Privilege, Work Product and Patient Safety: 
The Interplay Between the Patient Safety and Quality 
Improvement Act of 2005 and Missouri Law

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Agenda

Introduction – MOCPS Perspective

1. The Patient Safety and Quality Improvement Act of 2005 -
   a) Background
   b) Key Concepts
2. Privilege and Confidentiality Protections of the Act
3. Current Case Law
5. Maximization of Privileges
   a) Patient Safety Work Product
   b) Peer Review
   c) Attorney-Client
6. Questions and Answers
MOCPS Perspective

• Founding of MOCPS in 2005
  – Missouri Commission for Patient Safety
  – Founding members – desire to proactively address patient safety issues with a focus on improvement vs. a regulatory approach through legislation

• Patient Safety & Quality Improvement Act of 2005 (PSQIA)
  – intent to establish a culture supporting providers in working together to improve patient safety through federal protections

• MHA Adverse Event Initiative – September 2008
  – Inform patient of the adverse event
  – Waive payment related to the adverse event
  – Report event to a Patient Safety Organization (PSO)

MOCPS Perspective

• Health Reform Provisions –
  – AHRQ to establish a PSO Readmissions Program (ACA Section 3025)
  – Beginning 1/1/15, health plans may only contract with hospitals with >50 beds that have a Patient Safety Evaluation System (PSES) in place (ACA Section 131, (h)(1) – A PSES is established through work with a PSO)
  – Beginning 10/12, Medicare payments incentives to improve care, such as reducing infections, and payment reductions for high readmission rates (ACA, Sec. 3001, 3025)
  – Medicaid restricting payments for Healthcare Acquired Conditions (HACs) (harm to patients) (ACA Sec 2702)
  – Beginning 10/14, Medicare will reduce payment for high rates of HAC (ACA Sec 3008)

• Missouri Medicaid Rule – Effective July 2009
  – Modification expected to be published late 2011-early 2012

• Proactively address public, legislative, and payment pressures to improve quality and safety
What We Know About the Safety of Care in Missouri?

- Statistics about certain types of events
- Public reports
- Media expose’
- Personal stories
- Patient advocate blogs

But, we HAVEN’T known enough to make widespread improvement - types of errors, severity of harm, cause of errors – until now!

What do we know now? What could we know?

- For the period January 2010-August 2011
  - 50+ reporting facilities
  - 894 events
  - 527 HACs &/or SRE
  - 334 other adverse events
  - 18 near misses
  - 15 unsafe conditions

Preliminary data
Incidents by Event Type

- Infection: 39%
- Medication / Other Substance: 17%
- Fall: 19%
- Other: 12%
- Pressure Ulcer: 7%
- Surgery / Anesthesia: 3%
- Other: 0%
- Device / Supply: 2%
- Blood: 1%

Harm Experienced from Reported Events

- Additional treatment: 29%
- Temporary harm: 29%
- No harm: 29%
- Unknown: 7%
- Emotional distress or inconvenience: 1%
- Death: 3%
- Permanent harm: 2%
- Unknown: 3%

Preliminary data

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Level of Harm - Falls

Reported SREs & Harm
Total by HAC Type

HACs by HAC Type

- Falls and Trauma: 38.0%
- Vascular Catheter-Associated Infection: 11.0%
- Catheter-Associated Urinary Tract Infection (UTI): 5.0%
- Catheter-Associated Bloodstream Infection (BSI): 0.7%
- Other HAIs: 3.6%
- Acute Lung Injury: 1.4%
- Organ Failure: 0.4%
- Septic Shock: 0.4%
- Post-Operative Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE): 0.0%
- Foreign Object Retained After Surgery: 1.1%

Preliminary data

HAC – Falls & Trauma Outcomes

HAC Outcomes from Falls & Trauma

- Fractures: 22%
- Intracranial Injuries: 4%
- Crushing Injuries: 4%
- Burns: 2%
- Dislocations: 1%

Preliminary data
Residual Harm of Intracranial Injuries

- 65% Permanent harm
- 13% Severe permanent harm
- 5% Death
- 4% Temporary harm
- 13% Unknown

Preliminary data

Where We Go from Here

- Oct-Nov 2011 - Regional PSO meetings
- Communication to CEOs/PSO Contacts
- Continue addressing barriers to PSO reporting
- Analyzing preliminary data & root causes
  - Identifying common issues, trends, issuing reports and alerts
- Collaborating with PSOs across the nation
- **Learning, Sharing the Learning, Prevention**
1. The Patient Safety and Quality Improvement Act of 2005

PSQIA Background

- Allows creation of PSOs
- Threshold for provider: contract and reporting
- Patient Safety Evaluation System (PSES)
- Patient Safety Work Product (PSWP)
- Privilege Protections (no forced production)
- Confidentiality (limited voluntary production)
- Workforce: PSES and others

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Key Concept: Patient Safety Evaluation System (PSES)

• “The collection, management, or analysis of information for reporting to or by a PSO”
• It is the mechanism by which information can be collected, maintained, analyzed and communicated
• It exists whenever the provider engages in patient safety activities for the purpose of reporting to a PSO
• It exists whenever the PSO engages in these activities for patient safety purposes


Non-Legal Definition of PSES

• Provider defines it
• Broad or narrow
• Can put almost any patient safety work in it
• All deliberations and analysis that go on in PSES are PSWP and protected
• A particular committee can be in AND out for different functions
Key Concept: Patient Safety Work Product (PSWP)

Any data, reports, records, memoranda, analyses, or written or oral statements which:

• Are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, or
• Are developed by a PSO for the conduct of patient safety activities, or
• Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES


Non-Legal Definition of PSWP

• Materials prepared by or for a component of the PSES
• NOT original business records
• NOT actual factual knowledge of staff
• Any evidence of the deliberations and analysis within the PSES
• NOT the actual changes made as a result of the work (new policies, educational programs, etc.)
• Privileged and confidential
What is NOT PSWP?

– Patient’s medical record
– Billing and discharge information
– Any other original patient or provider record
– Information collected, maintained or developed separately (for another purpose), or that exists separately from a PSES

2. Privilege and Confidentiality Protections of the PSQIA
PSWP Privilege Protections

• Patient Safety Work Product (PSWP) is privileged and is not subject to:
  – Federal, state or local civil, criminal or administrative subpoena
  – Discovery in Federal, state or local proceedings
  – FOIA disclosure
  – Admission in disciplinary proceedings against a provider
  – Admission in any civil, criminal, administrative rulemaking, or administrative adjudicatory proceeding

Exceptions to Privilege and Confidentiality Protections

• PSWP may be disclosed:
  – For use in a criminal proceeding, following an in camera determination by the Court that the PSWP
    • Contains evidence of a criminal act, and
    • Is material to the proceeding, and
    • Is not reasonably available from another source.
  – To obtain equitable relief as result of unauthorized disclosure of PSWP
  – If disclosure is authorized, in writing, by each provider identified in the work product.
Exceptions to Confidentiality Protections

• Disclosure within the provider’s workforce (42 CFR §3.20) (Definitions)
• Among Affiliated Providers (common ownership or management) (42 CFR §3.20)
• To the PSO
• The PSO can report de-identified information to its providers

Exceptions to Confidentiality Protections

• Disclosure for business operations
  – Examples – attorneys or accountants who sign agreements (workforce)
  – PSWP may not be further disclosed by these individuals
• Disclosure of non-identifiable PSWP:
  – anonymized as to provider,
  – de-identified as to protected health information, and
  – contextually de-identified so that the provider, patient or reporter cannot be identified
• Disclosure for research purposes (42 CFR §3.206(b)(iv)(B)(6))
Exceptions to Confidentiality

• Voluntary disclosure by a Provider to an accrediting body that accredits that Provider:
  
  – All identified providers must agree, in writing, to the disclosure; or, direct identifiers of any provider are removed
  – PSWP may not be further disclosed by the accrediting body
  – The accrediting body may not take action against a Provider based on good faith participation by the Provider in collection, development and maintenance of PSWP.
  – An accrediting body may not require a Provider to reveal its communications with a PSO (42 CFR §3.20(b)(8)(i)-(iii))

Exceptions to Confidentiality

• Disclosure to the FDA concerning an FDA-regulated product or activity, by an entity or contractor on behalf of the FDA or entity
  
  – PSWP may not be further disclosed by the FDA except for the purpose of evaluating the quality, safety or effectiveness of the product or activity
• Disclosure to law enforcement if information is believed to be necessary relating to the commission of a crime.
• Disclosure to the Secretary of HHS to investigate or determine compliance with the PSQIA or HIPAA.
Cannot Disclose to Surveyors

• CAN share all original documents; they can interview staff
• Incident reports can be in or out of PSES, facilities taking different approaches
• CAN talk generally about what issues went to PSES
• CAN share Action Plan
• This is a national issue
  – MOCPS and other PSOs are working with federal, regional and state officials from CMS and AHRQ to obtain clarification for providers, PSOs and surveyors on PSWP disclosure.

Background – Law on Privilege and Confidentiality
PRIVILEGES AND CONFIDENTIALITY PROTECTION

A. GENERAL RULES REGARDING DISCOVERY

Missouri Supreme Court Rule 56.01(b)

1. Discovery of anything “not privileged, that is relevant”
2. Privileged matters absolutely non-discoverable

B. ATTORNEY-CLIENT PRIVILEGE

1. Confidential communication, oral or written, between attorney and client with reference to litigation pending or contemplated
2. Purpose of communication must be to secure legal advice
C. ATTORNEY WORK PRODUCT PRIVILEGE

1. Created in preparation for litigation (tangible)
   - Tangible – 56.01(b)(3) – Only upon showing party seeking discovery has substantial need and unable without undue hardship to obtain substantial equivalent

2. Thoughts and mental impressions (intangible)
   - Intangible – Not discoverable

DOCUMENTS PROTECTED BY THE ATTORNEY-CLIENT PRIVILEGE

1. Statements – Where a risk manager investigates an incident and takes a statement from an employee, that statement forwarded to the insurance company or attorney is an attorney client communication.

2. Incident reports – for example, if an employee prepares an incident report for his insurer and that report is forwarded to the insurer and then to the attorney, that document (incident report) is considered an attorney client communication.

   There are exceptions: Routine incident reports that just track future loss prevention are not privileged. They have to be for the purpose of investigating a claim.
PSO PROTECTION vs. ATTORNEY-CLIENT PRIVILEGE

1. Privilege protects information shared between attorney and client for purpose of securing legal advice (remember narrow scope of issues)
   - Incident report created for purposes of identifying and reporting possible cases to RM → insurance company → attorney
   - Statements collected for attorney
2. Work performed for other purposes is NOT privileged, even if provided to attorney

WAIVER OF ATTORNEY-CLIENT PRIVILEGE REGARDING DISCLOSURE TO PSO

1. Very narrow range of material protected
2. RCA is not an attorney-client document
3. Quality documents are not attorney-client documents
4. Risk of Waiver – all documents waived on that issue
5. Peer review documents do not trigger waiver if disclosed to PSO
D. MISSOURI PEER REVIEW PRIVILEGE

“Except as otherwise provided in this section, the interviews, memoranda, proceedings, findings, deliberations, reports, and minutes of peer review committees or the existence of same, concerning the health care provided any patient are privileged . . . .”

“No person who was in attendance at any peer review committee proceeding shall be permitted or required to disclose any information acquired in connection with or in the course of such proceedings, or to disclose any opinions, recommendations, or evaluation of the committee or board, or any members thereof”

Mo. Rev. Stat 537.035.4

MISSOURI PEER REVIEW PRIVILEGE (Cont’d)

Exceptions:
1) Information otherwise discoverable or admissible from original sources not immune – merely because presented during peer review
2) Member, employee, agent of peer review committee or any person appearing before committee cannot be prevented from testifying about matters in personal knowledge
3) Disclosure of any peer review information shall not waive or have any effect on its confidentiality, non-discoverability or non-admissibility

Mo. Rev. Stat 537.035
MISSOURI PEER REVIEW CASES

1. **Faith Hospital v. Enright**, 706 S.W.2d 852 (Mo. banc 1986)
   - Peer review documents concerning health care provided patient are privileged
   - Credentials committee documents – discoverable unless concern health care provided patient

MISSOURI PEER REVIEW CASES (CONT’D)

2. **St. Anthony’s Medical Center v. Provaznik**, 863 S.W.2d 21 (Mo. App. E.D. 1993)
   - Interrogatories seeking detailed information concerning reports or meetings related to treatment of patient fell squarely within peer review privilege
MISSOURI PEER REVIEW CASES (CONT’D)

3. **Lester E. Cox Medical Center v. Darnold**, (944 S.W.2d 213 (Mo. banc 1997))
   - Interrogatories demanded disclosure of information protected by peer review (quality assurance, quality assessment and/or quality management report of committee)

MISSOURI PEER REVIEW CASES (CONT’D)


   Outside report requested by peer review committee not protected.
   a. Outside doctor not a member of peer review committee
   b. Not a peer review committee report
      1) Statute does not include reports commissioned or reviewed by a peer review committee
MISSOURI PEER REVIEW CASES (CONT’D)

2) Report not sought as part of consideration to grant privileges
3) Wanted report to defend later lawsuits because doctor failed to complete fellowship in spine surgery
c. Other Issues:
   1) Plaintiffs already had most of documents, therefore, not entitled to permanent writ because defendant could not show that they would be spared from absolute irreparable harm;

MISSOURI PEER REVIEW CASES (CONT’D)

Other Issues (Cont’d):

   2) LeBlanc v. Research Belton Hospital, 278 S.W.3d 201 (Mo. App. W.D. 2008) held that there was qualified immunity for individuals “if their negligence in granting staff privileges derives from their good faith reliance on a peer review committee’s recommendation,” but did not prevent recognition of the cause of action of negligent credentialing in Missouri, and in no way discussed the discoverability of reports prepared by outside sources pursuant to 537.035.4.

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MISSOURI’S PEER REVIEW PRIVILEGE

1. Protects the materials related to the investigation/assessment of “the healthcare provided to any patient”
2. Disclosure (including the PSO) does not waive the privilege (subsection 4)
3. Information can be subpoenaed by licensing boards
4. Available to parties involved in hearings, in lawsuits related to privileging
5. Risk of picking and choosing what to disclose
6. Federal court may or may not recognize state privilege, especially in cases based on federal law

Mo. Rev. Stat. 537.035

WHY USE PEER REVIEW PRIVILEGE?

Remember the potential of doing work within peer review committee but outside PSES
- Products can be used in credentialing process/medical staff action
- Products can be used to defend actions in claim by involved provider
- Still have significant protections
- Individuals involved in properly structured peer review have immunity under HCQIA
3. Current Case Law

III. CURRENT CASE LAW
(DISCUSSING PSQIA)

   - Provider of vascular access service sued hospital system
   - Motion to compel records relating to audit of services
   - Defendant claimed Tennessee Peer Review
   - Report to committees discontinuing use of outside vendor was not privileged under peer review
CURRENT CASE LAW (Cont’d)

Lee Medical, Inc. v. Beecher

- Court discussed expansion of Peer review and PSQIA
  Congress . . . Create[d] a tightly crafted federal
  privilege for “patient safety work product” actually
  reported to a “patient safety organization.
  Patient safety work product that is not actually reported is
  not privileged.

CURRENT CASE LAW (Cont’d)

2. Schlegel v. Kaiser Foundation Health Plan – No. CIV 07-
   - Plaintiff sued Kaiser re transplant program
   - Motion to compel documents
   - Defendant argued state law peer review and PSQIA
   - No evidence that investigations conducted by Kaiser,
     California Department of Managed Health Care,
     UNOS and CMS were prepared for and reported to
     PSO
CURRENT CASE LAW (Cont’d)

   - Plaintiff sued NIH re research protocol
   - Motion to compel documents related to monitoring of NIH research protocol
   - Defendant argued Maryland peer review
   - No peer review in jurisdiction

CURRENT CASE LAW (Cont’d)

Dieffenbach v. United States of America

- Court recognized qualified privilege for confidential evaluative materials produced by NIH review process based on:
  1) Intent of Congress in passing PSQIA
  2) Public policy evident in Maryland privilege law
  3) The particular circumstance of case
CURRENT CASE LAW (Cont’d)

4. **Illinois Department of Financial and Professional Regulation v. Walgreens**
   - IDFPR sought medication error reports
   - Walgreens asserted PSWP Privilege
   - Affidavit testimony proved PSWP applied by showing that only documents subject to subpoena were part of PSES
   - Court did not review individual reports in camera

   Court found PSWP privilege applied based on classification and location of documents
   Case has been appealed

CURRENT CASE LAW (Cont’d)


Medical Malpractice Action Against Norton Hospitals, Inc.
   - Plaintiff’s motion to compel Sentinel Event Records and Root Cause Analysis
   - Defendant objected based on attorney client, work product and PSQIA privilege

   Court’s Analysis
   1. **Attorney/Client Privilege Does Not Apply**
      - Not prepared for purpose of facilitating the rendition of legal services
      - Prepared for complying with Joint Commission and for purpose of providing to PSO.
CURRENT CASE LAW (Cont’d)

2. Work Product Privilege Does Not Apply
- Not prepared in anticipation of litigation
- Prepared to comply with hospital reporting requirements

3. PSQIA Privilege Applies
   a. Court relied on KD v. Dieffenbach
      - Encourage “culture of safety”
      - Congressional intent that communications be protected to foster openness in the interest of improved patient safety
   b. Court finds area preempted by federal law
      - Protective order granted for Sentinel Event and RCA materials reported to PSO

4. Value of Patient Safety Work Product Protections – Case Studies

5. Maximization of Privileges
Updated Interpretations

• In Fall 2010, AHRQ and OCR made the following interpretation:

  Once deliberations & analyses occur within the PSES, those deliberations & analyses cannot be removed from PSES
  – D&A that happens in the PSES stays in the PSES!
  – Cannot be shared outside of workforce

Maximizing Federal Protections Without Losing Utility

✓ Identification of different tracks for post-event work—PARALLEL PATHWAYS: THE RIGHT WORK IN THE RIGHT PLACE
✓ Case Studies
Deliberations & Analysis

- No definition in the regulations, yet a very important concept
- General guidance:
  - Beyond the facts, or the “what, when and where”
  - The point at which you begin drilling down to the “how and why”

Committee Work

Unless defined in the PSES, non-event specific patient safety work (i.e. quality/safety committees or workgroups that work on issues that are not necessarily event-specific) cannot receive federal protections under the Patient Safety and Quality Improvement Act
Case Study: Wrong Site Surgery

A 38-year-old female with a long history of right knee pain was scheduled to have a right total knee replacement at a teaching hospital. The patient was placed under general anesthesia in the operating room before the site was marked. The attending explained to the junior and senior residents how the procedure should evolve. Unbeknownst to the team, the X-rays had been marked incorrectly. The junior resident incised the left leg. Perceiving that it would take 20 minutes before they would expose the knee itself, the attending surgeon left the operating room and went back to his office. Soon after he left, the senior resident was called away for an emergency.
Case Study: Wrong Site Surgery

The junior resident proceeded without the attending surgeon and carried down the incision to the bony structures, but had not cut bone. When the attending surgeon returned, he looked at the schedule posted outside the room (R TKR). Upon entering, he immediately discovered 1) his senior resident had been called away, 2) his junior resident was involved in separating and clearing the muscle and tissue from the joint, and 3) the resident was operating on the wrong side. They immediately closed the left leg and proceeded to work on the right leg without difficulty.

Examples of Broad Findings

• There is a culture of the attending surgeons skipping out of key parts of surgery
• There is a pattern of insufficient ED specialty coverage, which means senior residents are often pulled out of surgery
• The surgeons bully the staff into skipping identification protocols
• Staffing patterns in the registration/testing area lead to late starts
Examples of Findings (Protect or Not?)

- There is a culture of the attending surgeons skipping out of key parts of surgery. Did he this time?
- There is a pattern of insufficient ED specialty coverage, which means senior residents are often pulled out of surgery. Was this case inappropriate for the junior resident?
- The surgeons bully the staff into skipping identification protocols. Why was protocol not followed here? Is the protocol itself adequate?
- Staffing patterns in the registration/testing area lead to late starts. Did this case start late? Was the staff hurried?

Best Use of Expert Report

- They are often most helpful to the patient safety process, but most harmful if disclosed.
  - DIVIDE THE ASSIGNMENT INTO SEGMENTS, based on the purpose of each activity
  - ASK FOR SEPARATE REPORTS, even if it costs more
  - Think about using separate experts based on purpose of report
Multiple Reports

- Report of XXX experts prepared at request of ABC hospital:
  - Policies for attending oversight?
    - Does staff understand them?
    - Are they routinely followed?
  - Specialty coverage for ED:
    - Is there appropriate coverage scheduled so that residents who need to be in surgery can be there?
  - Policies for time-out, etc.
    - Policies adequate?
    - Facility practices support them?
  - Recommendations

- Report of XXX experts prepared at request of Peer Review body of ABC hospital:
  - Review of attending’s medical records and outcomes
  - Interview with attending and residents re attending’s practices
  - Impact of practices on patient outcomes
  - Is attending meeting oversight obligations of contract with hospital? (Sets standard)
  - Conclusions on standard of practice

Apply to Case Study

- Four broad issues: Peer Review and/or PSES
  - Physician Oversight of residents: Possible contract action, possible credentialing: Peer Review
  - Role of attending in setting up surgery as negligence: possible peer review
  - Bullying (behaviors of this doc or others) Peer review
  - The general culture/policies in the OR: PSES
  - ED specialty coverage problem: PSES
  - Late starts: PSES
Reinventing (different) Wheels

- Provider can share PSWP with its own attorney
  (42 CFR § 3.2, p 70798 [definition of “workforce”; ]; § 3.206 (b)(9))
- The attorney cannot disclose it to others
- The attorney can use the information to formulate a defense, but cannot present the deliberations and analysis generated within PSES or reported to PSO
- Attorneys will probably get new/different experts
  – Support acts of individuals (including joint defense)
  – Support policy
  – Good witness

6. Questions and Answers
Common Questions

1. **CMS**: What if CMS requests PSWP during surveys/complaint investigations?
2. **Transparency**: What if my hospital is migrating to full transparency with patients/families following adverse events? Will working with a PSO allow this?
3. **PSWP**: I feel hesitant “locking down” a document as PSWP when some unforeseen need may arise in the future to use it for a different purpose. What would I do in such a situation?
4. **Deliberations & Analysis**: I am uncomfortable with AHRQ’s interpretation that once deliberations & analysis occurs inside the PSES then it cannot be removed. What if the severity of an adverse event is not discovered until the Root Cause Analysis takes place? In such a case, what would my hospital do if it needed to share information that could be considered deliberations & analysis with the media or others outside of its workforce?

OTHER QUESTIONS?

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