

CBA Health Law Committee

Patient Safety Organizations Overview, Benefits and Practical Applications Under Health Care Reform

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Objectives

- **Discuss the advantages/disadvantages of participating in a PSO**
- **Articulate the confidentiality and privilege provisions**
- **Review hypothetical scenarios on how PSO protections can be applied**
- **Examine what risk management work product materials would and would not be eligible for protection**
- **Describe other quality of care benefits achieved through PSO participation**

The Patient Safety Act

- **Background**
- **Purpose**
- **Who is Covered under the Act and What is Required**
- **The PSES and Reporting to a PSO**
- **Confidentiality and Privilege Protections**

Background

- **Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act)**
 - **Signed into law July 29, 2005**
- **Final rule published November 21, 2008**
- **Rule took effect January 19, 2009**

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**

Patient Safety and Quality Improvement Act (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? Regulatory Mandates

Illinois Health Care Adverse Event Reporting Law

- Implementation in 2010
- Calls for reporting of twenty-four specific “never” events to the state, along with root cause analysis and corrective action plans
- PSO participation will enable learning from experience of others and consultation in developing these mandatory resources
- PSO provides protection for supporting documents but not the RCA and action plan submitted to state (unless re-created)

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? TJC Sentinel Event Alert

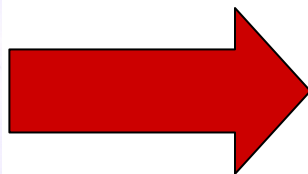
- Leadership Committed to Safety
 - “A safe clinical environment is strengthened when work processes allow leaders and staff to discuss and learn about safety issues together.”
 - “A thorough and appropriate evaluation of adverse events is necessary to help prevent future occurrences.”
 - Suggested Actions: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

Why Participate in a PSO? 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**

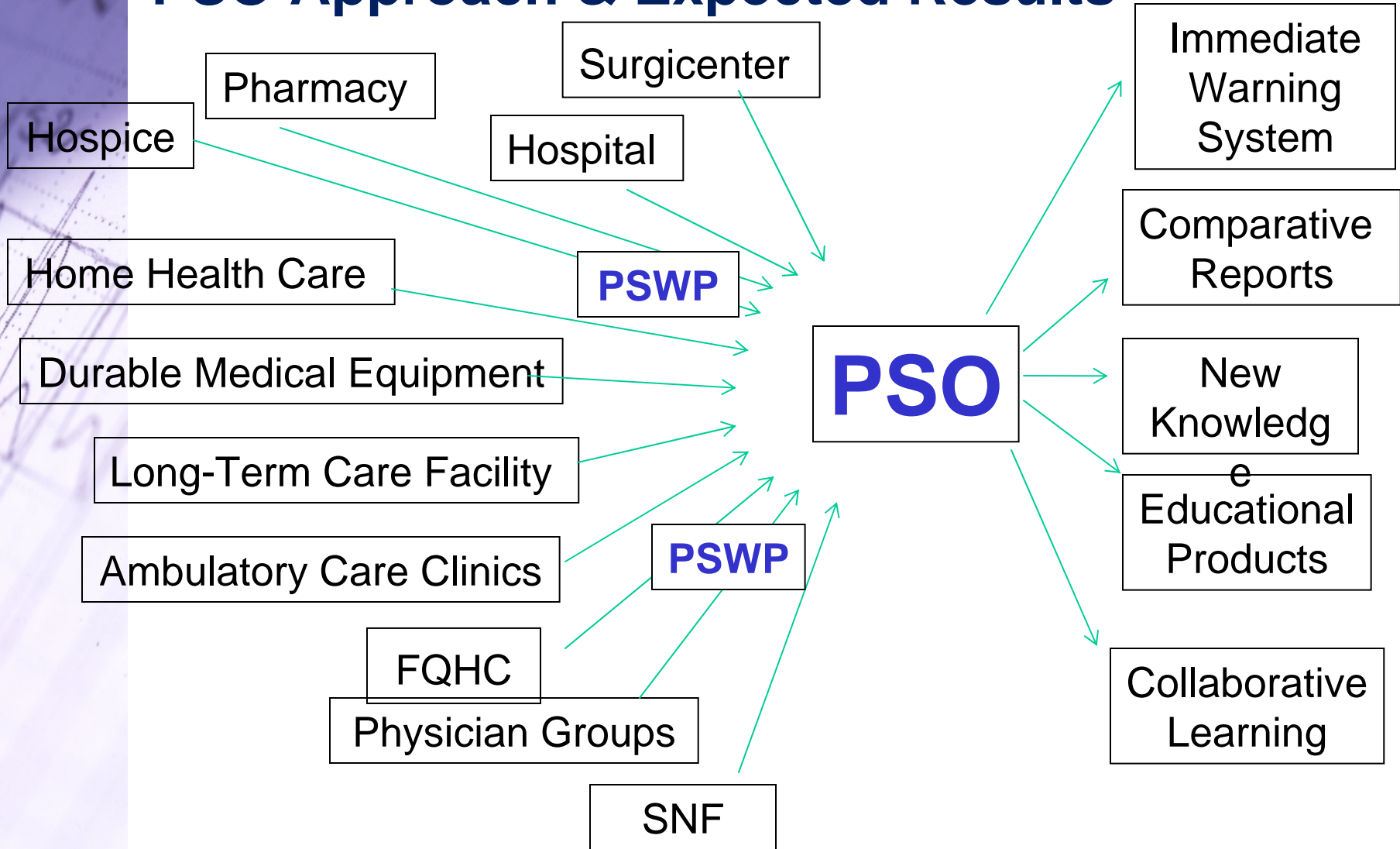


Further accelerating the speed with which solutions can be identified for the risks and hazards associated with patient care through the magnifying effect of data aggregation

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?

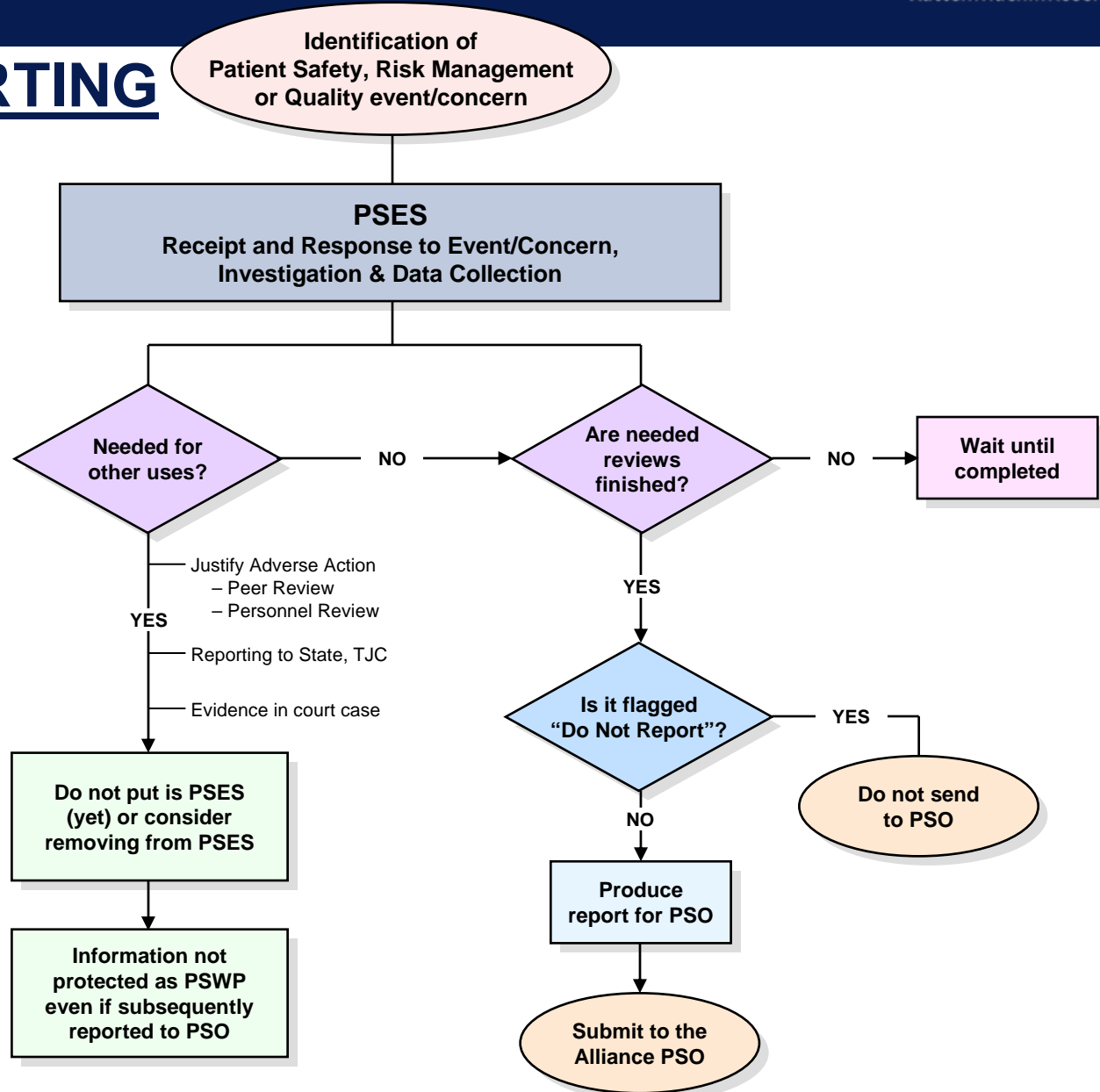
- Patient's medical record, billing and discharge information, or any other original patient or provider information
- Information that is collected, maintained, or developed separately, or exists separately, from a PSES. *Such separate information or a copy thereof reported to a PSO shall not by reason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

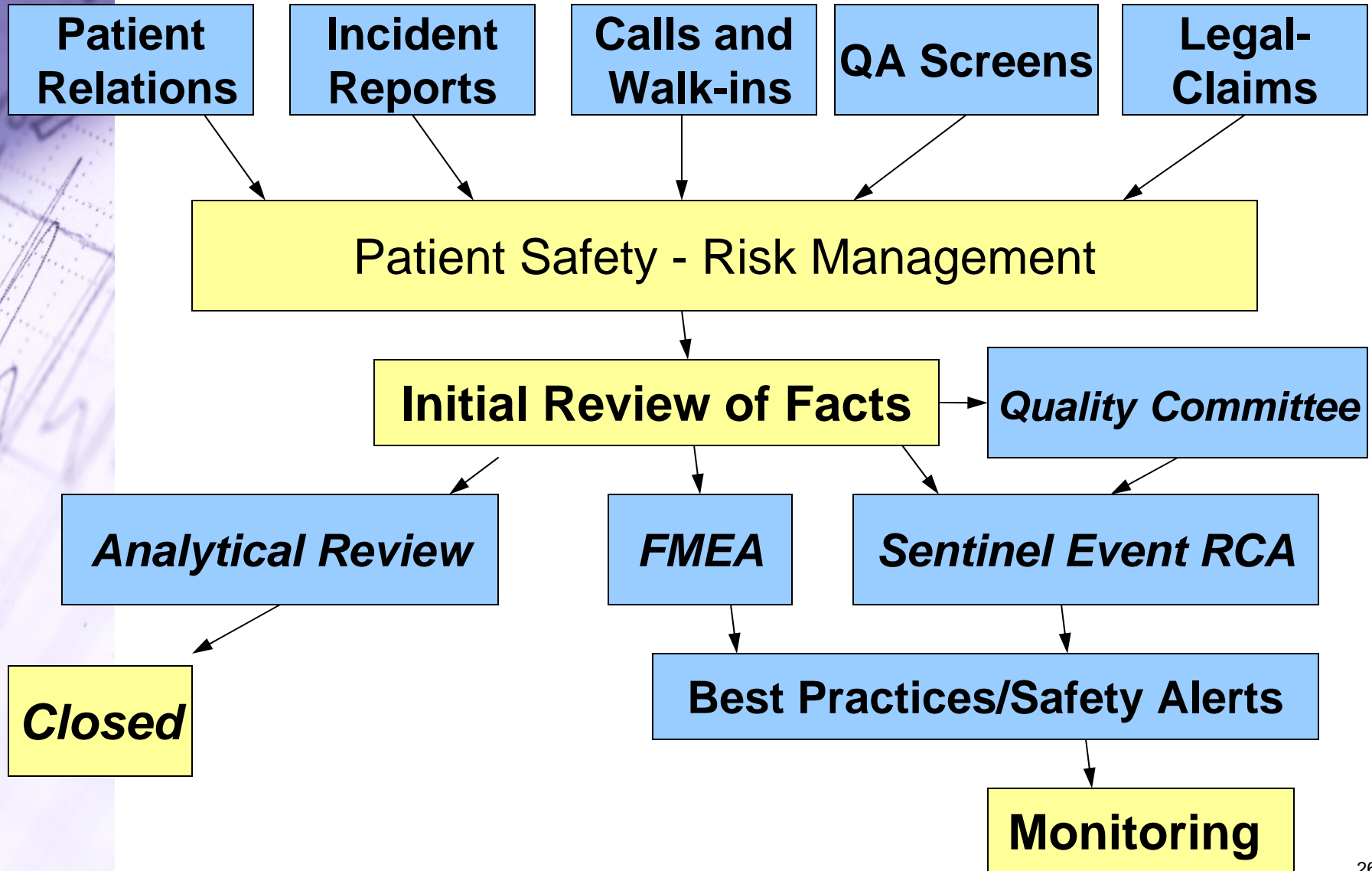
Suggested criteria

- 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

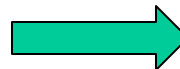
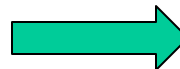
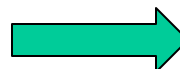
- Examples:
 - Insulin given to the wrong patient
 - Wrong patient taken to the OR/procedure room
 - Patient with pacemaker scheduled for MRI
 - Patients found with multiple fentanyl patches
 - Neonates or infants given excessive doses of heparin
 - Wrong tissue type

Don't limit focus to outcomes

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

NEAR MISSES

- Wrong infant taken to mother's bedside
- Unlabeled bag of donor blood found in blood bank
- Sites not being marked
- Pain medication given too soon



SENTINEL EVENTS

- Infant discharged to wrong family
- Transfusion-related death from ABO incompatibility
- Surgery on wrong body part
- Death from opiate/narcotic overdose

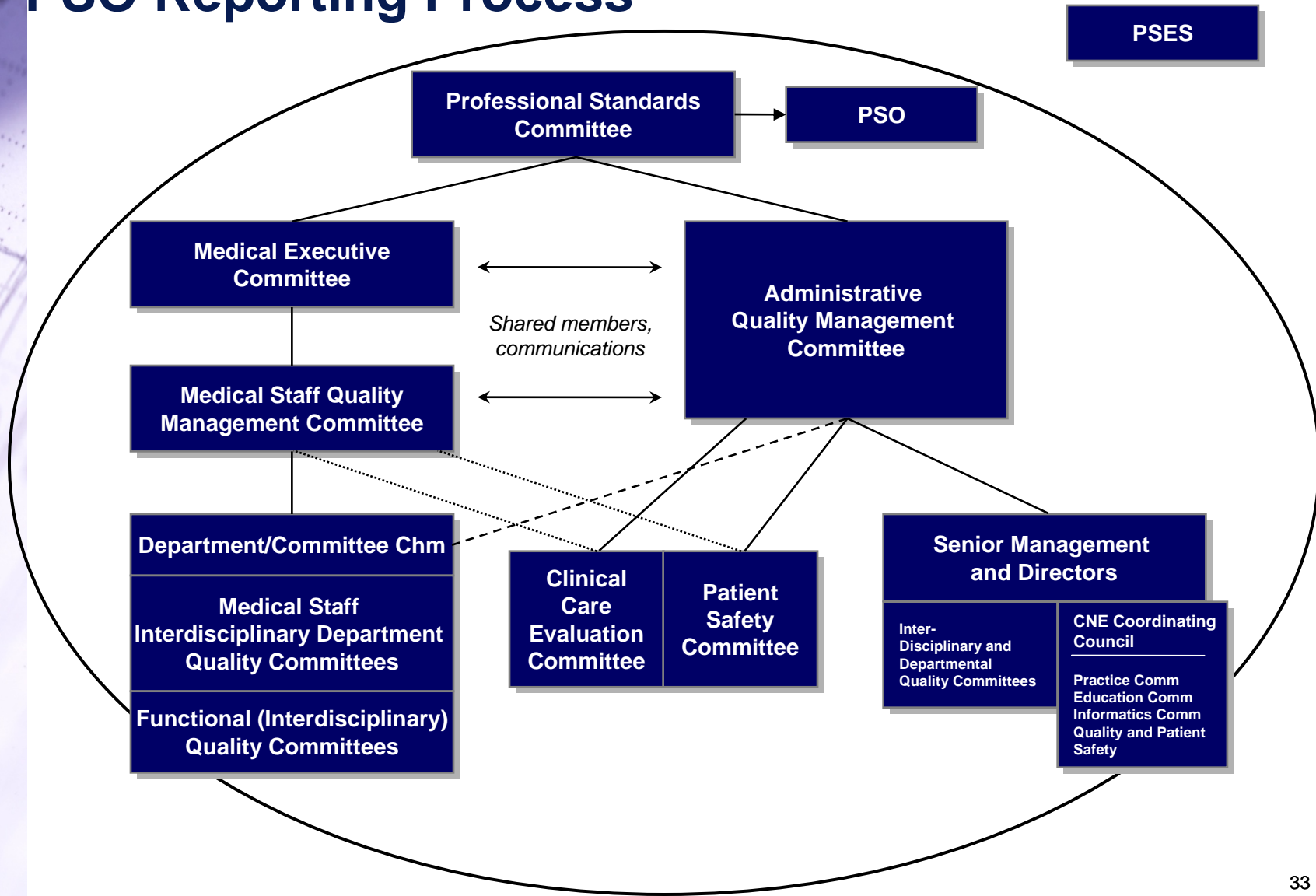
Steps to PSO Reporting

- **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**

Inventory of Data to Improve Patient Safety, Healthcare Quality or Outcomes

Indicator	Data Source	Data Collected by	Reported to	Frequency
Allegation of abuse	Incident reports	Staff witness or aware	VP Nursing, If confirmed State Board of Nursing	Upon occurrence and 3 reports per year
Medication errors	Incident reports, Medical Record	Provider that made the error, Staff witness or aware	Risk Management, RM committee, Patient safety officer, Medication Safety Committee, Harm score I – State adverse event reporting	200 per month
Unplanned Returns to Surgery	Surgery log, Peer Review worksheets, Medical Record	QI Specialist	Risk Management, Patient safety officer, RM committee, Quality committee, MEC, Surgery Peer Review Committee, National Surgical Outcome Project If due to Retained Foreign Object, State adverse reporting	10 per month

PSO Reporting Process



PSO

Professional Standards Committee

PSO

Medical Executive Committee

Administrative Quality Management Committee

Shared members, communications

Medical Staff Quality Management Committee

Department/Committee Chm
Medical Staff Interdisciplinary Department Quality Committees
Functional (Interdisciplinary) Quality Committees

Clinical Care Evaluation Committee

Patient Safety Committee

Senior Management and Directors
Inter-Disciplinary and Departmental Quality Committees
CNE Coordinating Council
Practice Comm
Education Comm
Informatics Comm
Quality and Patient Safety

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:

PSWP is confidential and not subject to disclosure

Exceptions:

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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 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 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**

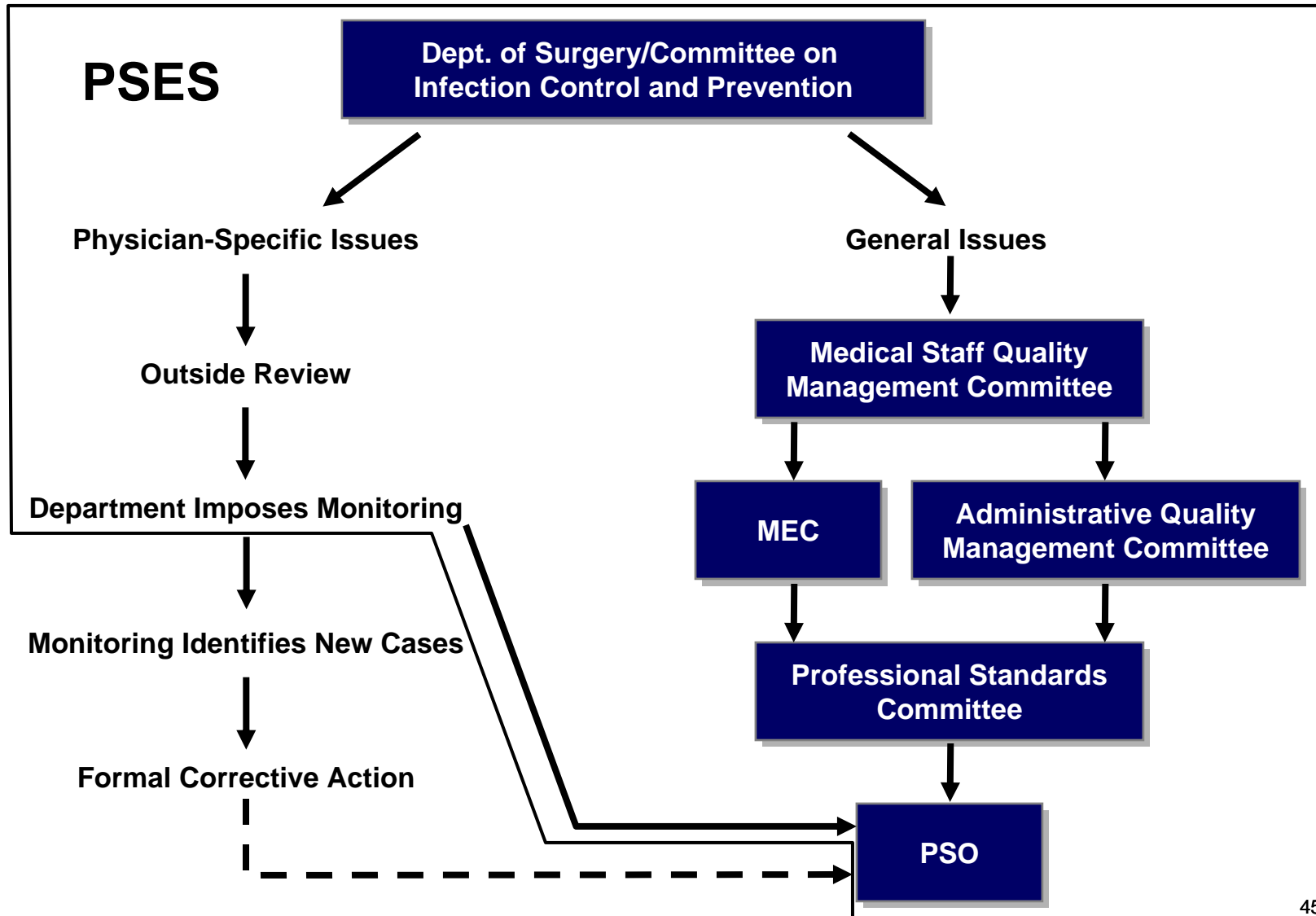
Hypothetical: Post Op Infections

- **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

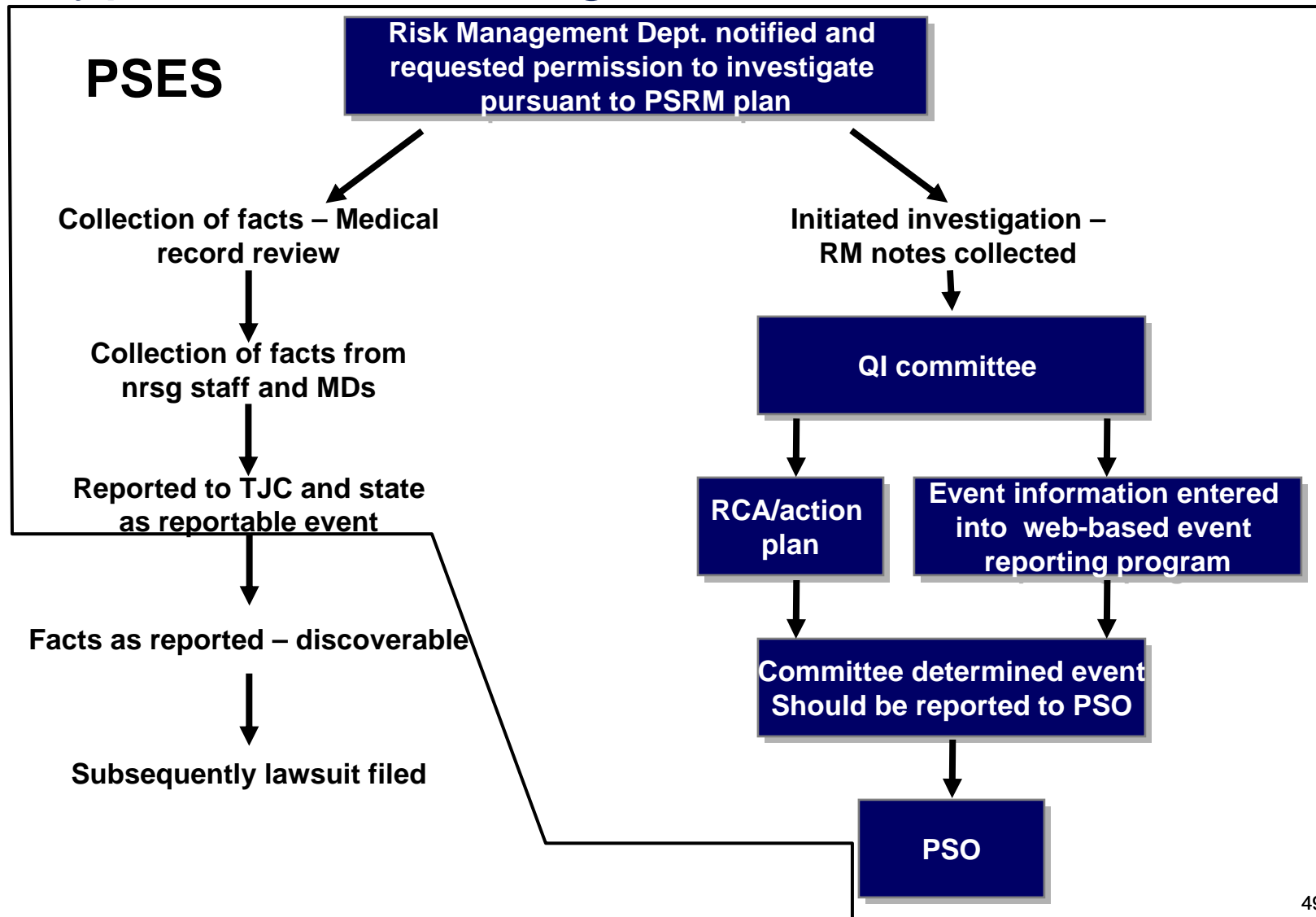
Hypothetical: Wrong Breast Milk

- 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

Positive Trajectory
of Change

Heightened
Awareness
through
Reporting

Best
Practices
Identified
through the
Amplified
Power of
Aggregated
Data

Enhanced
Patient Safety
and Improved
Patient
Outcomes
through
Implementation