

***New Federal Legislation and its  
Impact on Medical Malpractice  
Litigation: The Impact of the  
Federal Patient Safety Act for Your  
Healthcare Clients***

Sponsored by:

Clarity Group, Inc. and Clarity PSO



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# *Clarity Group, Inc.*

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Clarity's mission is to enable healthcare providers to execute on their vision for excellence through consultative and technology solutions that assist them in ...

- Effectively managing the risk, quality, and safety of their healthcare services, and ...
- Effectively managing the financial and professional liability risk exposure associated with the delivery of their healthcare services.

# *Clarity PSO, A Division of Clarity Group Inc.*

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- Certification listed by AHRQ
- Quarterly comparative reports, evidence based recommendations
- In-depth statistical analysis for improvement opportunities
- Education and resource development
- Medical Advisory Council comprised of national experts in high risk fields
- Root Cause Analysis (onsite and consultative)
- Proactive Risk Assessments (surgical/invasive procedures, sedation, anesthesia, blood management etc.)
- AHRQ Culture of Safety Electronic Survey and Analysis

# *Goals for Today's Program*

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- Review the basic tenets and protections afforded under the Patient Safety Act
- Provide insight into the processes healthcare providers must comply with to gain access to the protections of the Act
- Provide opportunity for defense counsel to understand the areas the Act can be most helpful in preparing their defense against allegations of medical malpractice

# *Panel of Experts*

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## Moderator

Anna Hajek, President & CEO  
Clarity Group, Inc.

## Panel

Larry Patton, Consultant

Michael Callahan, Partner, Katten Muchin Rosenman LLP

Peggy Binzer, Counsel, Womble Carlyle, Washington, DC

Ellen Flynn, RN, MBA, JD, Executive Director, Clarity PSO

# *Patient Safety Act Background*

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- Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act)
- Signed into law July 29, 2005
- Final rule published November 21, 2008
- Effective Date: January 19, 2009

# *Impetus for the Act*

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- Landmark report, "To Err Is Human" by the Institute of Medicine in 1999
  - At least 44,000 people and potentially as many as 98,000 people die in U.S. hospitals each year due to preventable medical errors with national costs between \$17 billion and \$29 billion
  - The majority of medical errors do not result from individual recklessness or the actions of a particular group; rather, most errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent adverse events
    - ✓ Mistakes can best be prevented by designing the health care system at all levels to improve safety--making it harder to do something wrong and easier to do something right

# *Impetus for the Act (cont.)*

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- As compared to other high-risk industries, the health care system is behind in its attention to ensuring basic safety due to:
  - Fear of liability, professional sanctions, or injury to their reputation
  - Traditional state-based legal protections for such health care quality improvement activities are:
    - ✓ limited in scope
    - ✓ do not exist in all states
    - ✓ typically only apply to peer review in hospitals and do not cover other settings
    - ✓ seldom enable health care systems to pool data or share experiences
  - Limited potential for aggregation of a sufficient number of patient safety events to permit learning and improvement in patient safety

# *Patient Safety Act: Purpose*

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- To improve patient safety, healthcare quality and outcomes through the sharing of data within a protected collection, analysis and legal environment and across states that enable the identification and reduction of risks and hazards associated with patient care



# **De-Mystifying the Patient Safety Act: PSOs, PSWP and the PSES**

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# *Understanding the Patient Safety Rule:*



## *The Basics*

The Law, the Rule, the Protections

**The Law** – P.L. 109-41, The Patient Safety and Quality Improvement Act of 2005 (42 U.S.C., 299b-21-b-26)

**The Rule** – 42. C.F.R. Part 3

**The Protections** – Federal confidentiality and privilege protections

# *Understanding the Patient Safety Rule:*



## *The Basics*

### The Building Blocks of the Rule

**Patient Safety Organizations (PSOs)** – entities or components of entities that are listed by the Secretary after attesting that they meet the requirements of the Patient Safety Act and Rule.

**Patient Safety Work Product (PSWP)** – class of information that is privileged and protected

**Patient Safety Evaluation System (PSES)**– process by which PSWP is assembled or developed for reporting to or from a PSO; a provider's deliberations and analyses within a PSES are confidential and privileged

## *Understanding the Patient Safety Rule:*



### *Patient Safety Organizations (PSOs)*

#### Setting The Context

## **NOT a government reporting system**

- Providers are not required to work with PSOs
- PSOs are “consultants” to providers
- Providers pay PSOs for the services they want
- Providers decide what data to share; no required reporting
- Providers can require greater confidentiality

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## *Understanding the Patient Safety Rule:*



### *Patient Safety Organizations (PSOs)*

The Building Blocks of the Rule

## **Eligibility to be a PSO**

Any public or private entity, for-profit or not-for-profit, or a component of an entity can seek listing as a PSO with few exceptions:

- The Patient Safety Act excludes health insurance issuers and their components
- The Patient Safety Rule precludes the following entities from listing:
  - ✓ Accreditation and licensure entities
  - ✓ Regulators and their agents (such as QIOs)
  - ✓ Entities operating a Federal, State, local or Tribal mandatory reporting system.

HOWEVER, components of excluded entities (other than health insurers) can seek listing provided the component organization meets additional requirements. 14

## *Understanding the Patient Safety Rule:*



### *Patient Safety Organizations (PSOs)*

The Building Blocks of the Rule

## **Value of Working With a PSO**

- Federal confidentiality and privilege protections – subject to the requirements in the Patient Safety Rule – apply at the provider’s facilities and at the PSO
- By aggregating data from multiple providers/other PSOs, a PSO can develop insights into ways to prevent patient harm
- Providers can collect/protect data across facilities system-wide
- PSO can support and enhance your culture of safety, help you create a “learning environment,” and contribute to improved provider and patient satisfaction

# *Understanding the Patient Safety Rule :*

## *Patient Safety Work Product*



A PSO is Key to the Confidentiality and Privilege Protections

### **Three Ways Information Becomes Patient Safety Work Product**

1. Information is assembled or developed by a provider for reporting to a PSO and are reported to a PSO

2. Identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a provider's Patient Safety Evaluation System

3. Developed by a PSO for the conduct of patient safety activities

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# *Understanding the Patient Safety Rule:*



## *Patient Safety Work Product*

Critical Role of a Provider's Patient Safety Evaluation System in the Final Rule

### **Protection Upon Collection**

Information that is ***documented*** as assembled or developed within a provider's patient safety evaluation system would become patient safety work product upon collection

Provider must document that the information was collected for reporting to a PSO and the date of collection

Documenting the operation of the PSES is not required but is strongly recommended as a "best practice"

# *Understanding the Patient Safety Rule:*



## *Patient Safety Work Product*

Limitations on What Information Can Become Patient Safety Work Product

### **NOT Possible to protect**

- Original patient or provider records – such as patient’s original medical record, billing and discharge information
- Information that is collected, maintained, or developed separately or exists separately from, a patient safety evaluation system
- Information for meeting provider’s external reporting requirements

## *Understanding the Patient Safety Rule:*



### *Patient Safety Work Product*

Critical Role of a Provider's Patient Safety Evaluation System in the Final Rule

## **Analyses and Deliberations Always Protected**

Analysis and deliberations of the information within the provider's PSES or the PSO are protected as patient safety work product

## **Voluntary Removal**

A provider may also voluntarily remove information – before it is reported to a PSO – and ***document*** that the provider no longer intends to report it to a PSO

# *Understanding the Patient Safety Rule:*



## *Patient Safety Work Product*

Confidentiality and Privilege Protections: Use Versus Disclosure

### **USE**

Unlike HIPAA, the Patient Safety Rule does NOT regulate sharing of patient safety work product within an entity (or within a component PSO)

### **DISCLOSURE**

Sharing of patient safety work product outside the legal entity (or outside the component PSO) are limited to permissible disclosures in Subpart C of the rule

# *Understanding the Patient Safety Rule:*



## *Patient Safety Work Product*

Confidentiality and Privilege Protections: Disclosures

### **Take Away Messages**

Do NOT report information from your PSES to a PSO until you know whether you will need to disclose it externally

Assemble or develop information separately if needed for:

- Federal, State, local, Tribal reporting requirements
- Accreditation, licensure or other contractual obligations
- Civil, administrative, criminal proceedings or proceedings of a professional disciplinary body

Unless rule permits, PSWP cannot be disclosed to public agencies <sup>21</sup>

# *Understanding the Patient Safety Rule:*



## *Responding to Oversight Entities*

An Example from the Notice of Proposed Rulemaking

Assumption: A root cause analysis of an adverse event is conducted within the provider's PSES or the PSO; an oversight entity now seeks all information provider has on the incident and its causes

Permissible to Share:

- All information regarding incident in facility's files outside PSES
- All corrective actions that the provider implements and, if requested by the oversight entity, the provider can track the impact of corrective actions on mortality and morbidity

# *Understanding the Patient Safety Rule:*



## *How the Pieces Fit Together*

Patient Safety Act Protections & Requests for PSWP by Oversight Entities

### Provider May Not Share:

- Any analysis of the event by the provider's PSES or the PSO
- Any deliberations regarding the event within the provider's PSES, the PSO, or communications between the PSO and provider
- Corrective actions recommended by PSES or PSO

If oversight entity insists on a root cause analysis, provider may conduct a new analysis outside its PSES

See discussion in NPRM preamble, *Federal Register*, February 12, 2008, pp. 8123-8124

# *Overview of PSO Confidentiality and Privilege Protections*

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## *Patient Safety Work Product*

- PSWP means any data, reports, records, memoranda, analyses (i.e. root cause analysis), or written or oral statements, or copies;
  - which could improve patient safety, health care quality, or health care outcomes and
  - which are assembled or developed for reporting to a PSO and are reported to a PSO and such information includes the date the info entered into the PSES or
  - are developed by a PSO for the conduct of patient safety activities or
  - which identify or constitute the deliberations or analyses of, or identify the factual reporting pursuant to a PSES

# *Patient Safety Work Product*

- PSWP does not include:
  - patient's medical record
  - billing and discharge information
  - any other original patient or provider info
  - information that is collected, maintained, or developed separately from a PSES
  - reporting to a PSO does not automatically make it PSWP
- PSWP assembled or developed for reporting to a PSO may be removed from a PSES and no longer considered PSWP if:
  - info has not yet been reported to a PSO and
  - provider documents the date of removal of info from PSES

## *Patient Safety Work Product - Privilege*

- PSWP is privileged and shall not be:
  - subject to a federal, state, local, Tribal, civil, criminal, or administrative subpoena or order, including a civil or administrative proceeding against a provider
  - subject to discovery
  - subject to FOIA or other similar law
  - admitted as evidence in any federal, state, local or Tribal governmental civil or criminal proceeding, administrative adjudicatory proceeding, including a proceeding against a provider
  - admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law

# *Patient Safety Work Product*

➤ Exceptions:

- disclosure of relevant PSWP for use in a criminal proceeding if a court determines, after an in camera inspection, that PSWP
  - ✓ contains evidence of a criminal act
  - ✓ is material to the proceeding
  - ✓ not reasonably available from any other source
- disclosure through a valid authorization if obtained from each provider prior to disclosure in writing, sufficiently in detail to fairly inform provider of nature and scope of disclosure

## *Patient Safety Work Product - Confidentiality*

- Confidentiality:
  - PSWP is confidential and not subject to disclosure
- Exceptions:
  - disclosure of relevant PSWP for use in a criminal proceeding if a court determines after an in camera inspection that PSWP
    - ✓ contains evidence of a criminal act
    - ✓ is material to the proceeding
    - ✓ not reasonably available from any other source
  - disclosure through a valid authorization if obtained from each provider prior to disclosure in writing, sufficiently in detail to fairly inform provider of nature and scope of disclosure

## *Patient Safety Work Product – Confidentiality*

- Exceptions (cont'd):
  - disclosure to a PSO for patient safety activities
  - disclosure to a contractor of a PSO or provider
  - disclosure among affiliated providers
  - disclosure to another PSO or provider if certain direct identifiers are removed
  - disclosure of non-identifiable PSWP
  - disclosure for research if by a HIPAA covered entity and contains PHI under some HIPAA exceptions
  - disclosure to FDA by provider or entity required to report to the FDA regarding quality, safety or effectiveness of a FDA-regulated product or activity or contractor acting on behalf of FDA

## *Patient Safety Work Product - Confidentiality*

### ➤ Exceptions (cont'd):

- voluntary disclosure to accrediting body by a provider of PSWP but if about a provider who is not making the disclosure provider agrees identifiers are removed
  - ✓ accrediting body may not further disclose
  - ✓ may not take any accrediting action against provider not can it require provider to reveal PSO communications
- disclosure for business operations to attorney, accountants and other professionals who cannot re-disclose
- disclosure to law enforcement relating to an event that constitutes the commission of a crime or if disclosing person reasonably suspects constitutes commission of a crime and is necessary for criminal enforcement purposes

## *Interaction with HIPAA Privacy Regulations*

- If HIPAA applies, must comply with both HIPAA Privacy Rule and PSO Rule:
  - PSOs will be Business Associates of HIPAA Covered Entities.
  - Patient safety activities of HIPAA Covered Entities deemed health care operations.
  - However, not all providers are HIPAA Covered Entities and identifiable PSWP will not always contain PHI.

## *Interaction with HIPAA Privacy Regulations*

### ➤ PSWP vs. PHI

- Non-identification standard for PSWP confidentiality exception is adapted from HIPAA Privacy Rule de-identification standard.
- HIPAA requirements for disclosures for Research, (more broadly defined), incorporated by reference as applicable to PSWP.
- PSWP exception to privilege and confidentiality for law enforcement much narrower.
- No minimum necessary standard for PSWP, but discloser “strongly” encouraged to consider how much PSWP is necessary.
- Notwithstanding PSWP confidentiality and privilege protection, disclosures of PSWP permitted to Secretary in order to enforce HIPAA Privacy Rule as well as PSO rule.

## *Interaction of PSO Protections with State Peer Review Protections and Peer Review Activities*

- Patient Safety Act is the first federal legislation to provide for a federal and state confidentiality and privilege statute for patient safety and peer review?
- Does it apply to state peer review activities?
  - In conversations with AHRQ officials the simple answer is Yes, But. . .
- Why do we care?
  - ✓ Physicians are able to use otherwise confidential peer review information to support federal claims such as antitrust, age, race and sex discrimination, ADA, etc.

## *Interaction of PSO Protections with State Peer Review Protections and Peer Review Activities*

- State claims such as breach of contract, tortious interference, defamation, etc., typically would be dismissed because confidential information not subject to discovery and could not be used to support the claim. If no evidence, then no basis on which to bring the lawsuit
- Some states, like Florida, no longer have a state confidentiality statute and therefore PSO rules offer important protection
- So, is there any downside to attempting to apply PSO protections to peer review activities?
  - Yes
  - Information collected and reported to PSO cannot be used in disciplinary proceedings against the physician

## *Interaction of PSO Protections with State Peer Review Protections and Peer Review Activities*

- If peer review materials become PSWP, cannot use information to support argument that hospital and medical staff met its patient obligations under Doctrine of Corporate Negligence, i.e., hospital has a duty to make sure that physicians are currently competent to exercise all of the clinical privileges granted to them because information is not discoverable or admissible (Frigo v. Silver Cross Hospital issue)
- So, what is a hospital to do?
  - Need to carefully structure Patient Safety Evaluation System to decide what will be collected and reported to a PSO keeping in mind that it cannot be used in disciplinary proceedings against a physician or to defend corporate negligence claims
  - Need to clearly understand what would be protected under state confidentiality statutes and what is not before designing PSES

## *Interaction of PSO Protections with State Peer Review Protections and Peer Review Activities*

- Remember, info collected but not yet reported to PSO can be withdrawn and therefore will not be considered PSWP but still can be protected under state law
- AHRQ representatives acknowledged that “disciplinary proceedings” could be defined under medical staff bylaws as not to include lesser remedial actions such as monitoring, proctoring, consultations and other actions that do not trigger hearing rights and/or Data Bond reports
- Need to clearly define in the bylaws and have accepted by the medical staff
- If information collected generally identifies conduct that could give rise to imposition of disciplinary action, information should be removed and documentation of removal should be evidenced if it otherwise would have been reported and considered PSWP.



# *Permitted Disclosures*

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# *Permitted Disclosures*

- Purpose – To allow the release of best practices and learning information but prevent the release of information that could be used against a provider in a malpractice or other tort case.
- Policy – The information available to a trial lawyer before the passage of the PSA would be available after its passage

# *Who Decides the Rules*

- Confidentiality Rules Implemented by HHS
- Privilege Rules to be Implemented by the Courts. Many unknowns:
  - Who can assert the privilege (privilege attaches to patient safety work product)
  - Burden of proof
  - Privileges narrowly construed

# *Rules for Disclosure*

- Disclosures Defined by Statute
  - No Confidentiality but Privilege Maintained
    - ✓ Authorized or unauthorized disclosure: privilege maintained and fines for disclosing are active for the recipient
    - ✓ May lose the ability to prove its privilege
  - No Privilege and Confidentiality
- Disclosures can be limited or delegated

# *Disclosure to Attorney for Purposes of Defense*

## ➤ HIPAA

- Malpractice defense - Health Care Operation
- Business Associates (BA) rules change Feb 17, 2010, BA's directly liable

➤ Patient Safety Work Product may not be admitted into evidence – privilege cannot be waived even if information is disclosed

➤ Patient Safety Work Product may be used to inform the defense attorney

# *Permitted Disclosures*

## *No Privilege or Confidentiality*

- Criminal Cases – after in camera inspection
- Voluntarily disclosed de-identified PSWP
- If all providers named in PSWP agree (redacted?)

# *Breaches of Confidentiality and Penalty*

- Fine - \$10,000 may be greater under contract
- HIPAA – new rules up to \$1.5 million/year
- State law causes of action – libel, defamation

# *Potential Misuse of the Patient Safety Act*

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# *Using PSWP for Disciplinary Actions*

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- Data collected for PSO reporting is used to take disciplinary actions versus learning
  - Equitable right of relief of reporter

**Create A Culture Of Safety**

# *Using PSWP to Meet External Mandatory Reporting*

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- PSWP cannot be used to meet external regulatory requirements
  - Organizations must still meet the requirements
- Data can be collected for reporting to a PSO and External Agency from the same source documents e.g., Medical Records (not PSWP)

**Initial report that is not PSWP does not prevent follow up investigation from being PSWP**

# *Data Collected for Another Purpose*

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- Attorney directing the collection of data in anticipation of litigation is different than PSWP being collected for the purpose of improving patient safety, healthcare quality of outcomes

**Proactively choose the best privilege(s)**

# *Organization Does Not Document PSES*

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- While not required by the final rule ...

**How can the organization defend its position  
when there is no documentation?**

# *PSA – Best Practices*

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## ➤ Organizations need :

- Plan how and when they will use PSOs
- Document their PSES
- Determine if the data that they would like sent to the PSO is the best source for another purpose
- Proactively determine the best way to protect their data from discovery during litigation

An Effective Patient Safety Organization is Your  
Partner in this Effort



# *Hypothetical Challenges: Malpractice*

## *Without PSO = Someone Gets Sued and Harm May Be Repeated*

- **Hospital 1:** Physician commits medical error on infant – acts fast and saves child’s life. Case peer reviewed.
  
- **Hospital 2:** Physician makes same error on infant – calls hospital 1 for help

*With PSO = No Law Suit Harm  
May be Prevented*

- Hospital 1 reports incident and analysis to PSO
- PSO reviews case and other similar cases  
sends best practices to pediatricians in  
Hospital 2
- Alternative Hospital 2 calls PSO who connects  
Hospital 1 to consult on the case

## *What a PSO can't Protect*

- PSO can't prevent lawsuits associated with an obvious medical error – wrong site surgery
- PSO can't prevent lawsuits where a plaintiff believes they are harmed
- PSO can't protect the fact that a hospital is participating in a PSO program
- Participating in a PSO may become the standard of care

# *What Can a PSO Protect*

- PSO can inform defense counsel on systematic error that resulted in the harm – Not wrong site, wrong person because of inadequate patient identification
- PSO can enhance patient confidence – aiming to be the safest in the nation
- Data that otherwise would be too risky to collect:
  - Bench marking – acting below the standard of care
  - Near Misses – trend data
  - Peer Review in states with eroded privileges
  - Information the State may use to set policy

# *Hypothetical*

Patient expired during surgery when the anesthesiologist turned the nitrogen on rather than the oxygen. The knob on the nitrogen was orange, while the knob on the oxygen was yellow. Under the lights in the operating room the knobs appeared to be the same color. The PSO had received many reports of near misses from this hospital about the colors of the knobs and the PSO had sent to hospital an alert about the danger and suggested a best practice to prevent the error from occurring. The hospital was reviewing the best practice recommendation at the time of the incident. The anesthesiologist told the patient's family about the error that caused the death.

## *Hypothetical Challenges*

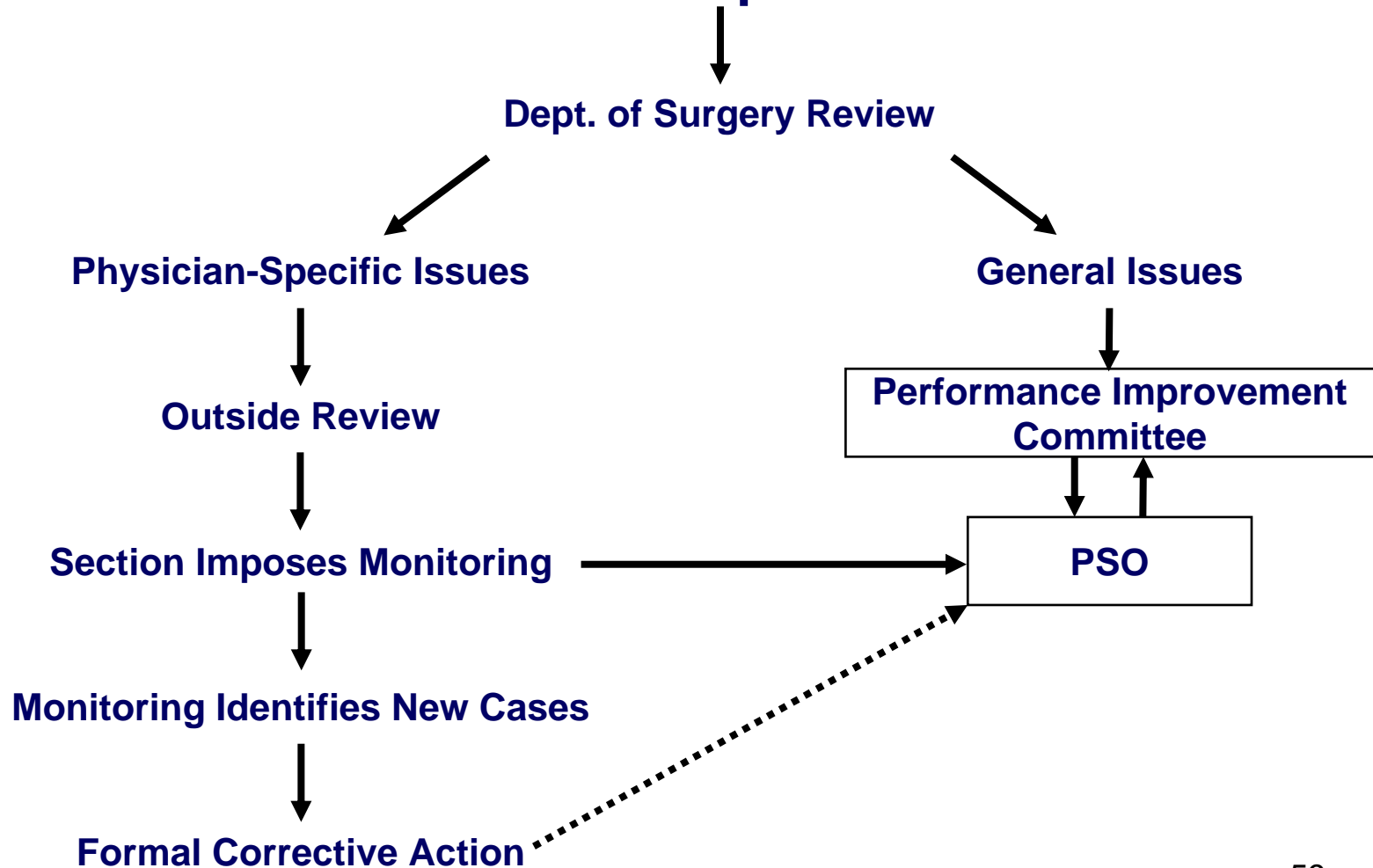
### *Peer Review/Corporate Negligence*

- Ortho group identified as having several post op infections as per screening criteria.
- Department of Surgery and Performance Improvement Committee decide to conduct review of all ortho groups in order to compare practices and results.
  - Data and review collected as part of PSES.
- Review identifies a number of questionable practices generally as well as best practices – reviewed, collected and reported to PSO
- Review also discloses member of targeted ortho group as having other identified issues including:
  - Total shoulder procedures in elderly patients.
  - Total ankle procedures in questionable patients.

## *Hypothetical - Post Op Infections*

- Untimely response to post op infections.
  - Issues identified are significant enough to trigger 3rd party review.
  - Third party review identifies issues that may lead to remedial/corrective action.
  - Decision is made by Department Chair that physician's cases need to be monitored for six month period.
    - ✓ Monitoring reveals repeat problems relating to questionable judgment and surgical technique which have resulted in adverse outcomes despite efforts to assist physician.
    - ✓ Department Chair recommends formal corrective action.

# Ortho Post Op Infections



***New Federal Legislation and its  
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**Participant Q & A**



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# *Program Summary*

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- Essential terms and processes of the PSA
- Key elements of how information can be used
- Key elements of how privilege can be lost
- Bottom – line ...
  - Healthcare has a real opportunity to positively impact patient care
  - Defense counsel can partner with their clients to help assure privilege protection

*New Federal Legislation and its Impact  
on Medical Malpractice Litigation: The  
Impact of the Federal Patient Safety  
Act for Your Healthcare Clients*

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**Thank  
You!**



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