PSO as PSWP.
- If a report of the event is required to meet other mandated or credentialing reporting requirements and is defined as non-PSWP, copies of the non-PSWP report may be submitted to the Center PSO for data purposes.

Additional Resources

- The Missouri Center for Patient Safety - www.mocps.org
- The Patient Safety and Quality Improvement Act of 2005 - www.pso.ahrq.gov/statute/pl109-41.htm
- Patient Safety Rule for PSOs - <http://edocket.access.gpo.gov/2008/pdf/E8-27475.pdf>
- Agency for Healthcare Research and Quality PSO information - www.pso.ahrq.gov

The above are suggested guidelines only and are not considered inclusive of all potentially relevant steps to establishing a PSES and defining PSWP. These suggested guidelines are not intended to be legal advice. Providers should not solely rely upon the above as the basis for its compliance with the Act and Final Rule, but seek independent counsel.