Toolkit for Designing a Patient Safety Evaluation System (PSES) & Defining Patient Safety Work Product (PSWP)

Introduction
The Patient Safety and Quality Improvement Act (PSQIA) 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 collects or assembles the information as part of a Patient Safety Evaluation System (PSES), with the intent of submitting it to a PSO.

*Clear identification of what information is considered PSWP and when this information becomes PSWP is an essential step in creating an environment to maintain the privilege and confidentiality protections intended by the PSQIA.* Defining and documenting a PSES, although not required, is encouraged by the Department of Health and Human Services and as a best practice to support the identification and protection for PSWP.

A PSES defines the processes or systems within an agency or organization for the collection, management and reporting of PSWP to a PSO. It can likely be established as a part of an agency or organization’s current quality improvement program. Under the PSQIA, a PSO may also establish a PSES to define processes for collection, management, and reporting of data and information submitted to the PSO. TQC PSO has established its own PSES for this purpose.

This toolkit provides both an overview and step-by-step approach to designing your PSES and defining PSWP.
Overview

Suggested Initial Steps
- Display your PSO certificate in a visible location. You may also want to copy the certificate and provide it to your accreditation team along with a customized memo for surveyors. See our sample memo for surveyors.
- Identify your primary and secondary contacts/liasons for the PSO
- Discuss with leadership your desired level of engagement/goals of belonging to the PSO
- Identify your core work-force (your subject matter experts on the PSO)
  - Modify the Workforce Agreement template for your organization and have your core workforce sign.
  - Document the position titles of your core workforce (Hint: This will become Appendix C of your new policy)

Next Steps
- Define your PSES
  Key recommendations:
  - Convene a small group to visually document the current information flow of patient safety activities at your organization. See the PSES Diagram.
  - Revise your patient safety activity information flow, if needed (Hint: This will become Appendix B of your PSES policy)
- Define the documents and management of PSWP
  Key recommendations:
  - Determine what information will be considered PSWP and where it will be stored
  - Using the patient safety activity information flow, create a list of the committees/departments that will handle PSWP
  - Review with leadership recommended PSWP submissions (all events and event investigations)
- With your core workforce, modify the Patient Safety Evaluation System Policy and Procedure template & obtain appropriate committee approvals.

Educate
- Educate & train your workforce after modifying the Workforce Training slides
  Key Recommendations:
  - Utilize your core workforce to assist with educating departments (extended workforce) that will be handling PSWP

Data Submission
- Identify users who will access, manage, and upload events into TQC PSO’s Safety Platform
  Key Recommendations:
  - Plan to submit near miss, unsafe condition, and incidents, event investigations
Step-By-Step Guide

**Step 1: Identify your primary contacts/liaisons with The Quality Center PSO (TQC PSO)**

**Action:** Select a primary contact person and a backup to serve as the liaison with The Quality Center PSO.

Select individuals with a good working knowledge of the organization’s safety reporting system and current quality, risk, medical staff and safety policies, procedures and practices.

These individuals will become knowledgeable about the Patient Safety Act of 2005, the Act’s Final Rule, and will serve as the spokesperson/contact for the organization; train the employee workforce and be responsible for disseminating pertinent information within the organization regarding PSO communication and activities.

**Step 2: Define your Patient Safety Evaluation System (PSES)**

A PSES defines the processes within an organization for the collection, management, analysis and reporting of Patient Safety Work Product (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. Information submitted into the PSES comes from multiple sources such as infection control, quality, risk management, etc. committees and departments.

**Action:** 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 processes; and how such information and data is being shared, processed and documented. (This may already be outlined in a policy related to your quality and safety program.)

Review the assessment of current systems and determine how it can evolve into a Patient Safety Evaluation System (PSES). Typically, your current system can be labeled as your PSES with just a few adjustments.

A note of caution with regards to including all risk management activities within your PSES: if there is a possibility of information being publicly disclosed (for example, in litigation), it should not be included.

**Action:** Document a flowchart of the flow of patient safety information and data within your system. See PSES Diagram for a sample. (Hint: This will become part of your PSES policy.)
**Action:** Include TQC PSO Safety Platform in your PSES description/flowchart to maintain the confidentiality and privilege protections.

---

### Step 3: Define your Patient Safety Work Product (PSWP)

**Accurately defining and managing PSWP is one of the most important steps to ensure the privilege and confidentiality protections when working with a PSO.** 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. Non-identifiable PSWP is not confidential or privileged under the Patient Safety Act and Final Rule.

**Identifiable PSWP:** Documents/information that includes identification of any provider that is a subject of the work, or any providers that participate in activities that are a subject of the work. It may also be considered identifiable because it contains patient-identification information which would invoke the HIPAA confidentiality regulations, or that identifies the individual who reported information in good faith.

**Non-identifiable PSWP:** Documents/information that is anonymous as to provider, de-identified as to protected health information, and contextually de-identified so that the provider, patient or reporter cannot be identified.

**Non-PSWP:** Original source documents such as the patient’s medical record, billing and discharge information and any other original patient or provider record CANNOT be considered PSWP. Mandated reports for compliance with federal and state requirements also CANNOT be considered PSWP.

However, a “copy” of information included on mandated reports, plus analyses, deliberations and improvements made relative to events resulting in a mandated report can be submitted to the PSO and considered PSWP along with its protection. This information can be used by the PSO for collective learning.

**Action:** Decide what information currently being developed by the organization will be considered PSWP. This can include patient safety reports, quality reports, written and verbal reports, committee minutes, notes, checklists, tally sheets, investigative notes, transcripts, recordings, peer review documents, root cause analyses – any discussions or documentation used for quality and patient safety improvement.

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. Other documents developed for the
purpose of analysis, review, quality improvement, risk management and patient safety improvement are also considered PSWP unless it is initially determined that this information will be needed elsewhere (professional proceedings, litigation, etc.)

**Action:** Determine where and how PSWP will be maintained, including what equipment/system it will be maintained in, server security, the physical location and who will have access to it.

PSWP should be stored in a secure physical or electronic space designed for the conduct of patient safety activities, and all paper and electronic documents should be labeled as PSWP.

**Action:** Develop criteria and a process for voluntary removal of PSWP from the PSES prior to submission to the PSO. This should include the maintenance of a log to document removal of PSWP.

PSWP that has not been reported to a PSO can be removed from your PSES. Event information may be assembled and developed within the organization’s PSES for purposes of reporting to a PSO, but at a later date determined to be needed to meet some other reporting requirement (disciplinary, mandatory, etc.). At that point the information may be removed from the organization’s PSES and used as required. If desired, a “copy” of such information may be submitted to the PSO, along with other supplemental information surrounding the event that were not part of the required reporting, which will enter the PSO’s PSES as PSWP and receive subsequent protections. Note: RCA analysis developed in the analysis and deliberations pathway cannot be removed.

**As a best practice, it is suggested that a log be maintained of PSWP that is removed from the PSES, including the date of removal, who authorized the removal and a comment of why the information is being removed for future trending. Your policy should include which personnel, or categories of personnel, are authorized to remove PSWP from the PSES.**

**Action:** Develop a process for voluntary disclosure of PSWP. This should include:
- An approving team who determines whether a disclosure is warranted and appropriate (we recommend including your counsel in these decisions)
- A log of requested and granted disclosures
- A process for obtaining and retaining copies of signed confidentiality agreements (for a minimum of 6 years)
Step 4: Define your workforce

The individuals involved in your quality improvement and patient safety activities will compromise your workforce. These individuals should have access to PSWP only for the purpose of carrying out their specific duties or tasks. Include appropriate staff if they participate in discussions involving PSWP during regular quality or safety meetings or discussions.

**Action:** Identify and document the position titles of your core-workforce and extended workforce. Individuals in your extended workforce may be identified by committee membership. (Hint, this will be included in your PSES policy.)

**Action:** Have all workforce members sign a confidentiality agreement (see [Workforce Agreement template](#)).

As committee membership changes, it will be important to have new members also sign a confidentiality agreement.

Step 5: Document your PSES, PSWP and workforce in a policy.

Defining and documenting a PSES, although not required by the PSQIA and accompanying Rule, is encouraged by the Department of Health and Human Services and TQC PSO as a best practice to support the identification and protection for PSWP.

The [Patient Safety Evaluation System Policy and Procedure template](#) can serve as a modifiable resource.

**Action:** Finalize and approve a PSES policy.

Step 6: Educate your workforce

All core workforce and extended workforce members should be educated on the PSQIA provisions, specifically those pertaining to confidentiality of information and protections in addition to your organization’s defined PSES and PSWP.

The [Workforce Training slides](#) may be used as a resource for education. Include highlights of the Patient Safety Act, how the PSES functions within your organization; the event submission process, roles and privileges within TQC PSO database, designated organizational contacts for TQC PSO; and civil monetary penalties for unauthorized disclosures of PSWP, etc.
Re-train these individuals periodically. Principals, such as employers, are liable under ordinary principles of agency law for a civil monetary penalty imposed on their employees or agents for each violation.

**Action:** Educate your organization’s leadership and board about TQC PSO and protections.

**Action:** Educate committees that will be handling PSWP.

Ideally, committee charters should indicate that committee members will be utilizing PSWP. For committees that invite guests or non-workforce members, PSWP should only be discussed during closed sessions. Minutes containing PSWP should be kept separate from other non-PSWP minutes and should not be distributed to non-committee members.

---

**Step 7: Submit information to TQC PSO**

**Action:** Determine what information will be submitted to TQC PSO.

For purposes of reporting to TQC PSO, data and information will be entered into TQC Patient Safety Platform; until the event is uploaded to the TQC PSO, the organization can make the final determination to 1) submit the event to the PSO or 2) remove it from the PSES.

**Action:** Identify the users authorized to carry out various privileges within TQC PSO database. To obtain user privileges, register at [www.nextplanesolutions.com](http://www.nextplanesolutions.com)

Authorized individuals will have access to TQC PSO Safety Platform and have the ability to: upload and edit events, manage users, approve what events will be submitted and run reports.

---

*Please note these are only suggested guidelines and are not considered inclusive of all potentially relevant steps to establish a PSES and defining of PSWP. These guidelines are not intended to be legal advice. Internal review and legal consultation in developing a PSES and defining PSWP is encouraged and recommended.*