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Partner PSO Learning Series

"Practical Applications of Patient Safety Standards to Adverse Event Scenarios"

Hosted by: MHA Keystone Center PSO

Guest Speaker: Michael R. Callahan, Partner, Health Care
Katten Muchin Rosenman LLP

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Practical Applications of Patient Safety Standards to Adverse Event Scenarios

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Speaker Bios

Michael R. Callahan, Partner - michael.callahan@kattenlaw.com

Michael R. Callahan assists hospital, health system and medical staff clients on a variety of health care legal issues related to accountable care organizations (ACOs), patient safety organizations (PSOs), health care antitrust issues, Health Insurance Portability and Accountability Act (HIPAA) and regulatory compliance, accreditation matters, general corporate transactions, medical staff credentialing and hospital/medical staff relations.

Michael's peers regard him as "one of the top guys […] for credentialing—he's got a wealth of experience" (Chambers USA). Additionally, his clients describe him as "always responsive and timely with assistance," and say he is "informed, professional and extremely helpful" and "would recommend him without reservation" (Chambers USA). Michael's clients also commend his versatility, and say "He is willing to put on the hat of an executive or entrepreneur while still giving legal advice," according to Chambers USA.

He is a frequent speaker on topics including ACOs, health care reform, PSOs, health care liability and peer review matters. He has presented around the country before organizations such as the American Health Lawyers Association, the American Medical Association, the American Hospital Association, the American Bar Association, the American College of Healthcare Executives, the National Association Medical Staff Services, the National Association for Healthcare Quality and the American Society for Healthcare Risk Management.

Michael was recently appointed as chair of the Medical Staff Credentialing and Peer Review Practice Group of the American Health Lawyers Association. He also was appointed as the public member representative on the board of directors of the National Association Medical Staff Services.

He was an adjunct professor in DePaul University's Master of Laws in Health Law Program, where he taught a course on managed care. After law school, he served as a law clerk to Justice Daniel P. Ward of the Illinois Supreme Court.

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Topics to be Covered

This program will review a number of patient safety scenarios involving adverse events, patient injuries, peer review issues and malpractice litigation. Among the areas to be addressed are the following:

- What information can be collected within a PSES and considered PSWP that 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?
- How is “deliberations and analysis” distinguishable from the reporting pathway for creating PSWP?
- What are the requirements and best practices for disclosing PSWP to third parties who are assisting providers in their patient safety activities, including lawyers, accountants and independent contractors?

Topics to be Covered (cont'd)

- Can a provider assert state, Patient Safety Act and attorney-client privileges at the same time?
- What types of risk management and litigation activities can and cannot be collected in a provider's PSES for reporting to a PSO and therefore be treated as PSWP?

Disclaimer

- The opinions expressed in this presentation do not reflect the official position of the Agency for Healthcare Research and Quality (AHRQ) or the Office of Civil Rights (OCR) or MHA Keystone Center.
- This information is not being offered as legal or medical advice.

Follow Up Questions

1. What is “functionally reported?”
   - The reporting pathway has two options:
     - Actual reporting which typically is electronic but could include physical reporting, i.e., delivery of PSWP
     - Functional reporting
   - Information relating to identified patient safety activities collected in a provider’s PSES which is not actually reported and is not treated as or qualifies as “deliberations or analysis” must be functionally reported.
   - Best practice steps for demonstrating the information has been functionally reported are:
     - Identify in your PSES the specific reports, analyses, and other patient safety information that you intend to treat as PSWP but are not actually reported to the PSO

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Follow up Questions (cont'd)

- Quality Committee monitors and reports
- RCAs
- Peer review investigations

- Make sure that the work product of these activities are not reports that must be prepared to meet a record keeping requirement
- The list of information which is being treated as functionally reported must be shared with the PSO
- You need to identify when information is functionally reported and document when this occurs
- Once functionally reported, PSO must be able to access this information as if it was actually reported – does not need permission

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Follow up Questions (cont'd)

2. Must all PSWP be either physically or functionally reported to be protected?
   - No
   - The other method for creating PSWP is through "deliberations or analysis" (D or A)
   - D or A is not a defined term under the Act and there is very little discussion in the NPRM on or the Preamble to the Final Rule about D or A
   - At a minimum, D or A applies to the verbal discussions and communications about a patient safety activity or event as long as it is conducted within the providers PSES

Follow up Questions (cont'd)

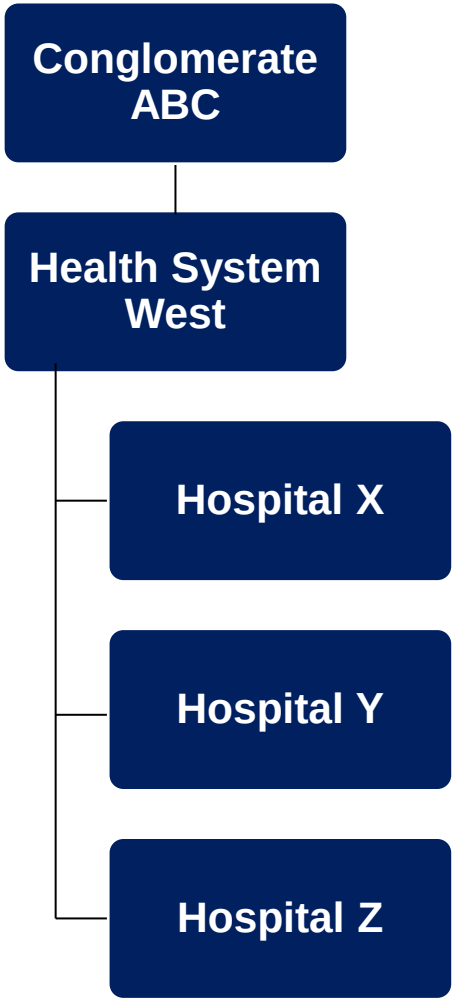
- The question is whether a report or other work product resulting from these discussions, i.e., an RCA, can be considered D or A and therefore automatically becomes PSWP without being reported or whether it must be actually or functionally reported in order to become PSWP
- Although AHRQ has not issued a Guidance or Guide to address this question, it is our understanding that AHRQ takes the position that an RCA prepared within the PSES can be considered PSWP without the need to actually or functionally report to a PSO because it would qualify as an analysis
- Any underlying "data" or information on which a report or analysis was based which does not qualify as D or A must be reported to the PSO if wishing to treat this data as PSWP
- REMEMBER: If you treat information as D or A it automatically becomes PSWP and therefore CANNOT BE DROPPED OUT.

Follow up Questions (cont'd)

- If a provider is adopting this interpretation of D or A it should document what activities are being treated as D or a versus what is being actually or functionally reported
- A best practice is to share this list of activities with the PSO because a PSO does not have legal access to D or A unlike functionally reported activities.

Follow up Questions (cont'd)

3. Can the hospitals within a regional health system share PSWP amongst themselves?
   - Yes – there is a disclosure exception which allows affiliated providers to share their identifiable PSWP
   - Which are affiliated providers?
     - Conglomerate ABC is not an affiliated provider unless it meets the definition of a parent organization.
     - Hospitals X, Y and Z are affiliated providers because they are legally separate entities, meet the definition of a provider, and are under common management or control with Hospital X.
     - Health System West also is an affiliated provider because it is a legally separate entity and qualifies as a provider because it manages and controls Hospital X.



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Follow up Questions (cont'd)

4. Is a medical record used for billing for Medicare/Medicaid billing an "original record" which therefore cannot be considered PSWP?
   - Yes

Follow up Questions (cont'd)

5. Do you have recommended language to be placed in a hospital affidavit to support that a document is PSWP?

- Document, document, document
  - PSO certification letter
  - PSO member agreement
  - PSES policies
  - Forms
  - Documentation of how and when PSWP is collected, reported or dropped out
  - Detailed affidavits
  - Demonstrated compliance with external record reporting and record keeping requirements

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.

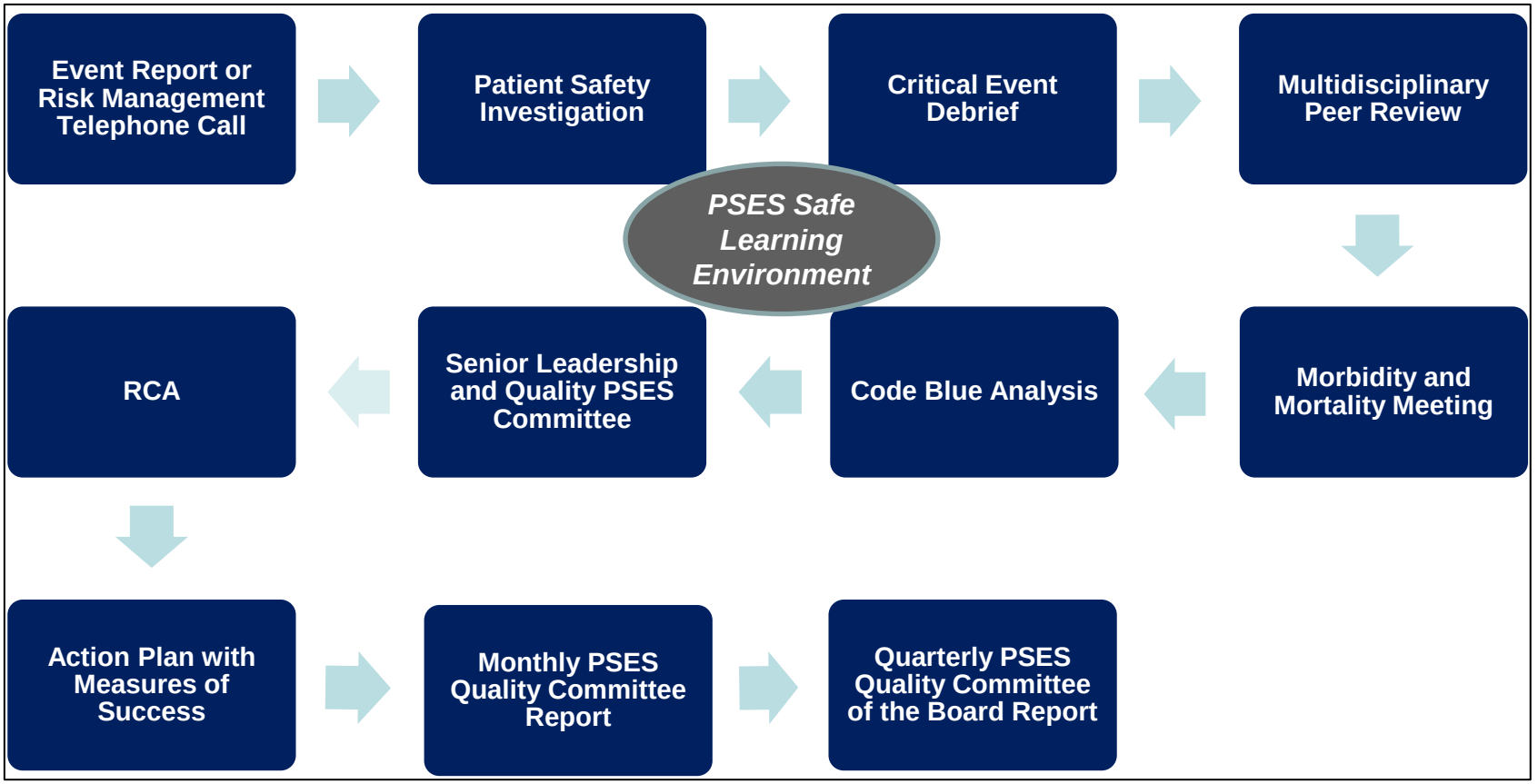
1. Patient fell at 1400 on 12/1/2015.
2. Nurse contacted the assigned resident physician at 1415.
3. Resident A examined patient, documented the event in the medical record and ordered a knee x-ray because the patient was complaining of knee pain.
4. Resident A documented no apparent injury after x-ray reviewed.
5. Nurse A entered a Safety Intelligence® event report at 1415.
6. Patient complained to Nurse B that she has a headache at 1700.

Patient Fall Case Study (cont'd)

7. Nurse B call resident B and received an order for Tylenol 500 mg prn headache.
8. Nurse B found patient on floor nonresponsive at 1800 and called a code blue.
9. Code team arrived at 1830 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.

Patient Fall Case Study: PSES Activity

Develop a plan to conduct all deliberations, analysis and communication within the PSES



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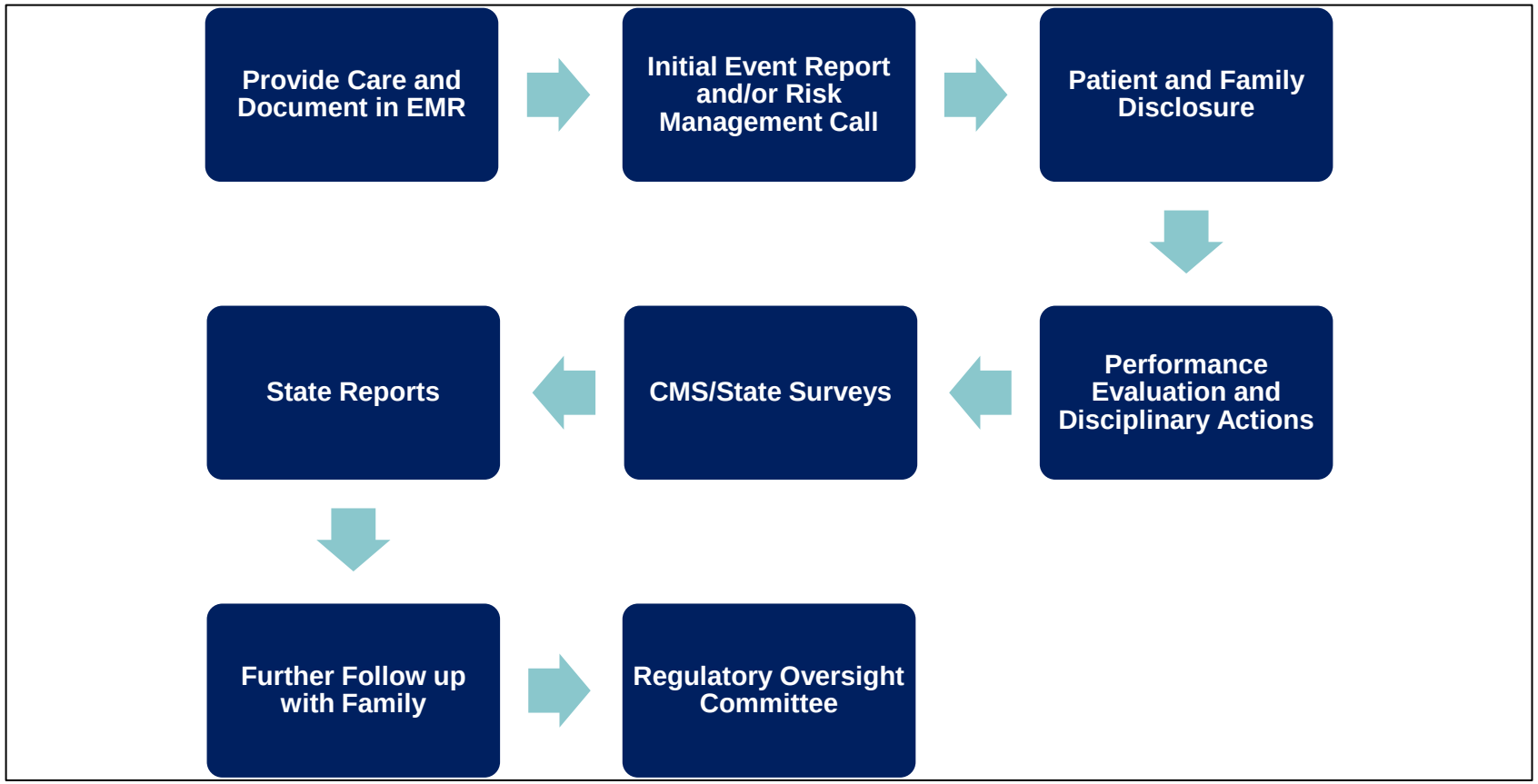
Patient Fall Case Study: Meet Regulatory and Ethical Obligations Outside PSES



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PSES Documentation is a Best Practice and Will Be Needed, if Privilege and Confidentiality Challenged

PSES policy provides as follows:

- Activities, documents and systems that comprise Hospital A'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.

Patient Fall 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, State, or The Joint Commission (TJC)?
- If the morbidity and mortality deliberation and analysis occurred within the PSES, what can be shared with during an ACGME survey?

Patient Fall Case Study: Analysis

- Factual 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.

Patient Fall Case Study: Analysis (cont'd)

- Morbidity and Mortality sessions can be completed within the PSES.
- The following data may be shared during an ACGME survey:
  - Meeting Date
  - Factual information and/or
  - Actions taken to improve care.

Patient Fall Case Study: Questions

- Safety Liaison wants to submit the RCA to the PSO as PSWP.
- Risk Manager, however, needs the RCA for mandatory state reporting and disciplinary actions, therefore does not want it reported to the PSO.

Questions

- Was the RCA created and maintained within the PSES?
- If reported to the PSO, can it be dropped out in order to report to the state?
- If removed from PSES before reporting, could a copy be sent to the PSO?
- What information must actually be given to the state where adverse event reporting is required?

Patient Fall Case Study: Analysis

- RCA conducted within PSES may not be removed but AHRQ takes the position that if it was a Bucket 1 (mandated report) or a Bucket 2 (record keeping) report it does not qualify as PSWP.
- Information reported to the PSO may not be removed to use for another purpose e.g., disciplinary action, 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.
- If reported to the state, a provider may choose to send a copy to its PSO and the information may become PSWP, but the original provider records remain unprotected (non-PSWP).
- During a survey, the state may be given facts about the event that are documented in the EMR, regulatory incident report and actions taken to improve care.

Patient Fall Case Study: Questions

Disclosure by Attending physician, nurse and risk manager

- Physician wants to share with family details about what happened.
- Family has also requested information about what is being done to prevent this from happening to someone else.

Questions

- What information may the team share with the family?
- Can the team share with the family actions taken to prevent this type of event from recurring?
- May the team share contributing factors identified during the RCA?

Patient Fall Case Study: Analysis

- Share facts about what happened with the patient and family These facts should be documented in the EMR. These facts are not PSWP.
- Share actions taken to improve care with the patient and family. Actions taken are not PSWP.
- Do not share privileged and confidential PSWP with the patient and family, e.g., event contributing factors.

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 of time:
  - 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. The following comments, questions and concerns were expressed.

Peer Review Case Study: Questions

Risk Manager

- Needs to contact insurance carrier and defense counsel regarding possible litigation in one or more of the adverse events.

Questions/Concerns

- Can she share PSWP with carrier?
- Can she share PSWP with defense counsel?

Peer Review Case Study: Analysis

- Under the Final Rule, there are a limited number of PSWP disclosure exceptions. Section 3.206(b)(9) 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 in order 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

- With respect to the insurance carrier, the business operations exception specifically was not extended to this category “at this time”. However, if the carrier is conducting, in part, patient safety activities such as benchmarking, risk analysis, studies, etc., and in order to do so needs access to some PSWP, Section 3.206(b)(4) allows disclosure of PSWP to contractors involved in patient safety activities. If not, the only other way is through a written authorization under Section 3.206(b)(3) “by the parties from whom the authorization is sought.”

Peer Review Case Study: Analysis (cont'd)

- **REMEMBER** – Once it has been reported to the PSO it CANNOT be disclosed to an outside independent party, such as a court. Because the attorney is an agent/fiduciary, PSWP can be disclosed to him/her even if it already has been reported. If not reported it can be removed, but it is no longer PSWP. However, the state confidentiality protections might apply.

Peer Review Case Study: Questions

Quality Manager

- Needs to send three never events reports to CMS. She is concerned that a CMS/state surveyor will show up to investigate and will demand to see any root cause analyses that are generated as well as some or all of the peer review materials that are developed as a result of the plan. What, if anything, does she have to give to CMS, The Joint Commission or any other third party?
  - Can the proposed morbidity/mortality study be done within the PSES and results shared? What entity should conduct the study?
  - What documents and records can or should be protected?

Peer Review Case Study: Analysis

- Final rule requires that reports that must be filed with the state or federal government and agencies, i.e., never events, adverse events, (Bucket 1 reports) must still be reported. These reports should not be submitted to a PSO, but a copy may be sent.
- Do these documents qualify as Bucket 2 reports?
- Everything else can be collected in the PSES for reporting to a PSO or possibly treated as D or A.
- CMS is on record as saying it will not require providers to turn over PSWP BUT you otherwise have to demonstrate compliance with QAPI requirements.
  - Be prepared to turn over the resulting action plan which is generated as part of the RCA.

Peer Review Case Study: Analysis

- TJC has taken the same position and will not require the hospital to turn over PSWP BUT Section 3.206(b)(8) allows for a voluntary disclosure to an accrediting body as long as certain identifiers are removed and the non-disclosing provider agrees to the disclosure, e.g., the physician.
- Keep in mind, if information collected in the PSES has not been functionally or actually reported and not treated as D or A it can be dropped out and turned over to a third party.
- With respect to the M&M study, this is a patient safety activity and thus can be included in the hospital's PSES. PSO can collect this PSWP from participating hospitals, create a study/report and send back to all. The report also is considered PSWP. It must be decided whether hospitals included in the study will or will not be identified.
- If hospitals/providers are identified, you must obtain written authorization in accordance with requirements in the final rule.

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 Bucket 1 or Bucket 2 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. Physician in this Scenario is independent and not employed or under contract.

Peer Review Case Study: Analysis

- You have to make this call on the front end when designing your PSES. Because there may be a corporate negligence claim, patient complaint, CMS/state surveyor, investigation, etc., you will want to take steps to maximize your confidentiality/privilege protections under state and/or federal law.

CMO and Department Chair

- Both have agreed to authorize a fitness for duty assessment. Depending on outcome, a 360 degree FPPE assessment will be conducted which will include peer interviews, direct proctoring of 10 cases and a requirement that he meet with the Department Chair when wanting to operate on morbidly obese patients.

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?

Peer Review Case Study: Analysis

- YES! Factors to consider when comparing PSQIA protections to state statutes/case law protections:
  - Scope of protected activities.
  - Scope of covered entities.
- Can the protections be waived if not properly disclosed?
- Can a corporate parent and/or ACO be covered even though it is not a licensed provider?
- Will federal courts in your jurisdiction allow a state court confidentiality statute to pre-empt a federal claim, i.e., antitrust, discrimination?
- Can the protected information be shared through your CIN?

Peer Review Case Study: Analysis

- The decision on whether to seek PSQIA and/or state protection is your choice. Some or all can be included in PSES because these clearly are patient safety activities. Arguably you can assert both privilege protections but would document that you are principally relying on the Patient Safety Act.
- Attorney-client work products privilege is different and would not apply to these materials.

Health System Proactive Risk Assessment Case Study

1. Health system ABC has a process where it conducts proactive risk assessments within its PSES and reports results to PSO.
2. Health system ABC has 2 Divisions (A and B) with 10 hospitals reporting to each division.
3. Health system ABC has identified that Division A organizations have not been following policy for sterilization of equipment and has identified that a trend in orthopedic infections may be related to this finding.
4. Health system ABC also has identified a trend in serious infections in Division B.
5. Health system ABC determined that it will disclose information to families.

QUESTIONS

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