Patient Safety Organizations: Legal Update and Practical Solutions After Walgreens Case

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Patient Safety and Quality Improvement Act of 2005 (PSQIA) Purpose

To encourage the expansion of voluntary, provider-driven initiatives to improve the quality and safety of health care; to promote rapid learning about the underlying causes of risks and harms in the delivery of health care; 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.

Why Participate in a PSO?

- Regulatory mandates
- Employer and payer demands
- Just Culture – Joint Commission Sentinel Alert
- It's good business

Why Participate in a PSO?
TJC Sentinel Event Alert

- Leadership Committed to Safety
  - "A safe clinical environment is strengthened when work processes allow leaders and staff to discuss and learn about safety issues together."
  - "A thorough and appropriate evaluation of adverse events is necessary to help prevent future occurrences."
  - Suggested Actions:
    - "….hold open discussions …that focus on learning and improvement….."

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

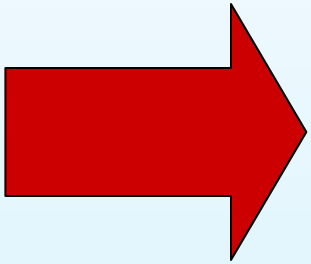
Denial or reduction of reimbursement by payers and PHP initiatives

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.

Long-Term Goals of the PSQIA

- 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

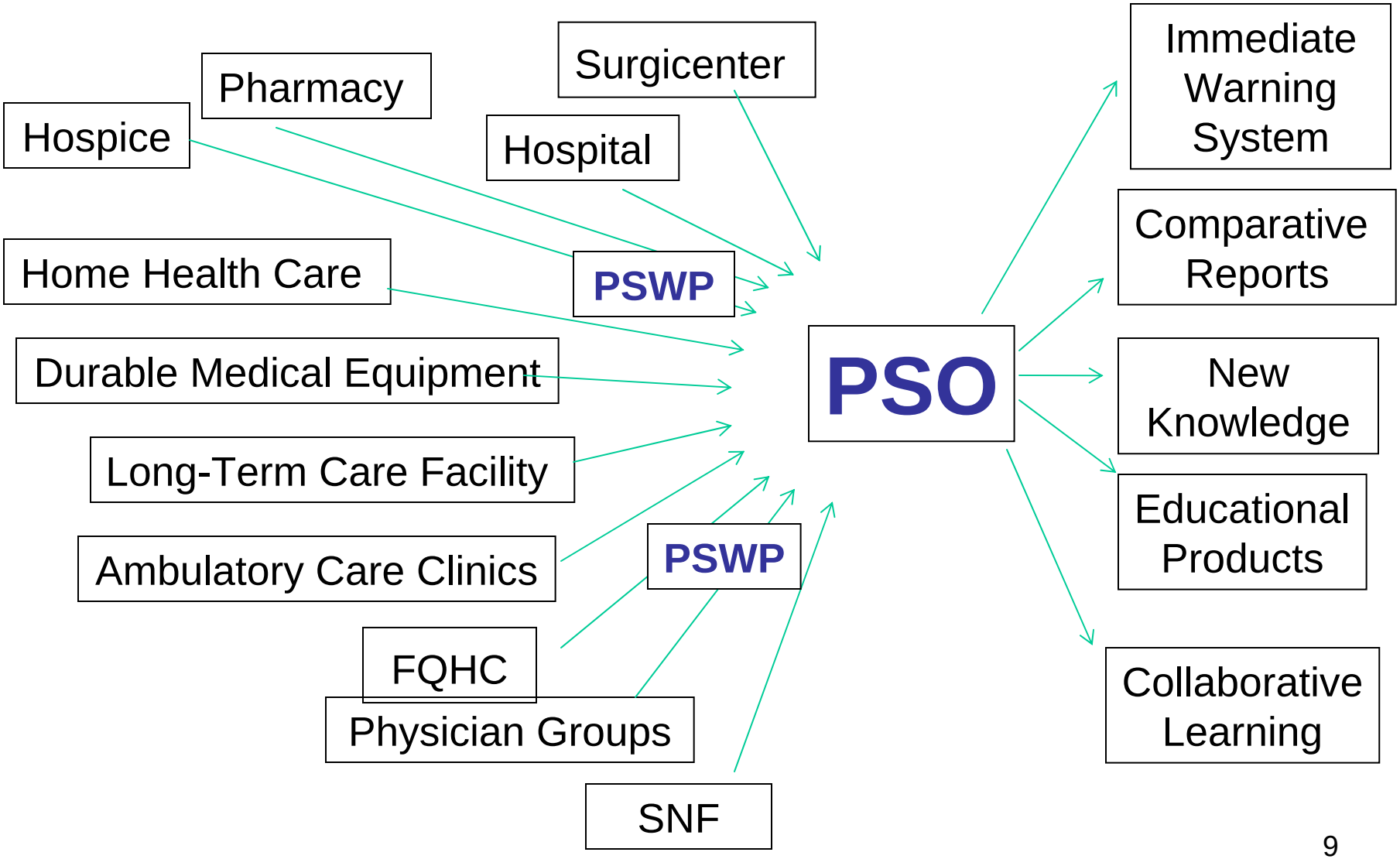


Further accelerating the speed with which solutions can be identified for the risks and hazards associated with patient care through the magnifying effect of data aggregation

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 (PSOs)
- Protects PSWP collected on behalf of providers by PSOs, e.g., Root Cause Analysis, Proactive Risk Assessment

PSO Approach & Expected Results



Essential Terms of the Patient Safety Act

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

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 is sent to the PSO is protected from discovery as PSWP

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, health care quality, or health care outcomes;

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?

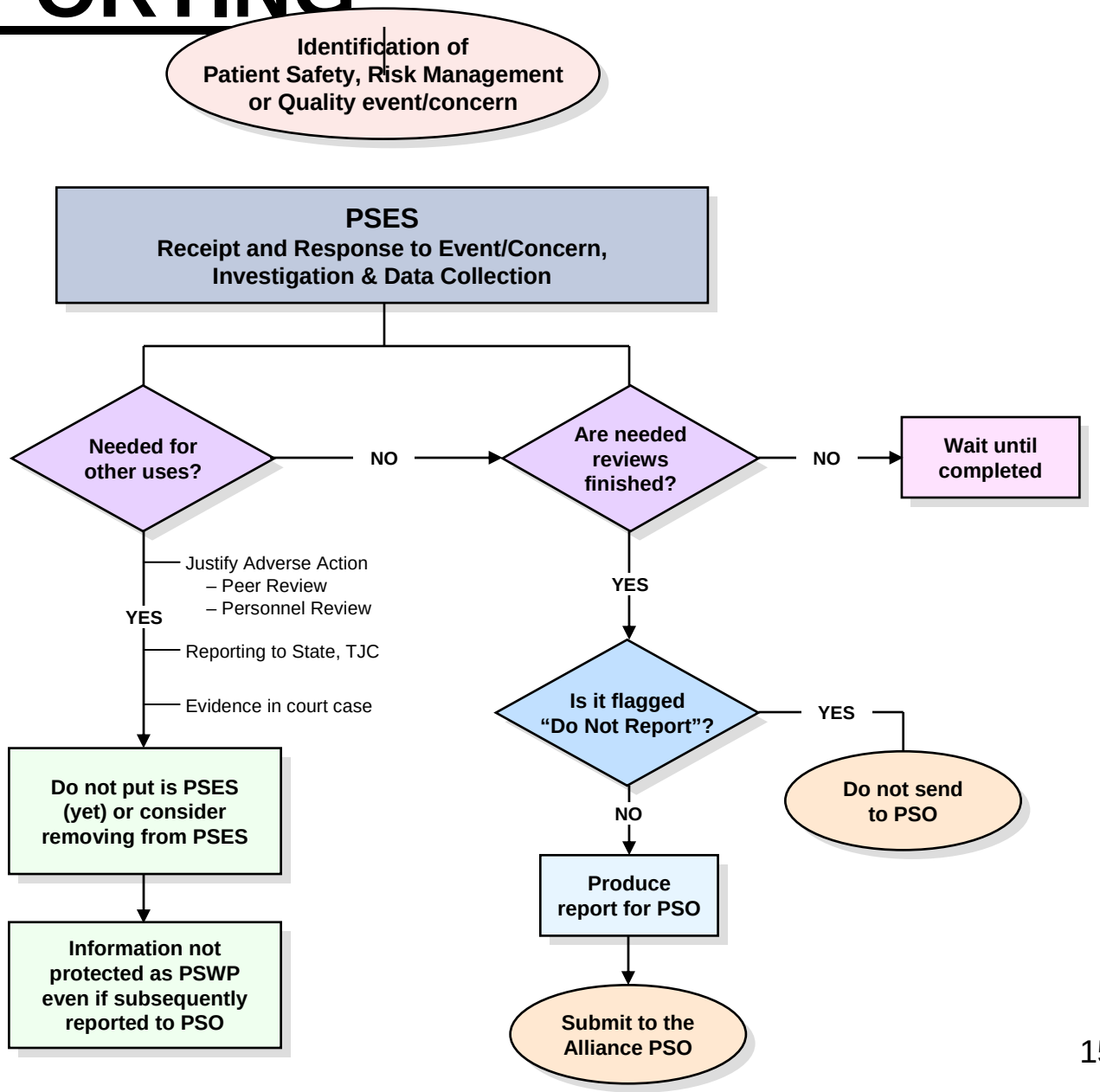
- Patient's medical record, billing and discharge information, or any other original patient or provider information
- Information that is collected, maintained, or developed separately, or exists separately, from a PSES. Such separate information or a copy thereof reported to a PSO shall not by reason 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

What is Required?

Establish and Implement a Patient Safety Evaluation System (PSES), that:

- Collects data to improve patient safety, healthcare quality and healthcare outcomes
- Reviews data and takes action when needed to mitigate harm or improve care
- Analyzes data and makes recommendations to continuously improve patient safety, healthcare quality and healthcare outcomes
- Conducts RCAs, Proactive Risk Assessments, in-depth reviews, and aggregate RCAs
- Determines which data will/will not be reported to the PSO
- Reports to PSO(s)

PSO REPORTING



Designing Your PSES

- Events or Processes to be Reported
  - Adverse events, sentinel events, never events, near misses, HAC, unsafe conditions, RCA, etc
- Committee Reports/Minutes Regarding Events
  - PI/Quality committee, Patient safety committee, Risk Management committee, MEC, BOD
- Structures to Support PSES
  - PI plan, safety plan, RM plan, event reporting and investigation policies, procedures and practices, grievance policies and procedures

Event/Incident Reporting Policy

- Modify existing policies as needed to reflect the purpose of internal event reporting is to …
  - Improve patient safety, healthcare quality and patient outcomes
  - Provide learning opportunity through 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 organization wide 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**
- **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

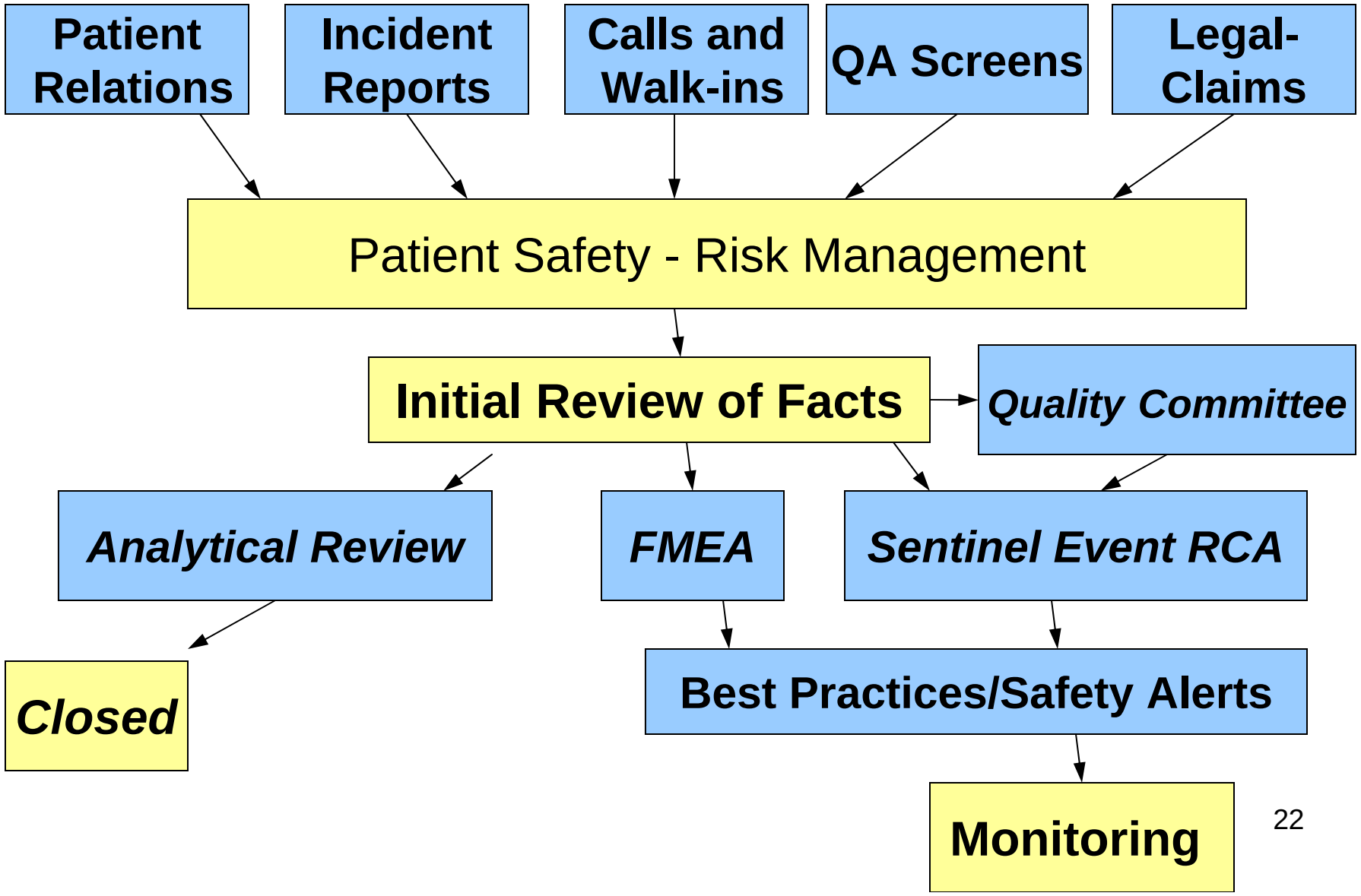
Suggested criteria

- 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**
- **Risk Management – incident reports, investigation notes, interview notes, RCA notes, notes rec'd phone calls or hallway conversations, notes from PS rounds**
- **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**

Risk Management & Patient Safety Events Flow



PA Patient Safety Authority: Reports Identify Trends

- Hidden sources of Latex in Healthcare Products
- Use of X-Rays for Incorrect Needle Counts
- Patient Identification Issues
- Falls Associated with Wheelchairs
- Electrosurgical Units and the Risk of Surgical Fires
- A Rare but Potentially Fatal Complication of Colonoscopy
- Fetal Lacerations Associated with Cesarean Section
- Medication Errors Linked to Name Confusion
- When Patients Speak-Collaboration in Patient Safety
- Anesthesia Awareness
- Problems Related to Informed Consent
- Dangerous Abbreviations in Surgery
- Focus on High Alert Medications
- Bed Exit Alarms to Reduce Falls
- Confusion between Insulin and Tuberculin Syringes (Supplementary)
- The Role of Empowerment in Patient Safety
- Risk of Unnecessary Gallbladder Surgery
- Changing Catheters Over a Wire (Supplementary)
- Abbreviations: A Shortcut to Medication Errors
- Lost Surgical Specimens

PA Patient Safety Authority: Reports Provide Useful Information

- Examples:
  - One misunderstood colored wristband led to regional standardization
  - A hospital had a “sandbag” fly into the MRI core & screened their other sandbags throughout the facility
  - A report from a behavioral health unit of patients getting implements of self-harm in the ED

Learning Lessons the Easy Way

- Examples:
  - Insulin given to the wrong patient
  - Wrong patient taken to the OR/procedure room
  - Patient with pacemaker scheduled for MRI
  - Patients found with multiple fentanyl patches
  - Neonates or infants given excessive doses of heparin
  - Wrong tissue type

Don’t Limit Focus to Outcomes

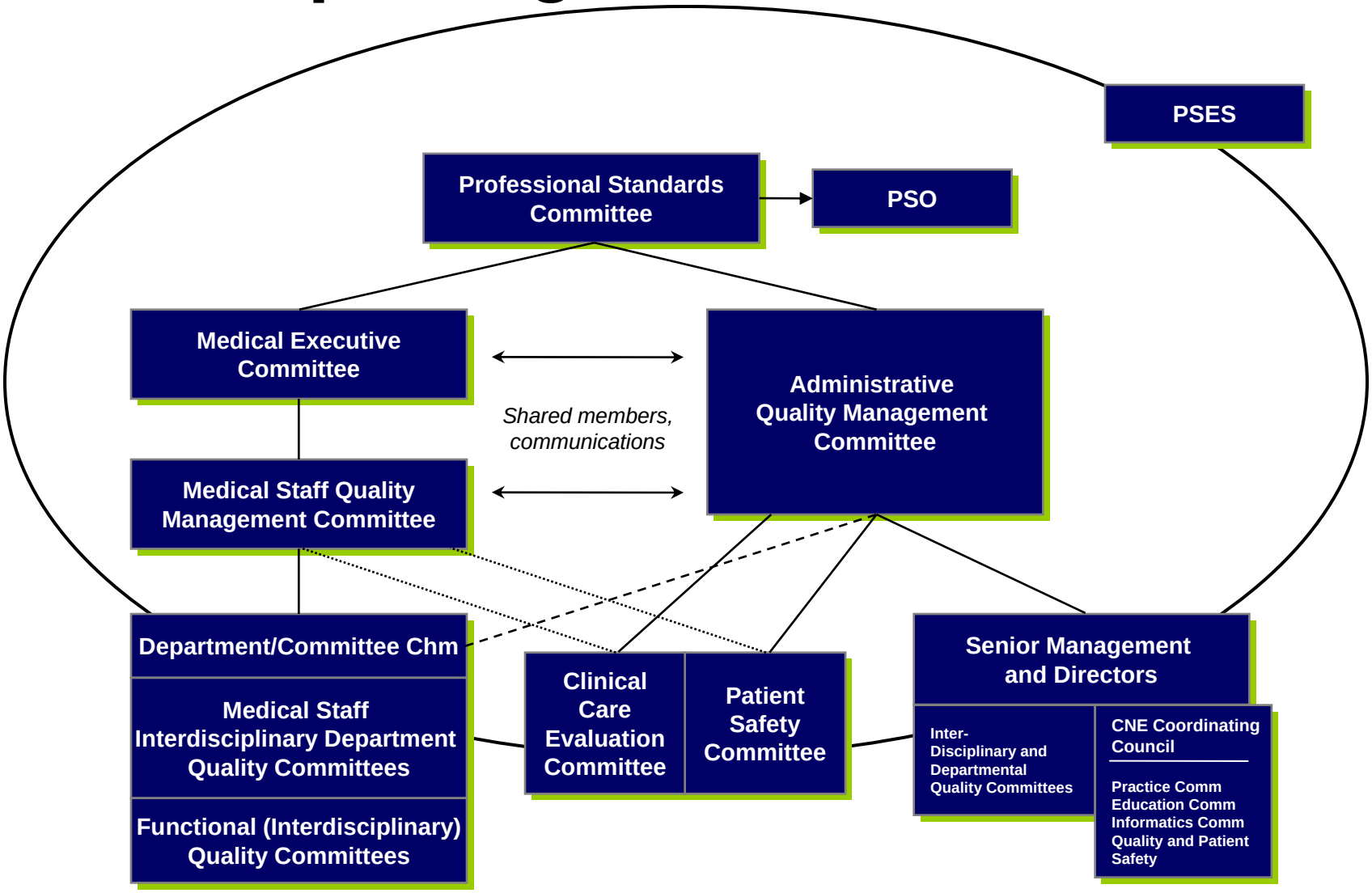
- What types of near miss reports would have predicted your last Sentinel Event?

NEAR MISSES	SENTINEL EVENTS
• Wrong infant taken to mother’s bedside	• Infant discharged to wrong family
• Unlabeled bag of donor blood found in blood bank	• Transfusion-related death from ABO incompatibility
• Sites not being marked	• Surgery on wrong body part
• Pain medication given too soon	• Death from opiate/narcotic overdose

Steps to PSO Reporting

- Inventory Data Currently Collected
  - Patient safety, quality of care, healthcare outcomes
- Prioritize Data that will be submitted to a PSO and become PSWP; what data will do the most to support improving the culture of safety
- Establish a system for data collection and review
  - Standardized data collection will both enhance benchmarking comparisons and ultimately comply with AHRQ's mandate for PSOs to collect standardized data; AHRQ's "Common Formats" or another common format
  - Agree to the processes that the PSES will follow to determine PSWP
- Create appropriate policies: Event Reporting; PSES, PSO Reporting

PSO Reporting Process



Mandatory Reporting to State Agencies

Providers have flexibility in defining and structuring their PSES, as well as determining what information is to become PSWP and, thus, protected from disclosure

- Use information that is not PSWP to fulfill mandatory reporting obligations e.g., Medical Records, Surgery Logs, etc.
- Report subjective incident report data to PSO for protections
  - Investigation notes, interview notes, forensics, etc.

Confidentiality and Privilege Protections

Patient Safety Work Product

In order 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

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:

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Patient Safety Work Product Confidentiality

Exceptions (cont'd):

- Disclosure to a PSO for patent 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 nor 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 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

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

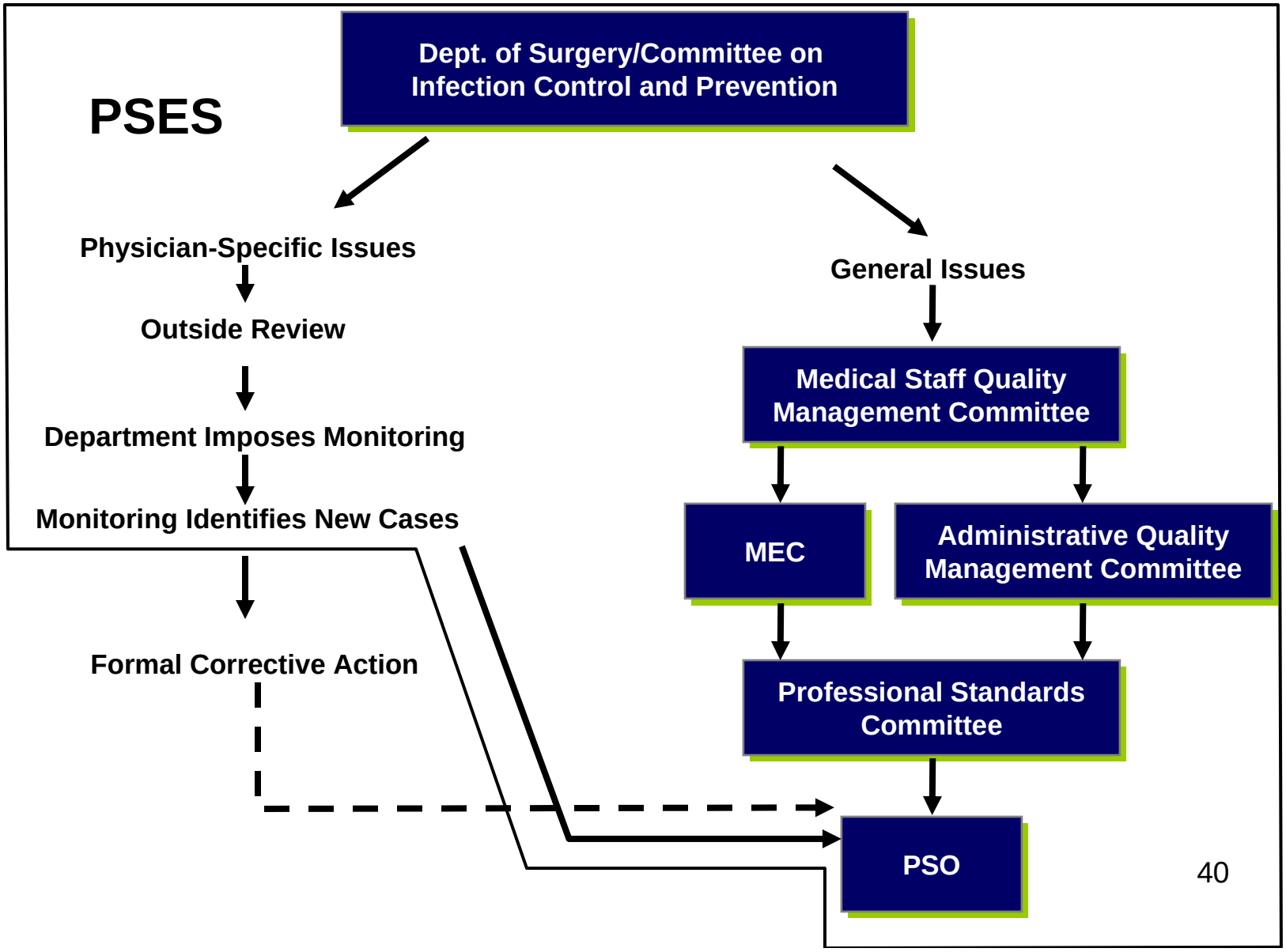
Hypothetical: Post Op Infections

- Ortho group identified as having several post op 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

Hypothetical: Post Op Infections

  - Untimely response to post op infections
- Issues identified are significant enough to trigger 3rd 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

Hypothetical: Ortho Post Op Infections



Hypothetical: Wrong Breast Milk

- 3 month old premie in NICU received 15ccs of breast milk in an IV line
- Infant weighed 5lbs, 3 oz.
- Infant in isolette through which all lines (feeding tube, IVs, EKG cord, arterial line, etc). were fed through
- Within 20 minutes the baby exhibited signs of respiratory distress and was placed back on the ventilator

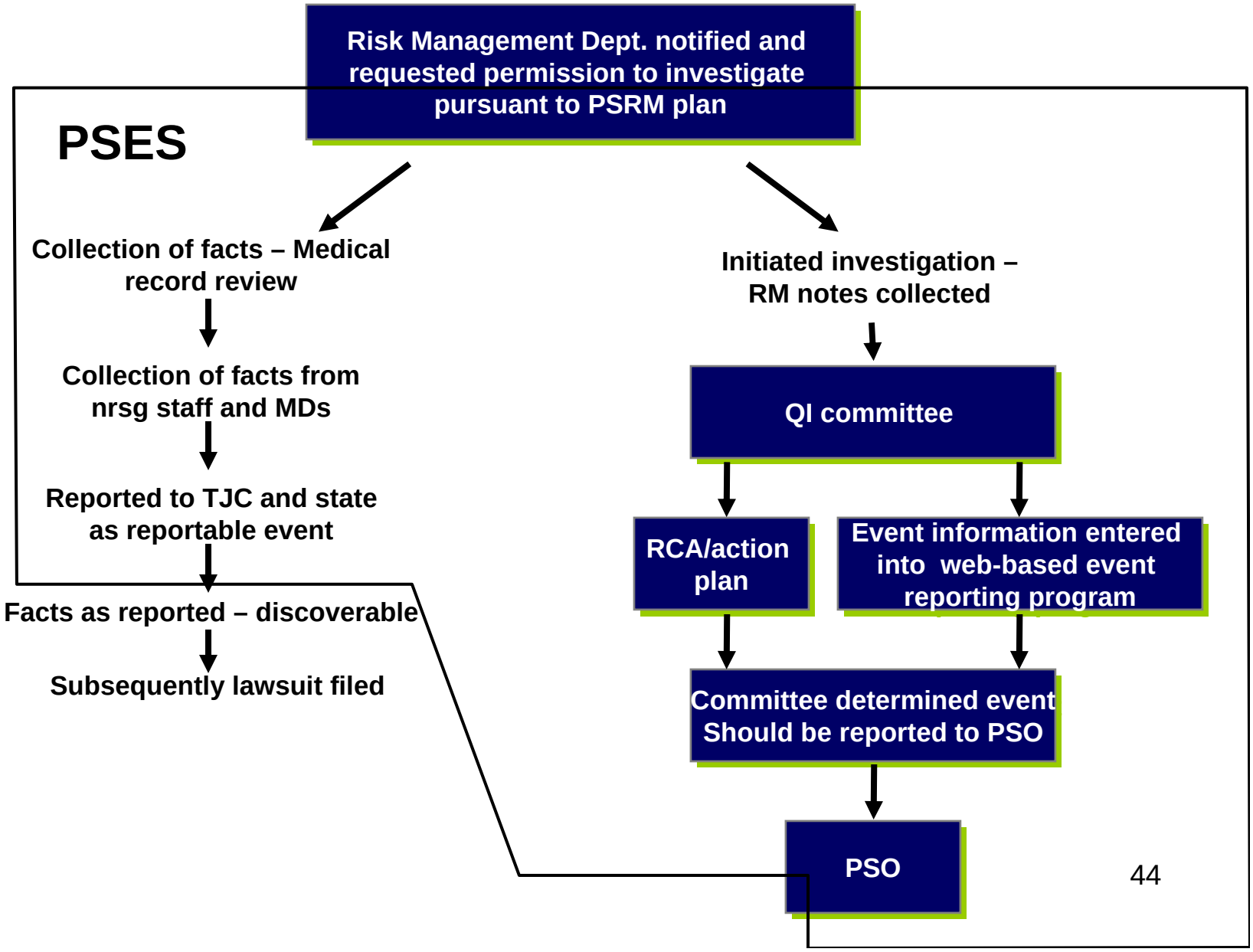
Hypothetical: Wrong Breast Milk

- Risk management rec'd call at 6:15AM – notes taken to capture details of event
- Medical record reviewed by RM – notes taken
- Staff interviewed – RM notes taken
- IV line equipment changed out and sequestered - sent to forensics lab with expected report in 2 weeks
- Chair of QI committee requested RCA - Group pulled together and started within 24 hours of event
- Graphics of room design/layout as well as position of isolette and lines submitted as part of RCA

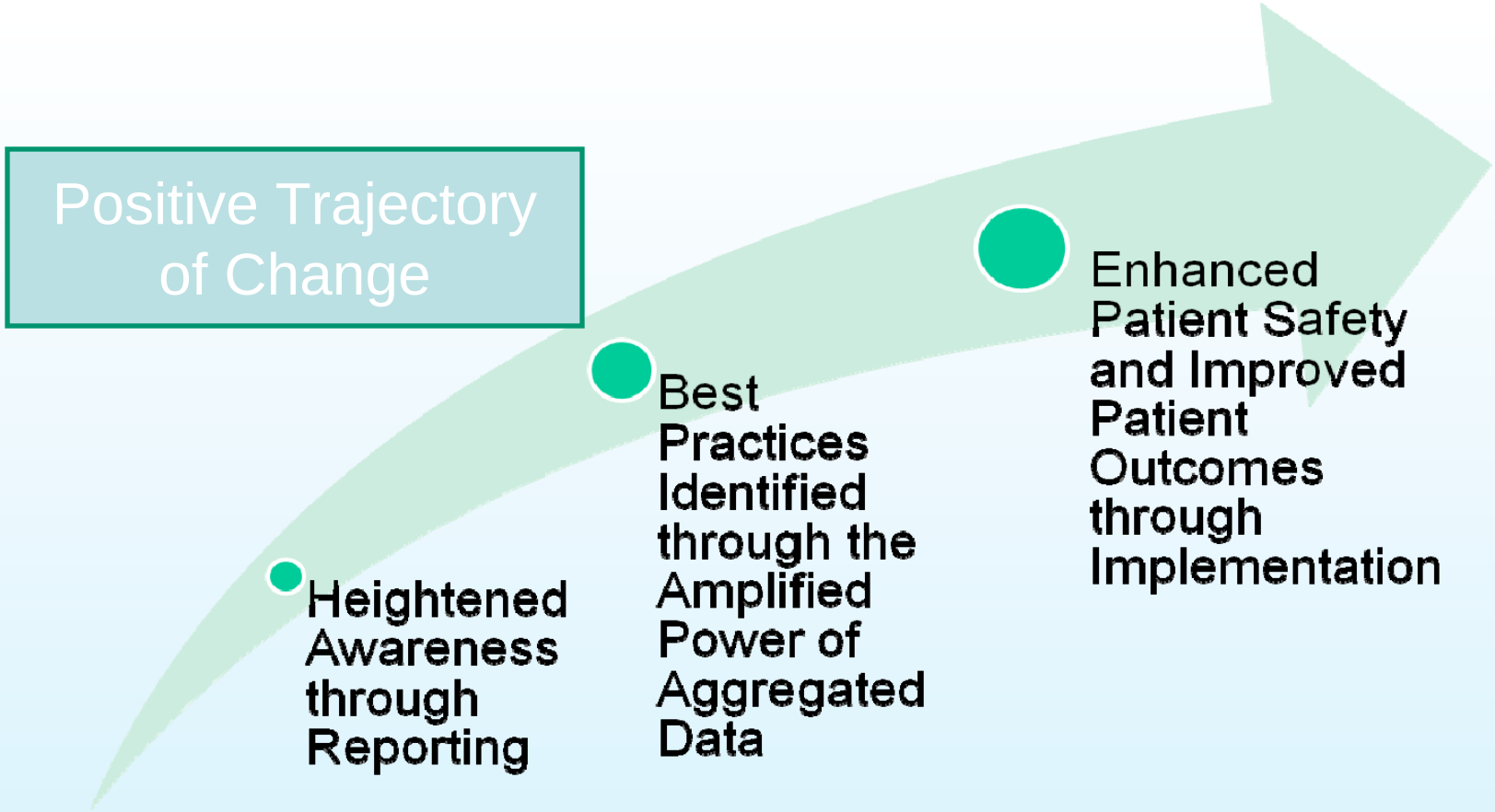
Hypothetical: Wrong Breast Milk

- Risk management communicated with national databank for neonatal events and obtained date and time in which to expect a call from another organization that experienced same event
- Risk management and several staff participated in that subsequent phone call – notes taken
- After phone call course of treatment significantly modified to match experience of other organization and that reflected the lessons learned
- Infant survived

Hypothetical: Wrong Breast Milk



PSO: Advancing Patient Safety



PSO Legal Decisions

Walgreens Trial Court Decision

Illinois Department of Financial and Professional Regulation v. Walgreens (Illinois, 4/7/11)

- On July 1, 2010, Walgreens was served with separate subpoenas requesting "all incident reports of medication errors" from 10/31/07 through 7/1/10, involving three of its pharmacists who apparently were under investigation by the Illinois Department of Professional Regulation ("IDFPR") and the Pharmacy Board.
- Walgreens, which had created The Patient Safety Research Foundation, Inc. ("PSRF"), a component PSO that was certified by AHRQ on January 9, 2009, only retained such reports for a single year. What reports it had were collected as part of its PSES and reported to PSRF.

Walgreens Trial Court Decision

- Consequently, Walgreens declined to produce the reports arguing they were PSWP and therefore not subject to discovery under the PSQIA.
- The IDFPR sued Walgreens which responded by filing a Motion to Dismiss.
- Although the IDFPR acknowledged that the PSQIA preempts conflicting state law, it essentially argued that Walgreens had not met its burden of establishing that:
  - That the incident report was actually or functionally reported to a PSO; and
  - That the reports were also not maintained separately from a PSES thereby waiving the privilege.

Walgreens Appellate Court Decision

- Walgreens submitted affidavits to contend that the responsive documents were collected as part of its Strategic Reporting and Analytical Reporting System ("STARS") that are reported to PSRF and further, that it did not create, maintain or otherwise have in its possession any other incident reports other than the STARS reports.
- IDFPR had submitted its own affidavits which attempted to show that in defense of an age discrimination case brought by one of its pharmacy managers, Walgreens had introduced case inquiry and other reports similar to STARS to establish that the manager was terminated for cause.

Walgreens Appellate Court Decision

- IDFPR argued that this served as evidence that reports, other than STARS reports existed and, further, that such reports were used for different purposes, in this case, to support the manager's termination.
  - It should be noted that these reports were prepared in 2006 and 2007.
- Trial court ruled in favor of Walgreens Motion to Dismiss finding that: "Walgreens STARS reports are incident reports of medication errors sought by the Department in its subpoenas and are patient safety work product and are confidential, privileged and protected from discovery under The Federal Patient Safety and Quality

Walgreens Appellate Court Decision

Improvement Act (citation), which preempts contrary state laws purporting to permit the Department to obtain such reports. . . ."

- The IDFPR appealed and oral argument before the 2nd District Illinois Appellate Court took place on March 6, 2012.
- Two amicus curiae briefs were submitted in support of Walgreens by numerous PSOs from around the country and the AMA.
- On May 29, 2012, the Appellate Court affirmed that the trial court's decision to dismiss the IDFPR lawsuit.

Walgreens Appellate Court Decision

"The Patient Safety Act 'announces a more general approval of the medical peer review process and more sweeping evidentiary protections for materials used therein' *KD ex rel. Dieffenbach v. United States*, 715 F. Supp. 2d 587, 595 (D. Del. 2010). According to Senate Report No. 108-196 (2003), the purpose of the Patient Safety Act is to encourage a 'culture of' Safety 'and quality in the United States health care system by 'providing for broad confidentiality and legal protections of information collected and reported voluntarily for the purposes of improving the quality of legal protections of information collected and reported voluntarily for the purposes of improving the quality of medical care and patient safety.' S. Rep. No. 108-196, at 3 (2003). The Patient Safety Act provides that

Walgreens Appellate Court Decision

'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 proceeding.' 42 U.S.C. § 299b-22(a)(2006). Patient safety work product includes any data, reports, records, memoranda, analyses, or written or oral statements that are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization. 42 U.S.C. §299b-21(7) (2006). Excluded as patient safety work product is 'information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system [PSO]'. 42 U.S.C. § 299b-21(7)(B)(ii) (2006)."

Walgreens Appellate Court Decision

- The court rejected the IDFPR's arguments that the STARS reports could have been used for a purpose other than reporting to a PSO or that other incident reports were prepared by Walgreens which were responsive to the subpoenas because both claims were sufficiently rebutted by the two affidavits submitted b Walgreens.
- Although the age discrimination suit (See *Lindsey v. Walgreen Co.* (2009 WL 4730953 (N.D. Ill. Dec. 8, 2009, aff'd 615 F. 3d 873 (7th Cir. 2010)) (per curium)) did identify documents used by Walgreens to terminate the employee.

Walgreens Appellate Court Decision

- The court determined that these were “about policy violations, i.e., giving out medications for free and failing to follow directions from supervisors.”
- Because none of these documents were considered “incident reports of medication error,” which were the sole materials requested by the IDFPR, the court found them immaterial and affirmed the trial court’s decision to grant Walgreens’ motion to dismiss because no genuine issue of materials fact existed.

Recent PSO Trial Court Decisions

Morgan v. Community Medical Center Healthcare System (Pennsylvania, 6/15/2011)

- Case involves a malpractice suit filed against a hospital claiming that it negligently discharged the plaintiff from the emergency room who had sustained injuries as a result of a motorcycle injury.
- Plaintiff contends that he received IV morphine while in the ED but did not receive any evaluation of his condition prior to discharge contrary to hospital policy. He subsequently walked out of the ED but fell, struck his head on concrete and was readmitted with a subdural hematoma.
- Plaintiff sought and obtained a trial court order for the hospital to produce an incident report regarding the event. The hospital appealed.

Recent PSO Trial Court Decisions

(cont'd)

- Hospital argued that the incident report was privileged and not subject to discovery under both its state confidentiality statute and the PSQIA.
- With respect to the state statute, as is true in many states, the protection only applies if the hospital meets its burden of establishing that the report was solely prepared for the purpose of complying with the Pennsylvania Safety Act.
- Plaintiff argued, and the court agreed, that the report could have been prepared principally for other purposes such as for insurance, police reports, risk management, etc. and therefore the report was subject to discovery even if later submitted to a patient safety committee on the board of directors.

Recent PSO Trial Court Decisions

(cont'd)

- With respect to the PSQIA, the court applied a similar analysis – was the incident report collected, maintained or developed separately or does it exist separately from a PSES. If so, even if reported to a PSO, it is not protected.
- As with the state statute, court determined that hospital had not met its burden of establishing that the report "was prepared solely for reporting to a patient safety organization and not also for another purpose."

Recent PSO Trial Court Decisions (cont'd)

Francher v. Shields (Kentucky, 8/16/11)

- Case involved a medical malpractice action in which plaintiff sought to compel discovery of documents including sentinel event record and a root cause analysis prepared by defendant hospital.
- Hospital asserted attorney-client communications, work product and PSQIA protections.

Recent PSO Trial Court Decisions (cont'd)

  - Keep in mind that the Kentucky Supreme Court has struck down three legislative attempts to provide confidentiality protection for peer review activity in malpractice cases.
- Because the requested documents were prepared for the "purpose of complying [with] [T]he Joint Commission's requirements and for the purpose of providing information to its patient safety organization", it was not intended for or prepared solely for the purpose rendering legal services and therefore, documents were not protected under any of the attorney-client privileges.

Recent PSO Trial Court Decisions

(cont'd)

- In noting that no Kentucky court had addressed either the issue of PSQIA protections or the issue of pre-emption, i.e., "a state law that conflicts with federal law is without effect", court cited favorably to *K.D. ex rel Dieffebach v. U.S.* (715 F Supp 2d 587) (D. Del. 2010).
- Although it did not apply the PSQIA in the context of a request to discover an NIH cardiac study, the Fancher Court, citing to K.D., stated:

Recent PSO Trial Court Decisions (Cont'd)

"The Court then went on to discuss the Patent Safety Quality improvement Act of 2005. The Court noted that the Act, 'announces a more general approval of the medical peer review process and more sweeping evidentiary protections for materials used therein', and then concluded that, since the same type of peer review system was in place at the National Institutes of Health, the privilege should apply to protect data from discovery."

Recent PSO Trial Court Decisions

(cont'd)

- Regarding the issue of pre-emption, the Court identified the Senate's intent under the PSQIA to move beyond blame and punishment relating to health care errors and instead to encourage a "culture of safety" by providing broad confidentiality and privilege protections.

Recent PSO Trial Court Decisions (cont'd)

- "Thus, there is a clear statement of a Congressional intent that such communications be protected in order to foster openness in the interest of improved patient safety. The court therefore finds that the area has been preempted by federal law."
- In addressing Section 3.20, Subsection 2(B)(iii)(A), which defines "patient safety work product," and would seem to allow for the discovery of PSWP in a "criminal, civil or administrative proceeding", the court determined that such discovery "could have a chilling effect on accurate reporting of such events."

Recent PSO Trial Court Decisions (cont'd)

  - Court fails to note that this section only applies to information that is not PSWP.
- Court further noted that the underlying facts, (such as a medical record) are not protected and can be given to an expert for analysis.
- That this information is submitted to other entities, such as the Joint Commission was "not dispositive."
- Court granted a protective order "as to the sentinel event and root cause analysis materials reported to its patient safety organization as well as its policies and procedures."

Reasons for Moving Forward with Participation in a PSO

- The Patient Safety Act applies to all state licensed providers, including hospitals, physicians, nursing homes, home health agencies, nurses, hospice providers and others.
- The protections offered under the Patient Safety Act to patient safety activities and providers are much broader than those provided, if at all, under the state law.
- The confidentiality and privileging protections can be immediately implemented with a simple board resolution in advance of actually establishing a provider's patient safety evaluation system or contracting with or establishing its own component PSO. Documentation of this decision and all patient safety activities is extremely important in order to successfully defend against discovery requests such as in the Walgreens case.

Reasons for Moving Forward with Participation in a PSO

- As a practical matter, a provider's PSES can start with its existing peer review, quality management and risk management policies and procedures.
- The PSO protections can coexist with current state confidentiality and privilege laws.
- A CMS certified Accountable Care Organization (ACO) must participate in a PSO in order to negotiate with the yet-to-be established state insurance exchanges.
- Providers can create their own PSO.

Reasons for Moving Forward with Participation in a PSO

- Providers can contract with any of the nearly 80 certified PSOs around the country, even if not established in their own state.
- For the first time, licensed providers can now take advantage of a statute that offers protections in both the state and federal courts and administrative proceedings.
- Providers participating in PSOs can both obtain independent analysis and studies provided by the PSO in terms of peer benchmarking, identification of best practices, comparative and internal quality evaluations, etc.

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- Most plaintiffs/agencies will make the following types of arguments in seeking access to claimed patient safety work product:
  - Did the provider or PSO establish a PSES?
  - Was the subpoenaed information identified by the provider/PSO as part of its PSES?
  - Was it actually collected and either actually or functionally reported to the PSO? Is there evidence/documentation of this report?
    - Plaintiff will seek to discover your PSES and documentation policies.

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- If not yet reported to the PSO, what is the justification for not doing so? How long has information been held? Does your PSES policy reflect this practice or standard for retention?
- Has information been dropped out and used for a different purpose?
- Is the information even eligible for protection?
- Was the information subject to mandatory federal or state reporting requirements?

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- What was the date information was collected as compared to the date on which the provider evidenced intent to participate in a PSO, and how was it documented?
- Is the provider/PSO attempting to use information that was reported or that cannot be dropped out, e.g., an analysis, for another purpose, such as to defend itself in a lawsuit or a government investigation?