

# Patient Safety

## Organizations: A

Fundamental Tool in the World of Health Care Reform, Enhanced Reimbursement, Quality Improvement and Confidentiality Protections

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# Topics

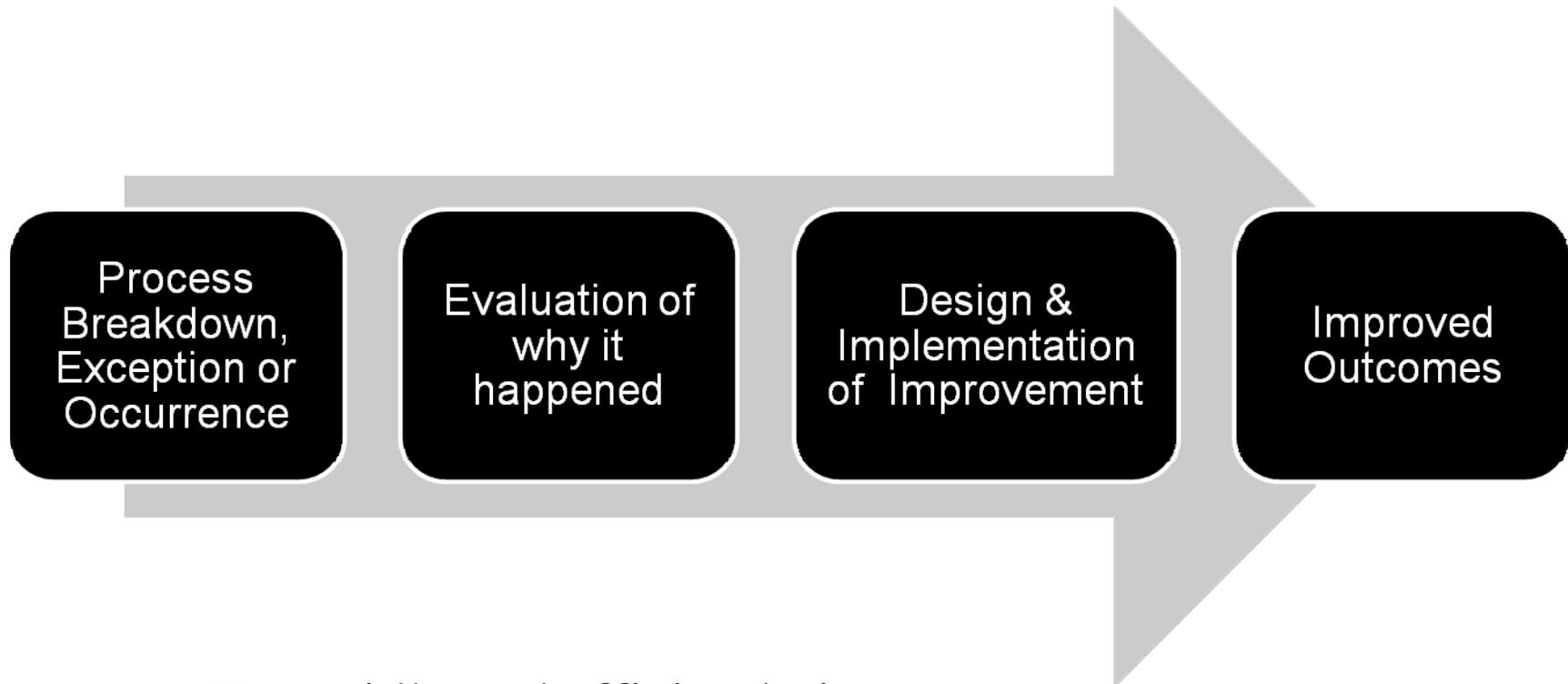
- Patient Safety Organizations – What they are
- How a PSO can be used to obtain federal and state protections beyond what your state currently provides
- Leveraging your data: Moving beyond protection to Improving performance through a PSO
- Risks of ignoring the PSO opportunity
- Three powerful next steps

# Patient Safety Organizations – What they are

# The Vital Importance of “Exception Data”

- Every day our facilities and practices are driving to make rapid, sustainable improvements in our safety, quality and outcomes.
- While there are many applications of technology-- healthcare is still a very ‘manual’ process.
- We rely on understanding “process exceptions or breakdowns” to understand these manual processes
- Historically, we have had only limited ways to collectively improve our processes through better use of data that helps us understand breakdowns in our processes.

# The Vital Importance of Exception Data



To rapidly and efficiently improve our process we need to take advantage of shared learning from aggregation of our “Exception” data – our problem, incident and occurrence reporting

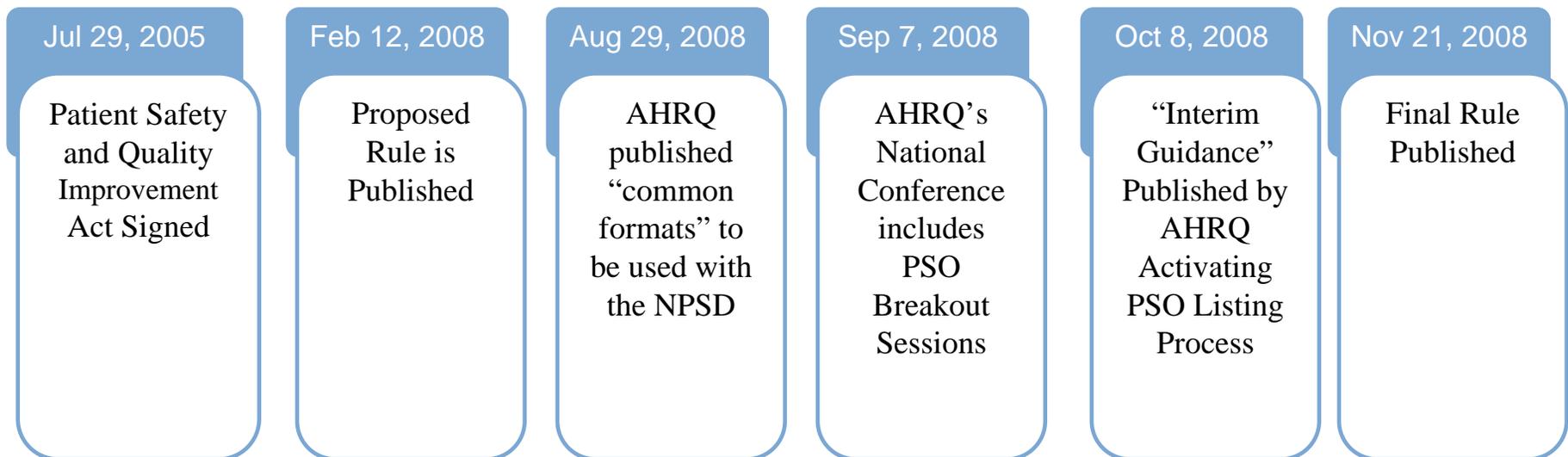
# Problems with Exception Data

- It is often not shared because of fear of litigation (Discovery, Confidentiality, Lawyers...)
- It requires different methods to 'add it up' and analyze it.
- It is often looked at in 'isolation' rather than 'aggregation'.

Exception data has not been used as effectively as it could be in Healthcare

# The Healthcare Industry Recognized this

- In 2005 the government decided that there needed to be a better way to share information about Medical Errors so the industry could improve faster.



The PSO Rule finally went into effect on January 19, 2009

# Key PSO Concepts

- Introduction to key PSO concepts
  - Protection
  - Aggregation
  - PSES
  - PSWP
  - Data Flow

# The PSO Rule

- The PSO Rule addressed two major areas:
  - A formal method to set up processes and organizations to collect and aggregate exception data.
  - Protections that keep the data confidential and protected from discovery
    - Added protections for the hospitals and care facilities
    - Protections for the “Aggregators”

# Patient Safety Act Purpose

- To encourage the expansion of voluntary, provider-driven initiatives to improve the quality and safety of healthcare; to promote rapid learning about the underlying causes of risks and harms in the delivery of healthcare; and to share those findings widely, thus speeding the pace of improvement.
  - Strategy to accomplish its purpose:
    - Encourage the development of PSOs
    - Establish strong federal and greater confidentiality and privilege protections
    - Facilitate the aggregation of a sufficient number of events in a protected legal environment

# Impetus for the Act

- Healthcare workers fear disclosure
- State-based peer review protections are:
  - Varied
  - Limited in scope
  - Not necessarily the same for all healthcare workers
- No existing federal protections
- Data reported within an organization is insufficient, viewed in isolation, and not in a standard format

# The Patient Safety Act

- Creates independent Patient Safety Organizations (PSO) that will receive protected data, analyze the data, and share recommendations with healthcare providers for improvement
- Provides federal and state legal privilege and confidentiality protections to information that is assembled and reported by providers to a PSO or developed by a PSO to conduct patient safety activities
- Limits the use of patient safety information in criminal, civil, and administrative proceedings and imposes monetary penalties for violations of confidentiality or privilege protections

# Who or What Does the Act Cover?

- Provides uniform protections against certain disciplinary actions for all healthcare workers and medical staff members
- Protects Patient Safety Work Product (PSWP) submitted by providers either directly or through their Patient Safety Evaluation System (PSES) to Patient Safety Organizations (PSO)
- Protects PSWP collected on behalf of providers by PSOs (e.g., root cause analysis, proactive risk assessment)

# The Patient Safety Act Does Not:

- Mandate provider participation in a PSO
- Make significant error reporting mandatory—defers to states
- Preempt stronger state protections
- Provide for any federal funding of PSOs

# Long-Term Goals of the Patient Safety Act

- Encourage the development of PSOs
- Foster a culture of safety through strong federal and state confidentiality and privilege protections
- Create the Network of Patient Safety Databases (NPSD) to provide an interactive, evidence-based management resource for providers that will receive, analyze, and report on de-identified and aggregated patient safety event information



Further accelerating the speed with which solutions can be identified for the risks and hazards associated with patient care through the magnifying effect of data aggregation

# Expected Results



Source: Katten Muchin Rosenman, LLP, headquartered in Chicago.

# Essential Terms of the Patient Safety Act you need to know

- Patient Safety Evaluation System (PSES)
- Patient Safety Work Product (PSWP)

# Patient Safety Evaluation System (PSES)

- PSES definition
- Body that manages the collection, management, or analysis of information for reporting to or by a PSO (CFR Part 3.20 [b][2])
  - Determines which data collected for the PSO is actually sent to the PSO and becomes Patient Safety Work Product (PSWP)
  - PSES analysis to determine which data that is sent to the PSO is protected from discovery as PSWP

The definition of the PSES is important to you because it defines potential changes in our workflow.

# Patient Safety Work Product (PSWP)

- PSWP definition
  - Any data, reports, records, memoranda, analyses (such as root cause analyses [RCA]), or written or oral statements (or copies of any of this material) which could improve patient safety, healthcare quality, or healthcare outcomes

# Patient Safety Work Product (PSWP) (cont.)

- And that:
  - Are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a PSES for reporting to a PSO, and such documentation includes the *date the information entered the PSES*; 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

# What is NOT PSWP?

- Patient's medical record, billing and discharge information, or any other original patient or provider information
- Information that is collected, maintained, or developed separately, or exists separately, from a PSES (*such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered PSWP*)
- PSWP assembled or developed by a provider for reporting to a PSO but removed from a PSES and no longer considered PSWP if:
  - Information has not yet been reported to a PSO; and
  - Provider documents the act and date of removal of such information from the PSES

The definition of the PSWP is important to you because it defines what information is protected.

How a PSO can be used to obtain federal and state protections beyond what your state currently provides

# 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
    - Is 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
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# Patient Safety Work Product Confidentiality (cont.)

- Exceptions (cont.):
  - 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 (cont.)

- Exceptions (cont.):
  - 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, nor can it require provider to reveal PSO communications
  - Disclosure for business operations to attorney, accountants, and other professionals who cannot redisclose
  - 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 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,
- 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 (cont.)

- 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

# Interaction of PSO Protections with State Peer Review Protections and Peer Review Activities (cont.)

- Remember that once it is removed and used for other purposes, it cannot be later reported and treated as PSWP
- It is therefore very important to reflect these options and alternative paths in designing peer review procedures and PSES in order to incorporate flexibility and maximum protections under state confidentiality and PSO protections
- If you decide to report to PSO, you may have to trigger new reviews that are outside PSES because, except for original records, such as medical records, you will not be able to rely on PSWP to take disciplinary action against the physician
- Also, keep in mind that PSWP reported to a PSO cannot be used to defend NMH/MNFF in a negligent credentialing action (Frigo case) or other legal action

# Enforcement

- Confidentiality

- Office of Civil Rights
- Compliance reviews will occur, and penalties of up to \$10,000 per incident may apply

- Privilege

- Adjudicated in the courts

# Summary of Key Points

- Patient Safety Organizations (PSOs) provide an important new tool in improving performance

How does this potentially  
change our workflow?

# Event/Incident Reporting Policy

- Modify existing policies as needed to reflect the purpose reporting is for:
  - Patient safety, healthcare quality, and outcome improvement
  - Reporting to a PSO
- Include a process (through the PSES) for the removal of incidents from PSES or separate system for:
  - Disciplinary action
  - Just culture
  - Mandatory state reporting
  - Independent/separate peer review

# Questions to Answer When Developing PSES Policy

- Who or what committee(s):
  - Collects data that will be reported to a PSO?
    - Single source or multiple sites?
    - Single department or organizationwide event reporting?
  - Analyzes data that will be reported to a PSO?
  - Removes data from PSES prior to reporting to a PSO?
  - Submits the data from the PSES to the PSO(s)?
    - Committee or individual authorized submission?

# Questions to Answer When Developing PSES Policy

- What data should be:
  - Collected to report to a PSO?
    - Patient safety data, healthcare quality, and outcomes data
      - \* Data cannot be used for adverse disciplinary, versus remedial, employment action, mandated state reporting, Joint Committee OPPE/FPPE
  - Removed from PSES prior to reporting to a PSO?
    - Criteria-based or subjective case-by-case decision-making
    - Peer review information that could lead to disciplinary action
- When is data:
  - Reported to PSES?
  - Removed from PSES?
  - Reported to PSO?
    - \* Each date must be documented

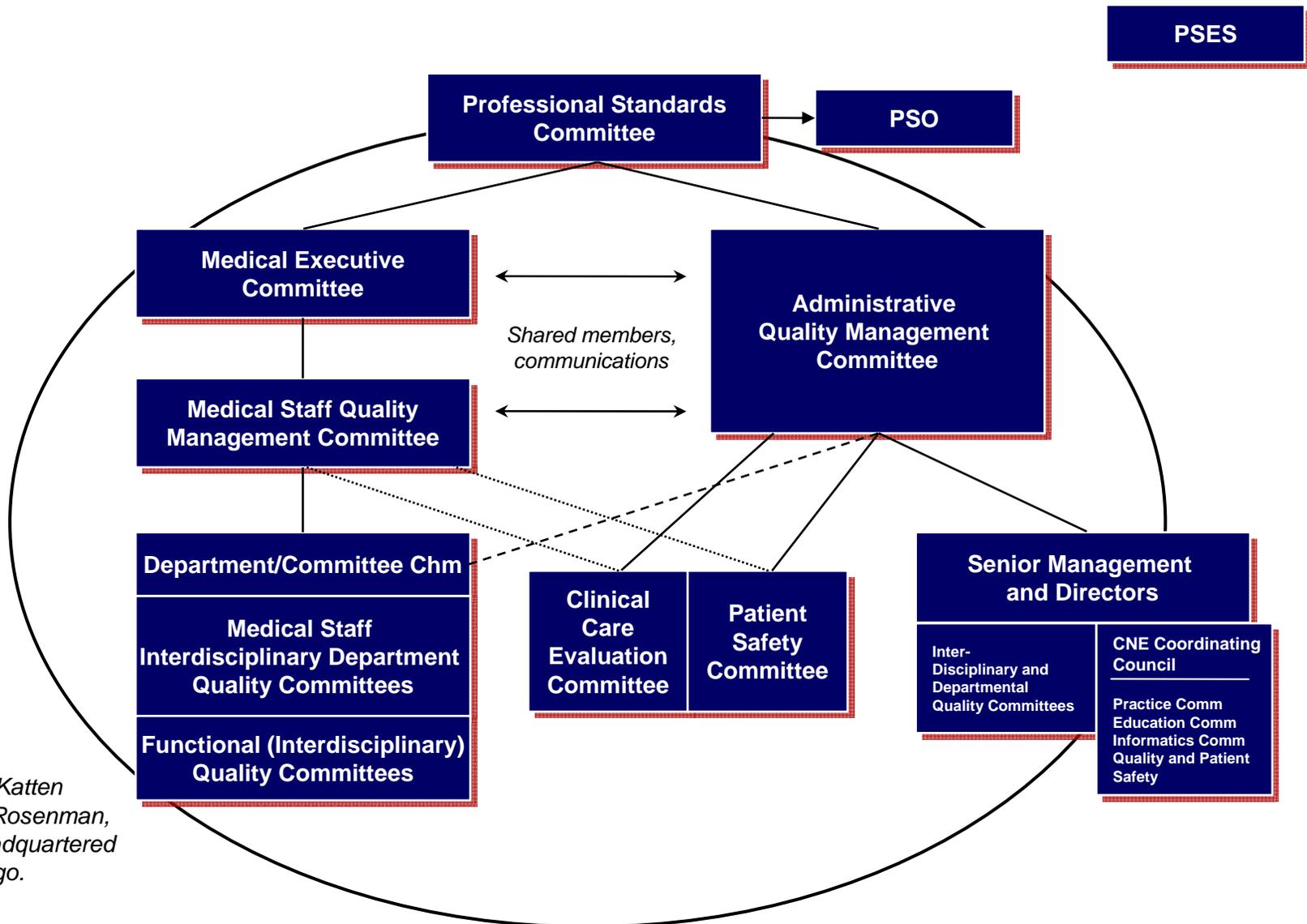
# How Does a Provider Determine Which Data Should Be Reported to a PSO?

- Criteria-based prioritization
  - Suggested criteria
    - Promotes culture of safety/improves care
    - Impressions/subjective data that is not available in the medical record
    - Information that could be damaging during litigation
    - Not required to report elsewhere
    - Required to report elsewhere, but data for reporting could be obtained from medical record
    - Data will not be used to make adverse employment decisions

# Types of Data PSES May Collect and Report to the PSO

- Medical error, FMEA or proactive risk assessments, root cause analysis
- Outcome/quality—may be practitioner-specific, sedation, complications, blood utilization etc.
- Peer review
- Committee minutes—safety, quality, quality and safety committee of the board, medication, blood, physician peer review

# PSO Reporting Process



Source: Katten Muchin Rosenman, LLP, headquartered in Chicago.

# Examples

# Example : Disclosure of Medical Errors

- Disclose to patient/family
  - Objective facts that are also documented in the medical record
  - Actions taken to prevent harm to another patient
- Report to PSO
  - Event report that contains staff members' impressions on why this event may have happened
  - Additional analyses to determine why the event happened
  - RCA recommendations

# Example: Medical Staff Evaluation

- Learning and quality improvement
  - Report to PSO:
    - Physician-specific reports
    - Findings, conclusions, recommendations from individual case peer review
- Reappointment/renewal of privileges
  - Do not report to PSO:
    - Ongoing professional practice evaluation (OPPE)
    - Focused professional practice evaluation (FPPE)

# Physician Evaluation Scenario

Provider receives first notice of a claim re: unplanned return to surgery for hemorrhage after tonsillectomy

## Not PSWP

Provider investigates claim under Attorney-Client Privilege

Is this an isolated incident or a pattern/trend?

Provider collects outcome data on tonsillectomies for reporting to PSO

## PSWP

PSO and PSES conduct in-depth review of 15 unplanned returns to surgery—each case is reviewed by a peer and recommendations are given to individual surgeons involved

## Not PSWP

Provider determines that unplanned return to surgery for hemorrhage after tonsillectomy should be on the ENT physician's OPPE and that any surgeon with greater than 3 occurrences in a quarter will go to focus review. Physician x exceeds threshold. Focus review occurs and privileges removed.

Source: Katten Muchin Rosenman, LLP, headquartered in Chicago.

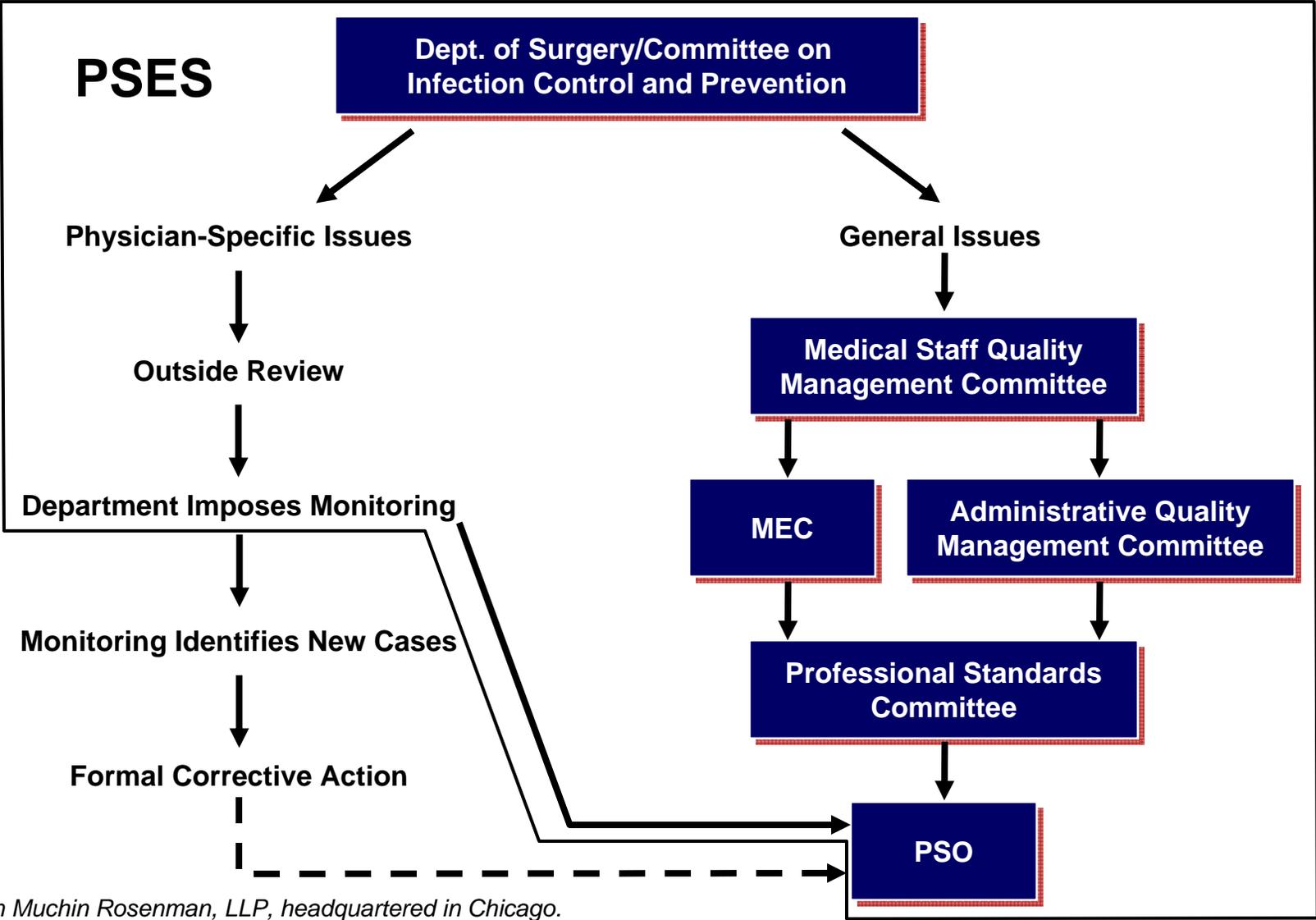
# Peer Review Hypothetical: Postop Infections

- Ortho group identified as having several postop infections as per screening criteria
- Department of Surgery and Committee on Infection Control and Prevention 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, which are not consistent with established infection control protocols
  - Data and analysis and recommendations eventually reported to PSO
- Review also discloses member of targeted ortho group as having other identified issues including:
  - Total shoulder procedures in elderly patients
  - Questionable total ankle procedures
  - Untimely response to postop infections

# Peer Review Hypothetical: Postop Infections (cont.)

- Issues identified are significant enough to trigger third-party review
- Third-party review identifies and confirms 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
  - Department chair recommends formal corrective action

# Peer Review Hypothetical: Postop Infections (cont.)



Source: Katten Muchin Rosenman, LLP, headquartered in Chicago.

Leveraging Your Data -  
Leveraging your data:  
Moving beyond protection  
to Improving performance  
through a PSO

# Magnitude, Direction, Variability & Rate

- Most Data Analysis ultimately comes down to understanding & Communicating the following:

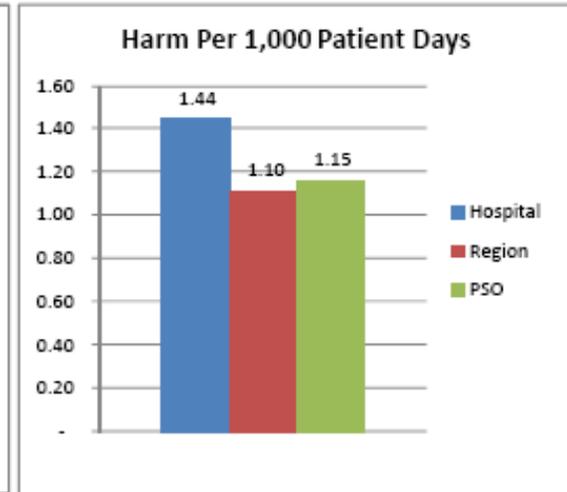
**Magnitude**

**Direction**

**Variability**

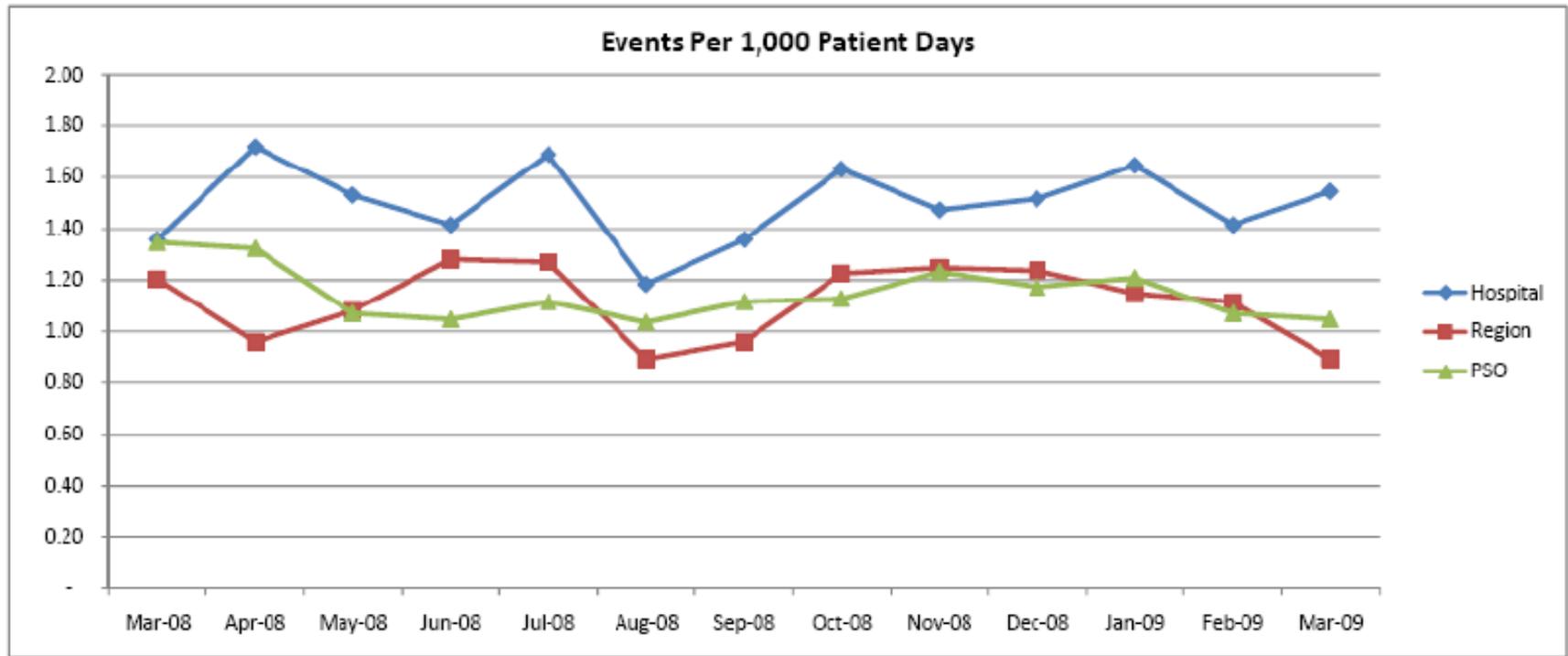
**Rate**

*Preventable: Almost certainly could have been prevented*



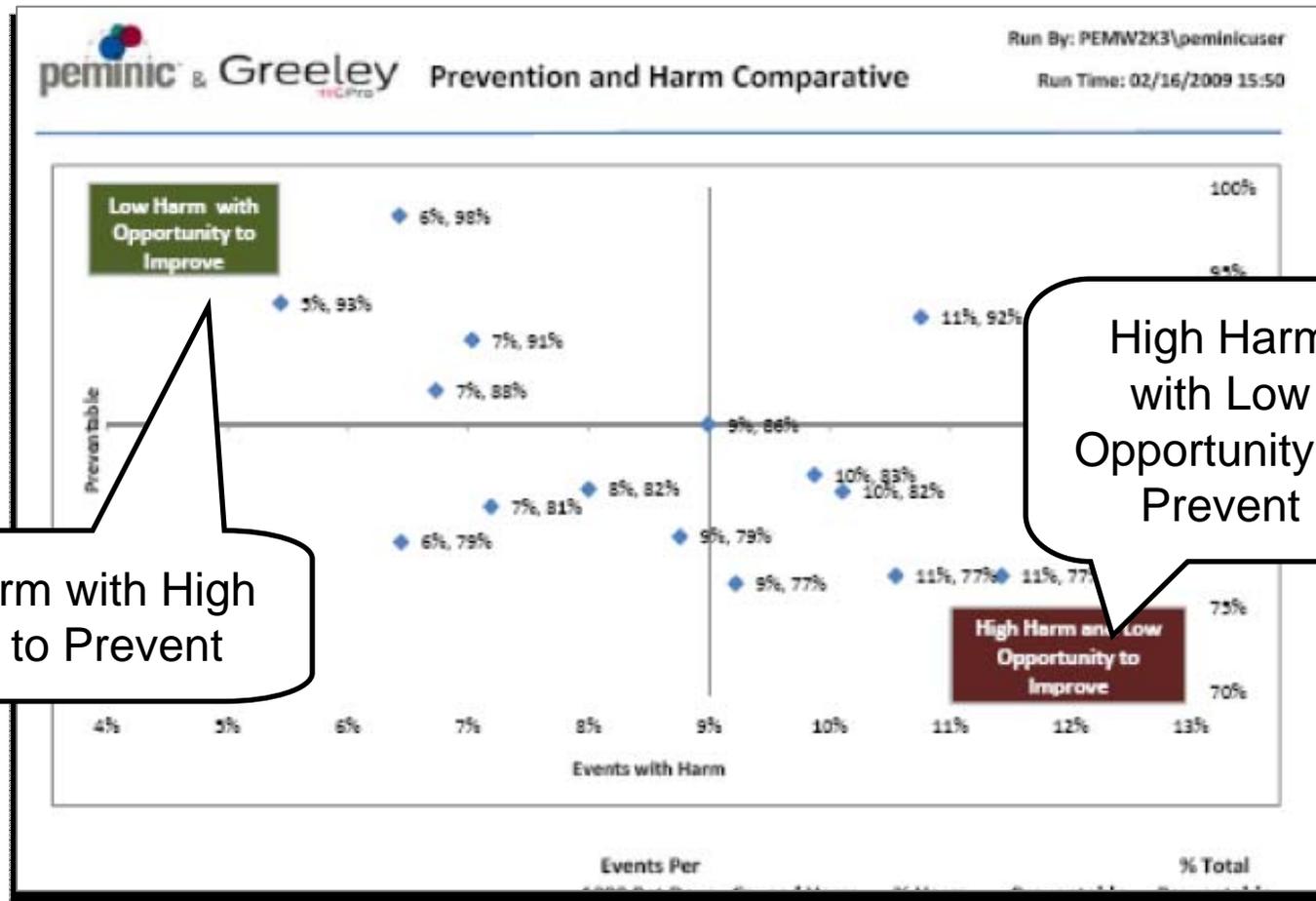
Severity	Hospital		Region		PSO	
	Count	%Total	Count	%Total	Count	%Total
A: Death	9	1.30%	106	1.29%	12,508	1.23%
B: Severe permanent bodily or psychological injury	17	2.46%	184	2.24%	21,896	2.15%
C: Permanent bodily or psychological injury, but not severe	44	6.36%	518	6.30%	59,570	5.86%
D: Bodily or psychological injury, but likely not permanent	73	10.55%	1,005	12.23%	122,610	12.05%
E: Additional treatment during admission or encounter and increased LOS	95	13.73%	1,023	12.45%	127,875	12.57%
F: Mild and transient, emotional stress, or pain or physical discomfort, no add'l tx	89	12.86%	781	9.50%	94,501	9.29%
G: Inconvenience	124	17.92%	1,707	20.77%	215,082	21.14%
H: Event reached patient, but no harm evident	183	26.45%	2,154	26.21%	269,250	26.46%
I: Unknown	58	8.38%	741	9.02%	94,107	9.25%
<b>Total</b>	<b>692</b>	<b>100%</b>	<b>8,219</b>	<b>100%</b>	<b>1,017,399</b>	<b>100%</b>
<b>Patient Days</b>	<b>164,762</b>		<b>2,568,438</b>		<b>299,235,000</b>	
<b>Total Events Per Patient Days: Total Events / Patient Days</b>						
	4.20		3.20		3.40	
<b>Total Harm Events Per Patient Days (Severity A - E)</b>						
	1.44		1.10		1.15	

Preventable: All Categories



	Mar-08	Apr-08	May-08	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Jan-09	Feb-09	Mar-09
Hospital	1.35	1.72	1.53	1.42	1.69	1.18	1.36	1.63	1.47	1.52	1.65	1.42	1.55
Region	1.20	0.96	1.08	1.28	1.27	0.89	0.96	1.23	1.25	1.24	1.15	1.12	0.89
PSO	1.35	1.32	1.07	1.05	1.12	1.04	1.12	1.13	1.23	1.17	1.21	1.07	1.05

# Typical Prevention & Harm Report



# Risks of ignoring the PSO opportunity

# Why Participate in a PSO?

- Regulatory mandates
- Employer and payer demands
- Just culture—New Joint Commission Sentinel Event Alert
- It's good business

# Why Participate in a PSO?

## Employer and Payer Demands

- Leapfrog Group challenge to all providers— adopt a four-pronged transparency strategy with patients when a “never event” occurs, including:
  - Apology
  - Internal root cause analysis
  - Waiver of related charges
  - Reporting for learning (can best be met through a PSO)
- Denial or reduction of reimbursement by payers and PHP initiatives

# Why Participate in a PSO?

## It's Good Business

- Consumer groups and advocates have called for substantially more engagement of the patient and the public in improving healthcare systems.
- Better and safer care should be more efficient care which costs less in dollars as well as in patient suffering, clinician frustration, and unhappiness.
- Healthcare providers want to provide the best possible care, but at times the fear of disciplinary action and/or liability prevents this. PSO provides a safe environment where providers can learn.

# Why Participate in a PSO?

## It's Good Business (cont'd)

- Healthcare reform initiatives clearly are tying reimbursement by federal and private payors to outcomes and adherence to protocols.
- OIG/DOJ are scrutinizing role of Boards and hospitals in monitoring quality and adopting evidenced-based standards. Failure to do so has resulted in prosecutions and multi-million dollar settlements.

# Why Participate in a PSO?

## It's Good Business (cont'd)

- Participation in a PSO will be seen as one indicia of compliance.
- In Missouri, all Medicaid providers are required to participate in a PSO.

# Three powerful next steps

- Begin planning for 'functional reporting'
- Aggregate, Aggregate, Aggregate
- Begin evaluating PSOs

# Patient Safety Work Product

- To optimize protection under the act:
  - Understand the protections afforded by the act
  - Inventory data from all sources to determine what can be protected
  - Internally define your PSES
  - Complete appropriate policies on collection, analysis, and reporting
  - Develop component PSO and/or select listed PSO