

Practical Applications of Reporting to a PSO

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I have no relationships with ineligible companies to disclose.

Definitions

- Patient Safety Organization (“PSO”): works with healthcare providers to help them improve patient safety and healthcare quality by analyzing data voluntarily reported by providers and provide feedback aimed at promoting learning and minimizing patient risk.
- Patient Safety Work Product (“PSWP”): information protected by the privilege and confidentiality protections of the Patient Safety Rule.
- Patient Safety Evaluation System (“PSES”): the collection, management or analysis of information for reporting to a PSO.
- Agency for Healthcare Research and Quality (“AHRQ”): federal agency charged with improving safety and quality of healthcare and certifying agency for PSOs.
- Patient Safety Rule: allows privileged reporting of patient safety info. to PSO

Agenda

This presentation will review various patient safety scenarios involving adverse events, patient injuries and peer review issues. The following issues will be addressed:

- What information can be collected within a PSES and reported to a PSO?
- What type of PSWP can be shared with internal and external parties?
- How does a licensed provider respond to a state or federal agency that is seeking information that the provider believes is PSWP?

Patient Fall Case Study

Behavioral Health Unit nurse manager calls risk management and reports that a patient who fell yesterday experienced a cardiac arrest during the night.

1. Patient fell at 2:00 a.m. on 12/1/2015.
2. Nurse contacted the assigned resident physician at 2:15 a.m.
3. Resident A examined patient, documented the event in the medical record and ordered a knee x-ray because the patient was complaining of knee pain.
4. Resident A documented no apparent injury after x-ray reviewed.
5. Nurse A entered a safety event report at 2:15 a.m.
6. Patient complained to Nurse B that she has a headache at 5:00 a.m.

Patient Fall Case Study, continued

7. Nurse B calls resident B and received an order for Tylenol 500 mg prn headache.
8. Nurse B found patient on floor nonresponsive at 6:00 a.m and called a code blue.
9. Code team arrived at 6:30 a.m. but patient could not be resuscitated.
10. Family was called and they came to the hospital. Family agreed to have an autopsy performed.
11. Autopsy results revealed a subdural hematoma was the cause of death.
12. Hospital staff and family meet to discuss what happen and actions taken to prevent a similar event.

PSES Activity

Develop a plan to conduct all deliberations, analysis and communication within the PSES. Example of a PSES safe learning environment:

- Event Report or Risk Management Telephone Call
- Patient Safety Investigation
- Critical Event Debrief
- Multidisciplinary peer review
- Quality PSES committee
- Root Cause Analysis
- Action Plan with Measure of Success
- Monthly PSES Quality Committee Report

PSES Documentation: Best Practices

PSES Policy Provides as Follows: Activities, documents and systems that comprise a hospital's PSES, include but are not limited to, the following:

- Patient Safety investigations
- Incident/Event Reporting System
- Morbidity/Mortality and Peer reviews
- Code Blue evaluations
- Critical event debrief sessions and RCA
- Patient Safety PSES Committee
- Quality Committee of the Board PSES Session Reports
- And other activities or actions that could improve patient safety, health care quality or health care outcomes

Case Study Questions

- Which information can become PSWP?
- Does it matter whether analysis and deliberations are conducted within or sent to the PSES?
- Could the PSO conduct the RCA within its PSES and what are the benefits?
- Can deliberations and analysis conducted within the PSES be shared with CMS, a state agency, or The Joint Commission (TJC)?

Case Study Analysis

- Information documented into the medical record cannot be PSWP.
- Facts collected for state reports are not PSWP.
- Does state or federal law have mandated reporting or record keeping requirements?
- Deliberation and analysis must be conducted within PSES to be considered PSWP – should document when this occurs.
- RCA may be conducted by PSO workforce which could offer an objective analysis of the event.
- PSWP cannot and should not be shared with anyone outside of the organization except when limited disclosure exceptions are met.

Case Study Analysis, continued

- RCA conducted within PSES may not be removed but AHRQ takes the position that if it was a mandated report or a record keeping report it does not qualify as PSWP.
- Information reported to the PSO may not be removed to use for another purpose, such as disciplinary action or state reports. It may be used for internal patient safety activities, educational and remedial measures. Data collected may be removed from the PSES before reporting to the PSO and used for disciplinary actions

Peer Review Case Study

- A loyal, highly respected senior orthopedic surgeon, who is one of the hospital's biggest admitters, had the following adverse patient events within a two-month period:
 - Wrong site pre-operative procedure;
 - Used the wrong orthopedic medical device in two patients, one of which was chosen by a medical device rep who was in the operating room;
 - Two other patients who were morbidly obese with cardiac conditions died shortly after their respective orthopedic procedures. The operations went forward despite objections from the surgeon's partners.
- After the second patient's death, a meeting was requested by the Chief Medical Officer at which the Department Chair, the Risk Manager, the Quality Manager, and the PSO Liaison were present.

Peer Review Case Study: Questions

- Risk Manager: Needs to contact insurance carrier and defense counsel regarding possible litigation in one or more adverse events.
- Questions/Concerns
 - Can Risk Manager share PSWP with carrier?
 - Can Risk Manager share PSWP with defense counsel?

Peer Review Case Study: Analysis

- Under the Patient Safety Rule, there are a limited number of PSWP disclosure exceptions. The Act allows disclosure for business operations to “professionals” including attorneys and accountants, in part, because they also owe a fiduciary obligation to their clients. Therefore, PSWP can be shared with defense counsel, but not if created primarily in anticipation of litigation and not for patient safety purposes.
- However, the question you should ask is whether counsel needs PSWP to defend any suit. This depends on the nature of the claims and what information is needed. Also, has the information been reported as PSWP to a PSO (actually or functionally), or is it being held within the PSES?

Peer Review Case Study: Analysis, continued

Disclosure to the insurance carrier:

- The business operations exception under the Patient Safety Rule specifically was not extended to this category.
- However, if the carrier is conducting, in part, patient safety activities such as benchmarking, risk analysis, studies, etc., and to do so needs access to some PSWP, the Patient Safety Rule allows disclosure of PSWP to contractors involved in patient safety activities.

Peer Review Case Study: Analysis, continued

- REMEMBER - Once PSWP has been reported to the PSO, it CANNOT be disclosed to an outside independent party, such as a court.
- PSWP can be disclosed to an attorney even if it already has been reported to the PSO because the attorney is an agent/fiduciary of the hospital.

Peer Review Case Study: Analysis

List of Documents – What can or should be protected

- Medical records – not protected under Patient Safety Act. Patients have legal right to obtain their records under state laws.
- Internal incident reports – if collected within PSES for reporting to a PSO and are not mandated or record-keeping reports, they are PSWP. Can be used for internal purposes and can be shared with counsel.
- Fitness for duty report – if physician is an employee, is the evaluation being conducted for HR purposes or for improving patient care and reducing risk? If being collected outside of PSES and/or for a purpose different from a patient safety activity, it will not qualify as PSWP. The report, however, can be submitted into the PSES for evaluation.

Peer Review Case Study: Question

- Can peer review activities and documents such as committee reports, peer review analyses, outside reviews, disciplinary proceedings, etc., be collected in a PSES for reporting to a PSO and therefore be considered PSWP?
- YES! Factors to consider when comparing PSQIA protections to state statutes/case law protections:
 - Scope of protected activities.
 - Scope of covered entities.

Q&A DISCUSSION

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