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The Patient Safety Act 14 Years Later: Lessons Learned and Mistakes to Avoid

Michael R. Callahan, Senior Counsel
Katten Muchin Rosenman LLP
312.902.5634
michael.callahan@katten.com

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Agenda

Designing More Effective PSES Policies

1. What patient safety activities to include in the PSES policy

2. Which PSWP to consider reporting to a PSO or to treat as privileged Deliberations or Analyses

3. Should peer review activities be included?

4. Can PSWP be used for disciplinary purposes?

5. HR and risk management PSWP access do's and don'ts

6. Some PSWP questions and answers

Patient Safety Activities

- Patient safety activities mean the following activities carried out by or on behalf of a PSO or a provider:

  — Efforts to improve patient safety and the quality of health care delivery.

  — The collection and analysis of patient safety work product.

  — The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

  — The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.

  — The maintenance of procedures to preserve confidentiality with respect to patient safety work product.
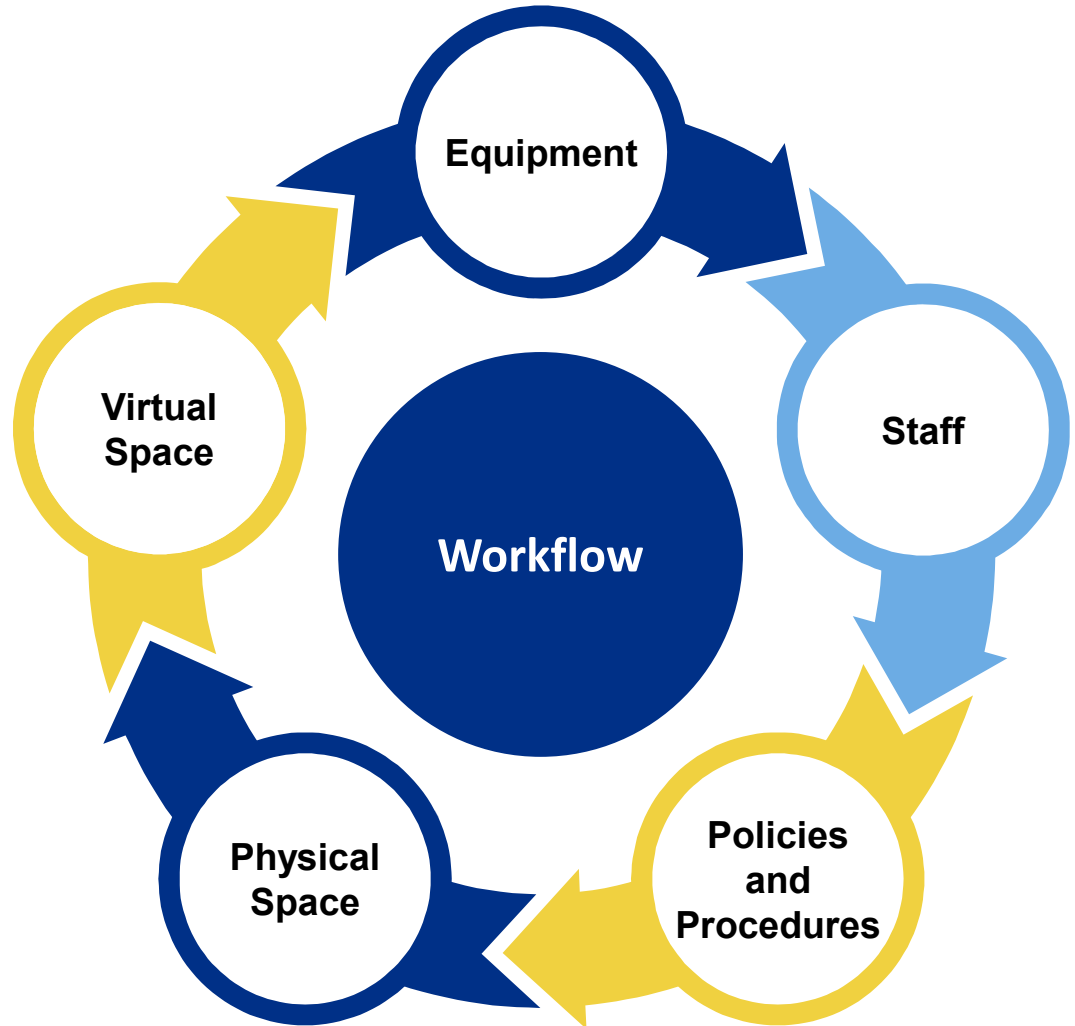
Patient Safety Activities

— The provision of appropriate security measures with respect to patient safety work product.

— The utilization of quality staff.

— Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

Patient Safety Evaluation System (PSES)

The collection, management, or analysis of information for reporting to or by a PSO. A provider's PSES is an important determinant of what can, and cannot, become patient safety work product.

PSES Operations

Establish and Implement a PSES to:

- Inventory all reports, analyses, committees, etc., involved in any and all patient safety activities as a PSES starting point

- Collect data to improve patient safety, healthcare quality and health care outcomes – must document date of collection

- Review data and take action when needed to mitigate harm or improve care

- Analyze data and make recommendations to continuously improve patient safety, healthcare quality and healthcare outcomes

- Conduct proactive risk assessments, in-depth reviews, and aggregate medication errors

- Determine which data will/will not be reported to the PSO and what will be treated as deliberations or analysis

- Report to PSO – must document date of report

- Conduct auditing procedures, adopt security measurements and enforce confidentiality policies

Example PSES Patient Safety Activities

- What types of information can be considered for inclusion in the PSES for collection and reporting to the PSO if used to promote patient safety and quality and treated as PSWP?

  — Medical error or proactive risk assessments, root cause analysis

  — Risk Management — Not all activities will qualify such as claims and litigation management, but incident reports, investigation notes, interview notes, RCA notes, etc., tied to activities within the PSES can be protected

  — Outcome/Quality—may be practitioner specific

  — Peer review

  — Relevant portions of Committee minutes for activities included in the PSES relating to improving patient quality and reducing risks

  — Deliberations or analysis

  — Incident/adverse event reports

PSES Policy Development

- **Develop Both a Specific and Broadly Worded PSES policy**
  - One of the fundamental documents for internal educational purposes as well as to be introduced to a court in demonstrating that the materials in dispute are indeed PSWP is a provider's PSES policy.
  - The courts are not going to simply accept the word of the hospital or other provider that information qualifies as PSWP.
  - The provider should conduct an inventory of all of its performance improvement, quality assurance, peer review and other related patient activities as well as the various committees, reports and other analyses being conducted within the organization.
  - This is the starting point when determining the scope of activities you wish to include within the PSES and therefore claim as privileged PSWP.
  - The details of these activities and the information to be protected should be reflected within the PSES.

PSES Policy Development

- — When seeking to claim privilege protections over an incident report, committee minutes or other internal analysis, a provider can then cite to the specific reference within the PSES as evidence of the hospital's intent to treat this information as PSWP.

- — The provider should also include the phrase "including but not limited to" a "catch all" to account for other privileged patient safety activities in the PSES policy.

- — PSES Policy needs to be updated annually.

- — May want to cross-reference to related policies.

- **Carefully Describe Your PSWP Pathway**

- — As reflected in the Appellate Court's decision in Daley, a provider can create PSWP via actual reporting, function reporting or through deliberations or analysis.

- — It is critical that your PSES policy distinguish which forms of information, incident reports, etc., are being actually reported to the PSO or scanned and downloaded and reported and what forms of information are being treated as deliberations or analysis.

PSES Policy Development

— As a practical matter, most patient safety activities can be characterized as deliberations or analysis.

— Information that is deliberations or analysis automatically becomes PSWP when collected within the PSES and does not need to be reported to the PSO although reporting is certainly an option.

— Most of the PSO appellate court decisions, including the <u>Daley</u> decision, involved actual reporting and not deliberations or analysis.

— <u>Rumsey v. Guthrie Clinic</u> is the first "deliberations or analysis" decision.

— Keep in mind too, that information which is being treated as deliberations or analysis cannot be "dropped out" and used for other purposes but can be shared if you meet one or more of the disclosure exceptions. These include disclosing to consultants, your attorney, and independent contractors that are assisting the hospital in patient safety activities and other disclosures permitted under the PSA.

Example Health System PSES

What Comprises the System's Patient Safety Evaluation System (PSES)?

- The PSES includes the collection, management and/or analysis of Patient Safety Concern information recorded in the System's Event Reporting System (ERS) for reporting to a PSO. **It includes information documented in the ERS and also deliberation and analysis of a Patient Safety Concern.**

  —A Patient Safety Concern includes:

    - A patient safety event that reached the patient, whether or not there was harm;

    - A near miss or close call - a patient safety event that did not reach the patient; or

    - An unsafe condition - circumstances that increase the probability of a patient safety event.

Example Health System PSES

—It may also include all activities, communications and information reported to or developed by individuals or committees, such as data analyses, Root Cause Analyses, outcome reports and minutes, for the purpose of improving patient safety and/or healthcare quality

Creation of PSWP

- PSWP is created automatically upon filing an event report in the ERS that involves a Patient Safety Concern. All Patient Safety Concern information is collected and/or developed with the intent to report to the PSO.

- If so designated by Authorized Staff, PSWP may encompass the data collection efforts leading up to making the Event report. The date of entry into the PSWP is the date these activities occur.

Example Health System PSES

- **PSWP is created when deliberations and analysis (D or A) related to a Patient Safety Concern is conducted**. The date of entry into the PSES is the date these activities occur. **PSWP protections will apply immediately. Deliberations and analysis cannot be de-designated as PSWP. Documents included in this category include but are not limited to**:
  — Failure Mode Effects Analysis (FMEA)
  — Root Cause Analysis (RCA) not otherwise reported in the ERS
  — Data analysis reports & comparative outcomes
  — Patient Safety Committee minutes
  — Quality Improvement Committee minutes

Example Health System PSES

- Patient Safety Activities
  - Patient Safety Activities may be conducted by any individual, committee or body that has assigned responsibility for any such activities. The workforce includes faculty, staff, trainees, volunteers, and contractors who perform work under the direct control of the health system. Committees include but are not limited to:
    - Patient Safety Committees
    - Clinical Performance Improvement Committees
    - Risk Management Committees
    - Chief Medical Officers/Chief Nursing Officers
    - OP Risk Services and/or Committees
    - Audits and Compliances Committee
    - Quality Improvement Committees
    - Medication Safety Committees
    - Health System Services Committee
    - Center for Healthcare Quality Innovation
    - OP Data Management System
    - Other committees with jurisdiction

What is "Peer Review"?

- Efforts to improve patient care and reduce morbidity or mortality
- Tracking, investigating and managing unacceptable behavior identified in Code of Conduct - Disruptive Behavior Policies
- Physician wellness evaluations and activities
- Evaluating healthcare providers regarding performance, skill, technique, competence, utilization and compliance with hospital and medical staff bylaws, rules, regulations and policies
- Review and establishment of standards of care
- Analyses undertaken for the purpose of reducing the risk of harm
- Peer review investigations and hearings
- All of the discussions, analyses and work product produced by these patient safety activities

Use of PSWP in Peer Review Disciplinary Matters

- Under a "just culture" approach, the goal is to move away from the "blame game" and instead use other remedial measures to help the physician, advanced practice nurse and other healthcare providers to "get back on track" in order to improve the future delivery of patient care services.

  — Examples include use of an FPPE plan, concurrent/retrospective review of cases, collegial intervention, monitoring, proctoring and reeducation

- At some point, if all of these efforts fail, the hospital and medical staff may have no other alternative but to consider the use of disciplinary action which, if approved by the Board of Directors, may result or require a report to the National Practitioner Data Bank or to the state.

- But can peer review PSWP be used for disciplinary actions?

Use of PSWP in Peer Review Disciplinary Matters

— The short answer is <u>Yes</u>. The Preamble to the Patient Safety Act specifically points out that PSWP can be used for this purpose.

- <u>But</u>

— Is this "use" consistent with Just Culture?

— If anticipating that the healthcare provider will sue if the recommended disciplinary action is upheld, you must keep in mind that PSWP cannot be introduced into any state or federal proceedings in order to defend the hospital's actions.

— The inability to introduce PSWP can both benefit the hospital, in the sense that the provider cannot discover or introduce PSWP into evidence to prove up a breach of contract, malicious interference, defamation or a discrimination action, but neither can the hospital introduce this privileged information—double-edged sword.

Use of PSWP in Peer Review Disciplinary Matters

- But if not using PSWP in a disciplinary hearing, how does the hospital make a sufficient "evidentiary" record to support the disciplinary action? What are the options?

  — Repeat the internal, external reviews and other PSWP on which the disciplinary action was based outside of the PSES.

  — Rely on the "facts" and medical record and non-privileged information to support the adverse decision.

  — If the information supporting the disciplinary action utilized the reporting method of creating PSWP, hold onto the information and drop it out for use in disciplinary hearings and possible litigation.

  — Keep in mind that a state peer review privilege may apply which has the same consequences concerning non-discovery or non-admissibility into evidence.

Use of PSWP for HR and Risk Management Purposes

- Remember the distinction between a "use" and a "disclosure"
  — PSWP can be used/shared for all internal purposes consistent with PSES and confidentiality requirements
  — An example of a permitted use is sharing PSWP with attorneys and accountants
  — PSWP, however, also can be used "outside of the PSES" but you should be able to document why such use is necessary in order to fulfill a business or related purpose
  — A "disclosure" is sharing PSWP to an unrelated third party which meets one of the permissible disclosure exceptions, i.e.:
    - Independent contractors
    - Accrediting bodies
    - Affiliated entities
    - From one PSO to another PSO

Use of PSWP for HR and Risk Management Purposes

— PSWP which is disclosed under one or more of the permissible disclosure exceptions remains PSWP—the privilege is not waived

— Sharing PSWP with HR and risk management is considered a use and not a disclosure

- Important considerations

— Must be able to establish that any PSWP which is shared with HR and/or risk management was developed for the purpose of improving patient care and not for employment or claims and litigation management purposes

— Does HR and risk management really need access to PSWP whether identifiable or non-identifiable?

— PSWP should not be placed in the employees HR File because

- Employees are legally entitled to access all file materials

Use of PSWP for HR and Risk Management Purposes

- PSWP is not subject to discovery or admissibility into evidence by any party. At some point therefore, hospitals cannot disclose PSWP when defending against a state (breach of contract) or federal (discrimination) claim

- HR needs to create its own non-privileged investigation record, notes, interviews, etc., which are then placed in the HR file and can be used in the event of litigation

- Risk management also can access PSWP but like HR, must create its own forms, reports, etc., for claims and litigation management which generally are discoverable

- For this other information, other privileges which could be available include attorney-client work product and communications, and the insured/insurer privilege

PSWP Questions and Answers

- What should be included or referenced in minutes/documentation in order to access the privilege?

  — Make sure the committees or activities producing the minutes are reflected in the PSES

  — Determine whether the minutes/reports are going to be actually reported to the PSO and are reported with the date on which they are reported or are being treated as deliberations or analysis – clarify which method is being utilized for the information in the PSES

  — The language "Privileged and Confidential under the Patient Safety and Quality Improvement Act of 2005 [and the _____ Act]" for those portions of the minutes you are treating as privileged

  — Some hospitals have an email system which includes this or similar language of privileged emails

PSWP Questions and Answers

—Remember, it is not fatal if this language is not inserted. It is more important that the minutes be identified in the PSES

- Who can review PWSP minutes/documentation?

—Workforce members who have been identified by the provider – these are the individuals who prepare or need to access PSWP as part of their job responsibilities

- What PSWP can be shared from the Peer Review process and who can see it?

—Workforce members

—Hospital identifiable PSWP can be shared with affiliated entities, including the parent corporation and their workforce members, who are members of the PSO and are in a single system PSES

PSWP Questions and Answers

—PSWP can be shared/disclosed if utilizing a permissible disclosure exception, i.e. attorneys, accountants, business associates, accreditation bodies, etc. (See Section 3.206 of the Final Rule)

- Is any report, analysis, study, etc., prepared by a PSO considered PSWP?

  —Yes

- If CMS or other government agency demands PSWP, must it be turned over to them?

  —No – HHS in its May, 2016 Guidance for Patient Safety Rule stated that government agencies cannot require providers to turn over PSWP, but must otherwise demonstrate compliance

PSWP Questions and Answers

- Sharing physician identifiable PSWP generated within a hospital is considered a use and not a disclosure and therefore can be shared with the hospital's workforce members
- In order to share physician identifiable PSWP generated in the hospital with outside entities, including affiliated providers, the physician must sign a written authorization permitting the disclosure of this information
  - Authorization can be included in a separate form or in the appointment/reappointment application, or an employment agreement.

Questions & Answers

Questions?

A nationally recognized advisor to health care providers across the country, Michael Callahan provides deeply informed business and legal counseling in all areas of hospital-physician relations and health care regulatory compliance and governmental investigations, including the Emergency Medical Treatment and Active Labor Act (EMTALA), the Health Insurance Portability and Accountability Act (HIPAA), Medicare Conditions of Participation (CoPs), hospital licensure and accreditation standards. He is widely respected for his leading work on the Patient Safety Act from a regulatory compliance, policy and litigation standpoint, including the development of patient safety organizations (PSOs).

The knowledge to identify efficient and practical solutions

Health systems, hospitals and physician groups large and small across the country come to Michael for practical, real-world guidance and answers to challenging legal and operational issues, which he can provide quickly because of his many years of experience. He understands the reality of hospital quality, peer review, risk management and related operational legal and regulatory complexities and can rely on a large client base in order to provide better and comparative solutions.

He also is sought out by many of the largest health systems around the country for his understanding and interpretation of the Patient Safety Act. In a case of first impression he advised a national pharmacy that became the first provider to successfully assert an evidentiary privilege under the Patient Safety Act. Since that case, he has represented or advised many hospitals, physician groups and other licensed providers in creating or contracting with federally certified PSOs and has been directly involved in most of the major state appellate and federal court decisions interpreting the Patient Safety Act.

Michael R. Callahan

Of Counsel
Health Care

Chicago Office

+1.312.902.5634

michael.callahan@katten.com

Katten Locations

CHARLOTTE
550 South Tryon Street
Suite 2900
Charlotte, NC 28202-4213
+1.704.444.2000 tel
+1.704.444.2050 fax

CHICAGO
525 West Monroe Street
Chicago, IL 60661-3693
+1.312.902.5200 tel
+1.312.902.1061 fax

DALLAS
2121 North Pearl Street
Suite 1100
Dallas, TX 75201-2591
+1.214.765.3600 tel
+1.214.765.3602 fax

LONDON
Paternoster House
65 St Paul's Churchyard
London EC4M 8AB
United Kingdom
+44 (0) 20 7776 7620 tel
+44 (0) 20 7776 7621 fax

**LOS ANGELES –
CENTURY CITY**
2029 Century Park East
Suite 2600
Los Angeles, CA 90067-3012
+1.310.788.4400 tel
+1.310.788.4471 fax

**LOS ANGELES –
DOWNTOWN**
515 South Flower Street
Suite 4150
Los Angeles, CA 90071-2212
+1.213.443.9000 tel
+1.213.443.9001 fax

NEW YORK
50 Rockefeller Plaza
New York, NY 10020-1605
+1.212.940.8800 tel
+1.212.940.8776 fax

ORANGE COUNTY
100 Spectrum Center Drive
Suite 1050
Irvine, CA 92618-4960
+1.714.966.6819 tel
+1.714.966.6821 fax

SHANGHAI
Suite 4906 Wheelock Square
1717 Nanjing Road West
Shanghai 200040
P.R. China
+86.21.6039.3222 tel
+86.21.6039.3223 fax

WASHINGTON, DC
2900 K Street NW
North Tower - Suite 200
Washington, DC 20007-5118
+1.202.625.3500 tel
+1.202.298.7570 fax