Learning Objectives

► Understand the regulatory requirements related to performance improvement
► Comprehend the legal system structure
► Recognize pertinent rules of civil procedure regarding discovery
► Recognize what information can become patient safety work product
► Apply lessons learned from cases presented
  ► Recognize the difference between initial event investigations and performance improvement
► Identify and commit to next steps....

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Patient Perspective: Why Do Patients Sue?

- Triggering event-error combined with serious harm/death
- Anger
- Surprise
- Distrust
- Risk of litigation may increase when the provider does not communicate outcomes of care, including errors

Source: Medscape Malpractice Report - Did they deserve to be sued?, Medscape, Jul 24, 2013. [cited 2017 Apr. 20].
Trends in Hospital Professional Liability Claims*

2019 Benchmark Projections

- Overall Frequency: 1.58%
- Indemnity Frequency: 0.72%
- Loss Rate: $2,860
- Claim Severity: $181,000

*Based on 579,684 occupied beds (33.6% of the beds in the country)


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Regulations
Healthcare Quality Improvement Act (HCQIA) (1985)

42 USC § 11101 - **Goals:**

- Improve the quality of healthcare
- Eradicate problem of incompetent physicians and dentists
- Reduce the threat from financial liability discouraging physicians from actively participating in effective professional peer review

**Mechanism:**

Allows healthcare facilities to engage in professional review including credentialing with limited immunity from liability -

*This does not provide privilege from discovery.*
Patient Safety and Quality Improvement Act (PSQIA) of 2005

- Creation of Patient Safety Organizations (PSO)
- Participating in PSO creates federal confidentiality protection preventing disclosure for certain records
- Protects patient safety work product (PSWP) from subpoena or discovery in both civil and criminal cases
- Privilege: “Notwithstanding any other provision of Federal state, or local law...patient safety work product shall be privileged and shall not be subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceedings, including a Federal, State, or local civil or administrative disciplinary proceeding against a provider (42 U.S.C.A. §299b-22(a))(emphasis added)

Source: Pub. L. No. 109-41
PSQIA-HHS Guidance re: PSWP & Providers’ External Obligations
May 24, 2016

- Outlines HHS interpretation of the Patient Safety Act
- Explains how information becomes PSWP
- Describes information that is not PSWP
- Emphasizes the importance of the purpose for which information was assembled or developed
Patient Safety & Affordable Care Act of 2010 (ACA)

- First-ever national system for providers to voluntarily report medical errors and near misses
- Assurance of confidentiality and protection from legal discovery.
- Allows providers to seek expertise in understanding patient safety events to prevent their occurrence in a protected legal environment

Organization Requirements:
- Develop a QAPI plan within year of final rule (Submit Plan to State/Discoverable)

Legal System & Discovery Process
Court Structure

- Federal Courts
  - District Court
  - Circuit Courts of Appeal
  - U.S. Supreme Court

- State Courts
  - Trial Court
  - Appellate Court
  - State Supreme Court
Discovery

- Guided by jurisdiction’s rules of civil procedure (Federal v. State)
- Discovery rules permit litigants to discover nonprivileged material or information that is relevant to the subject matter of the litigation
- In federal court, discovery is permitted of “any nonprivileged matter that is ... proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties’ relative access to relevant information, the parties’ resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.” (Chief Justice Roberts)

Federal Rules of Civil Procedure - Rule 26

- **Initial Disclosures:** Rule 26(a)(1)(A)...Except as exempted by Rule 26(a)(1)(B) or as otherwise stipulated or ordered by the court, a party must, without awaiting a discovery request provide...name and contact information for anyone likely to have discoverable information; description of all documents, electronically stored information (ESI), and tangible things, alleged damages, and a copy of any insurance policy.

- **26(b)(5) - Pretrial Discovery**
  - Identify items privileged from disclosure

- **26(c)(1) - Protective Orders** “A party or any person from whom discovery is sought may move for a protective order in the court where the action is pending…”
Federal Rules of Civil Procedure - Rule 34

(a) A party may serve on any other party a request ...:

1. to produce and permit the requesting party or its representative to inspect, copy, test, or sample the following items in the responding party’s possession, custody, or control:

2. to permit entry onto designated land or other property possessed or controlled by the responding party, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it. (34[a][1-2])

Objections: An objection must state whether any responsive materials are being withheld on the basis of that objection. (34[b][2][C])
Discovery Process - Electronically Stored Information

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http://www.edrm.net/frameworks-and-standards/edrm-model/
Examples of Electronically Stored Information

Federal Rules of Civil Procedure - Rule 45

- Quashing or Modifying a Subpoena - When Required - On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
  - (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
  - (iv) subjects a person to undue burden (45[d][3][A][iii])
Health Information Portability and Accountability Act of 1996 (HIPAA)

- “In the absence of a valid authorization, HIPAA permits the disclosure of protected health information in response to a subpoena only if the subpoena is accompanied by a court order, or the covered entity receives satisfactory assurances . . .”
- Cautionary tale: Byrne v. Avery Center for Obstetrics and Gynecology, 102 A.3d 32, 36 (2014 Conn)

Satisfactory Assurances

- A good-faith effort to provide the individual with written notice sufficient to permit the patient to raise objections to disclosure.

- The individual’s failure to raise a timely objection following notice, or the resolution of the individual’s objection by the court or other tribunal.

- Satisfactory assurances of efforts to obtain a qualified protective order refers to a written declaration and documentation of an order submitted to a court either jointly by the parties or by the requesting party.
Definition: Privileged Information

- A special legal right, exemption, or immunity granted to a person, or class of persons - an exception to a duty

- Protections outlined in Fed. R. Civ. P. 26(b)(3)
- Objection to interrogatories: Fed. R. Civ. P. 33(b)(1) and (4)
Definition: Attorney - Client Privilege

- Attorney-client privilege: The client’s right to refuse to disclose and to prevent any other person from disclosing confidential communications [for the purpose of obtaining legal advice] between the client and their attorney.

Source. Black’s Law Dictionary, 2019
Definition: Attorney-Work Product Privilege

- Attorney-work product privilege protects from disclosure to third parties materials that are prepared for legal counsel in anticipation of litigation. The privilege protects materials prepared by legal counsel in preparation of the claims or defenses of a client’s legal case, such as documents reflecting the attorney’s litigation strategy. The privilege is not ironclad; jurisdictions differ on the application of the privilege. (Fed. R. Civ. P. 26(b)(3))
Definition: Peer-Review Privilege

A privilege that protects from disclosure the proceedings and reports of a medical facility’s peer-review committee, which reviews and oversees the patient care and medical services provided by the staff.

Source. Black’s Law Dictionary, 2019
Definition: Patient Safety Work Product

Three ways information can become PSWP:

1. The information is prepared by a provider for reporting to a PSO and it is reported to the PSO.
2. The information is developed by a PSO for the conduct of patient safety activities.
3. The information identifies or constitute the deliberations or analysis of, or identifies the fact of reporting pursuant to, a patient safety evaluation system (PSES).

# Patient Safety Act Privilege and Confidentiality Prevail Over State Law Protections

**State Peer Review**
- Limited in scope of covered activities
- State law protections do not apply in federal claims
- State laws usually do not protect information when shared outside the institution — considered waived

![Balance Scale](image)

**Patient Safety Act**
- Consistent national standard
- Applies in all state and federal proceedings
- Scope of covered providers is broader
- Protections can never be waived
- PSWP can be more freely shared throughout a health care system
- PSES can include non-provider corporate

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Waiver of Privilege

- To abandon, renounce, or surrender a claim, privilege, or right, for example, voluntarily

- The voluntary relinquishment or abandonment - express or implied - of a legal right or advantage - with disclosure of privileged information results in a waiver of the privilege

- Pursuant to PSQIA, PSO participants benefit from a broad federal legal privilege that protects “patient safety work product” from subpoenas, discovery requests, and use in civil and criminal litigation against providers in any state or federal court and other tribunals, subject to a few narrow exceptions.
Types of Information at Risk of Disclosure

- Incident Reports - Internal
- Incident Reports - External
- Witness Statements
- Investigation Materials
- Root Cause Analyses
- Reactive Systems Analyses
- Predictive Systems Analyses
- Peer Review - Credentialing Materials
- Peer Review - Performance Indicators
Reality Check

- **Reality One:** There is no guarantee when speaking of confidentiality!

- **Reality Two:** Facts, circumstances, and legal reasoning are key components in securing protection for information from disclosure...
Case Analysis:
Regional Regulations

- Massachusetts:
  - Mass. Gen. Laws Ann. Chapter 111 §204 Confidentiality of medical peer review committee proceedings, report and record; exceptions; immunity

- Maine:
  - Me. Rev. Stat. Ann, tit. 32 §2596 Review Committee Member Immunity

- New Hampshire:
In Re: Block Island Fishing Inc., 323 F. Supp. 3d 158 (1st Cir. 2018)

- **Self-Evaluative Privilege**: Protects the “opinions and recommendations of corporate employees engaged in self-evaluation of the company’s policies for the purpose of improving health and safety, seeks to encourage candid self-criticism, and prevents a chilling effect on self analysis and self-evaluation prepared for the purpose of protecting the public by instituting practices assuring safer operations...”

- **At Issue**: Motion for Protective Order re: in part, internal investigation report of a collision

- **Holding**: [June 4, 2018] Applying the self-critical analysis test from the 9th Circuit, the 1st Circuit court granted the Motion for Protective Order re:
  - Self-critical analysis report
  - Privilege does NOT extend to objective, specific facts and materials
  - Subjective investigation and analysis was protected
Massachusetts - Federal

Test:

- The information must result from a critical self-analysis undertaken by the party seeking protection
- The public must have a strong interest in preserving the free flow of the type of information sought
- The information must be of the type whose flow would be curtailed if discovery were allowed
- The document at issue must have been prepared with the expectation that it would be kept confidential

Limitation: “Only subjective impressions and opinions, not objective facts are protected.”
Maine – Federal

Ali v. Long Creek Youth Development Center, 2019 WL 302488 (1st Cir 2019)

▶ Several statutes and rules implicated
  ▶ Federal Rule of Civil Procedure 26
  ▶ 14th Amendment to the U.S. Constitution
  ▶ Americans with Disabilities Act
  ▶ Self-Critical Analysis

▶ At Issue: A post-incident assessment of a claim of excessive force, failure to provide medical treatment, and ADA discrimination. Plaintiff requested documents related to internal investigations, actions taken in response to incident, supervisor’s review of the incident, a spreadsheet used to document the investigation activities and possibly findings, and peer review evaluation of the involved physician and nurse practitioner.

▶ Holding: [Jan. 21, 2019] The U.S. District Court granted plaintiff’s motion to compel concluding that the state defendants and Correct Care Solutions failed to meet their burden of demonstrating that the self-critical analysis and peer review privileges upon which they should rely should be recognized, or as to the former, even if recognized, would shield the documents in dispute.”
New Hampshire - State


- **N.H. Rev. Stat. Ann. §151:13-a** Proceedings of Hospital Committees; Confidentiality “records of interview and all reports summaries, minutes, memoranda, charts, statistics, and other documentation generated during the activities of a quality assurance committee.”

- **At issue:** A report prepared at a patient’s request; analysis conducted by the infection control committee to help determine whether the patient contracted herpes at the hospital during the birth of her child.

- **Holding:** The report prepared by the infection control committee was privileged from discovery. The basis:
  - A hospital may have more than one quality assurance committee within the meaning of the statute
  - The report prepared by the infection control committee fell within the statutory protections offered pursuant to RSA §151-13
  - The report was prepared after the patient’s release and in order to promote “quality assurance” at the hospital.
Florida - State Court

Charles v. Southern Baptist Hospital of Florida, Inc., 209 So. 3d 1199 (Fla. 2017) [Writ of Certiorari to U.S. Supreme Court filed May 31, 2017]


- **At Issue**: PSWP materials including incident reports involving all physicians for the 3 years before the adverse event up until discovery request was served.

- **Holding**: [Jan. 31, 2017]
  - PSWP - Incident reports are discoverable. PSQIA did not preempt Florida’s “Right-to-Know” Act
Interstate Medical Licensure Compact (IMLC)

- Maine: Became Law without Governor’s Signature under legislative document 1359 on June 8, 2017
- Massachusetts: not a IMLC state
PSO Membership
Considerations About Joining a PSO

- Federal Protections
  - Privilege and Confidentiality
- The “Learning Lab”
  - Discover Opportunities
- Foster a Culture of Safety
  - Encourage better reporting in a protected environment
  - For purposes of quality and safety improvements- not for punitive purposes
Patient Safety Act

Share
- Encourages data collection, aggregation and analysis amongst similar providers in a common format to allow for meaningful comparisons and easier identification of improvement opportunities.

Learn
- Facilitates development of a safe and protected learning space where providers focus on improving care versus legal or disciplinary implications of findings.
- Allows provider organizations to maintain a “Just” culture of accountability with deliberate PSES set-up.

Protect
- Enables healthcare providers to collaborate and learn from quality, safety and healthcare outcome initiatives that cross state lines without legal ramifications.

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Presentation Summary:
Earning and Asserting Privilege from Discovery

- Design complementary, integrated risk and quality systems
- Develop guidelines that direct activities
- Bundle practices that strengthen each other
- Sustain on-going compliance with guidelines as set
Action Recommendations
Action Recommendation One:

► **Know your Jurisdiction!**

► What are the state peer review protections
► How are courts ruling regarding:
  ► Incident/event reports
  ► Event investigation materials
  ► Peer review reports by peer practitioners
  ► Credentialing and privileging materials
Action Recommendation Two: Differentiate Between Initial Investigations and Performance Improvement

- Consideration 1: Establish a clear definition of reportable incidents
  - What must be reported
  - How is it reported
  - Who receives the initial reports
  - Who follow up on reports
  - Who decides next steps

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Action Recommendation Two: (con’t)

- Consideration 2: Just because a document is reviewed by the Performance Improvement or QAA committee, it is not necessarily protected from discovery

- Consideration 3: Patient Safety Work Product should include performance improvement recommendations
  - Primary purpose to demonstrate purpose of improvement
Action Recommendation Two: (Con’t)

- Consideration 4: A clear distinction between initial investigations and Performance Improvement activities is crucial
  - Interviews
    - Initial investigation:
      - Witnesses interviewed
      - Who, what, where, when
      - Fear
      - Bias
  - Performance Improvement
    - Wider scope of employees interviewed
    - How or why something happened
    - How can it be prevented in the future
    - Identify gaps
    - Systems review

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Action Recommendation Three: Design Risk and Quality Programs to Support Assertion of Privilege

- Design program in alignment with intent and letter of privilege requirements
  - QAA process triggered by IR receipt (stated in the plan)
- Design information flow and QAA review process to protect privilege based on regulations and state case law; implement process according to the plan
  - Establish process whereby IR are reported to the QAA committee
  - Route report to appropriate subcommittee
  - QAA Committee determines whether RCA will be conducted
  - Take remedial action
  - Provide recommendations for performance improvement
- Persistent adherence to the plan
- Submit IR to PSO
Action Recommendation Four:
Ensure QAA/QAPI Plan Outlines Structure that Preserves Privilege

- Purpose, Role, and Scope
- Membership & Meeting Schedule
  - Routine and *interim (post event)*
- List types of PSWP that are privileged and confidential (i.e., protected by state statute from disclosure.)
- List information that is not PSWP and therefore, discoverable
- Label all protected QAA documents “privileged and confidential” according to the applicable statute.
- Outline post incident actions
Questions?

Thank you.

Please contact: Deborah Ballantyne, JD, NHA, CPASRM, ECRI Institute, Risk Management Analyst, dballantyne@ecri.org
Resources
Resources

- Ali v. Long Creek Youth Development Center, 2019 WL 302488 (1sr Cir. 2019)
- Aon, Hospital Liability and Physician Professional Benchmark Analysis, executive Summary Oct. 2018
- Blacks Law Dictionary, 2019
- Centers for Medicare and Medicaid Services, Conditions of Participation:
  - 42 CFR §483.75(a)
  - 42 CFR §483.75(c)(4)
  - 42 CFR §483.75(h)
- Charles v. Southern Baptist Hospital of Florida, Inc., 209 So.3d 1199 (Fla. 2017)
- Federal Rules of Civil Procedure:
  - Rule 26
  - Rule 33
  - Rule 34
  - Rule 45

New England Regional Healthcare Risk Management Conference
Healthcare Quality Improvement Act, 42 USC §11101 (1985)
In re: Block Island Fishing, Inc., 325 F. Supp. 3d 158 (1st Cir. 2018)
Maine
Me. Rev. Stat. Ann, tit. 32 §2596 Review Committee Member Immunity
Massachusetts:
Mass. Gen. Laws Ann. Chapter 111 §204 Confidentiality of medical peer review committee proceedings, report and record; exceptions; immunity
Medscape Malpractice Report - Did they deserve to be sued?, Medscape, Jul 24, 2013. [cited 2017 Apr. 20].
New Hampshire: