

Patient Safety Organizations

A Practical Guide to Understanding and
Implementing a PSO Program and Managing
Confidentiality and Privilege Protections

February 19, 2009

Patient Safety Organizations

A Practical Guide to Understanding and
Implementing a PSO Program and Managing
Confidentiality and Privilege Protections

Carrie Nelson, MD, MS
Chair, Coalition for Quality
and Patient Safety of Chicagoland



The Coalition for Quality and Patient Safety of Chicagoland

- Successor to Chicago Patient Safety Forum
- Our mission is to mobilize the diverse healthcare stakeholders in metropolitan Chicago to provide the best possible care to every patient every time by eliminating preventable harm and implementing systemic change to ensure consistent excellence.



The Coalition for Quality and Patient Safety of Chicagoland

- Driving Improvements
- Patient Safety Organization
- Consumers playing a prominent role



The Patient Safety Act

- Background
- Purpose
- Who is covered under the Act
- Long-term Goals



Background

- Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act)
- Sponsored by James Jeffords (VT); 9 co-sponsors (including Frist and Kennedy)
- Signed into law July 29, 2005
- Final rule released 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 state laws protect information if shared outside the institution
- Data reported within an organization is insufficient, viewed in isolation and not in a standard format



Patient Safety Act Purpose

- 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



Why Participate in a PSO?

- Regulatory mandates
- Employer and payer demands
- It's good business



Why Participate in a PSO? Regulatory Mandates

- Illinois Health Care Adverse Event Reporting Law of 2005
 - Implementation this year
 - 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 fully protected legal framework



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
- Other employers groups



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



Four Sections of the Act

- Definitions
- Certification process and requirements
 - Improvement **MUST** be the primary activity of the PSO
- Privilege and Confidentiality
 - Modeled after HIPAA
 - More stringent State and individual contract provisions are not preempted
- Enforcement



Enforcement

- 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



The Patient Safety Act

- Creates independent Patient Safety Organizations (PSOs) 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 for all healthcare workers
- 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



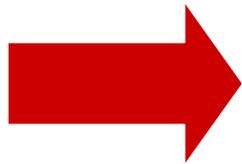
The Patient Safety Act Does Not

- Mandate provider participation in a PSO
- Does NOT make significant error reporting mandatory—defers to state
- Does not preempt stronger state protections
- Provide for any Federal funding of PSOs

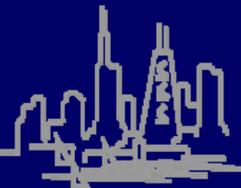


Long-Term Goals of the PSA

- 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



Patient Safety Organizations:

A Practical Guide to Understanding and Implementing a Program to Optimize Protection under the Patient Safety Act and Manage Confidentiality and Privilege Protections

Presented by:

Ellen Flynn, RN, MBA, JD

**Executive Director, Clarity PSO, A
Division of Clarity Group, Inc.**

eflynn@claritygrp.com



8600 West Bryn Mawr, Suite 120-N

Chicago, IL 60631

773-864-8295

www.claritygrp.com

The Mission of Clarity PSO, A Division of Clarity Group Inc

- To support the enhancement of patient safety through services designed to focus the efforts of healthcare providers on activities that will help create a culture of safety in their organizations.
- Our services are provided with integrity and personal attention, and incorporate high quality resources to advance healthcare quality, outcomes and safe practices in a variety of healthcare settings nationally.



Clarity PSO, A Division of Clarity Group Inc.

- Clarity Group, Inc.
 - Design and operational management of healthcare owned captive insurance companies
 - **Healthcare *SafetyZone*[®] Portal**
 - Online Event Reporting and Data Management Tool; immediate notification and ad hoc report writing and graphic capabilities
 - Claims Management
 - Risk, Quality and Safety Consulting Services: Data Analytics and PSO Support Services
- Clarity PSO
 - 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



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



Who is a Provider under the Act?

- An individual or entity licensed or otherwise authorized under state law to provide healthcare services
 - Hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice, renal dialysis facility, ambulatory surgery center, pharmacy, physician or healthcare practitioner's office including a group practice, long term care facility, behavioral health residential treatment facility, clinical laboratory
 - Also includes parent organization of organization described above



Who is a Provider under the Act?

- ✓ Physician, PA, RN, nurse practitioner, clinical nurse specialists CRNA, certified nurse midwife, psychologist, certifier social worker, registered dietician or nutrition professional, physical or occupational therapist, pharmacist or other individual healthcare practitioner
- ✓ Agencies, organizations, and individuals within Federal, State, local or Tribal governments that deliver healthcare, organizations engaged as contractors by Federal, State, local or Tribal governments to deliver healthcare or and individual healthcare practitioners employed or engaged as contractors by Federal, State, local or Tribal governments to deliver healthcare
- ✓ Federal, State, local or Tribal governments unit that manages or controls entities described in I or II



What is Required of a Provider?

- 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)



Event/Incident Reporting Policy

- Modify existing policies as needed to reflect the purpose is for 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
 - State reporting
 - Independent/separate peer review



Event Data Collection: Common Formats

- Developed by AHRQ to begin to standardize data collected
- Reviewed more than 30 data collection tools to obtain consensus on data to be collected
- Hospital Formats currently available
 - Send comments to NQF for improvement
- LTC - 2010
- Follow up / RCA
- Specialty organizations



<http://www.pso.ahrq.gov/formats/commonfmt.htm>

CLARITY PSO
Copyright © 2009

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 3 reports per year
Medication errors	Incident reports, Medical Record	Provider that made the error, Staff witness or aware	HSRC, 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	Surgery Peer Review Committee, National Surgical Outcome Project If due to Retained Foreign Object, State adverse reporting	10 per month

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

Example of Data Prioritization Grid

Data	Promotes Safety Culture	Impressions/ subjective data not available in the medical record (MR)	Potentially damaging	Not required to report elsewhere	Required to report elsewhere, but available in mr	Not used to make adverse employment decisions
Medication error report	X	X	X		X	X
Fall	X	X	X		X	X
Allegations of abuse	X	X	X		Not PSWP	
Blood Utilization Study	X	X	X	X		X

Questions To Answer When Developing PSES Policy

■ Who ...

- 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

Where Would PSES Data Collection/Analysis Occur?

Surgical Outcome Data



Committees



Risk or Quality Manager



Infection Control Practitioner



Front-line worker



The **Healthcare SafetyZone**®Portal is a registered trademark of Clarity Group, Inc.

CLARITY PSO
Copyright © 2009

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 employment action, state reporting, another purpose
 - 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

Questions To Answer When Developing PSES Policy

- Where does data go for analysis within and outside of the organization?
- Is the PSO listed by AHRQ?
- Will we submit data to a single PSO or multiple PSOs?



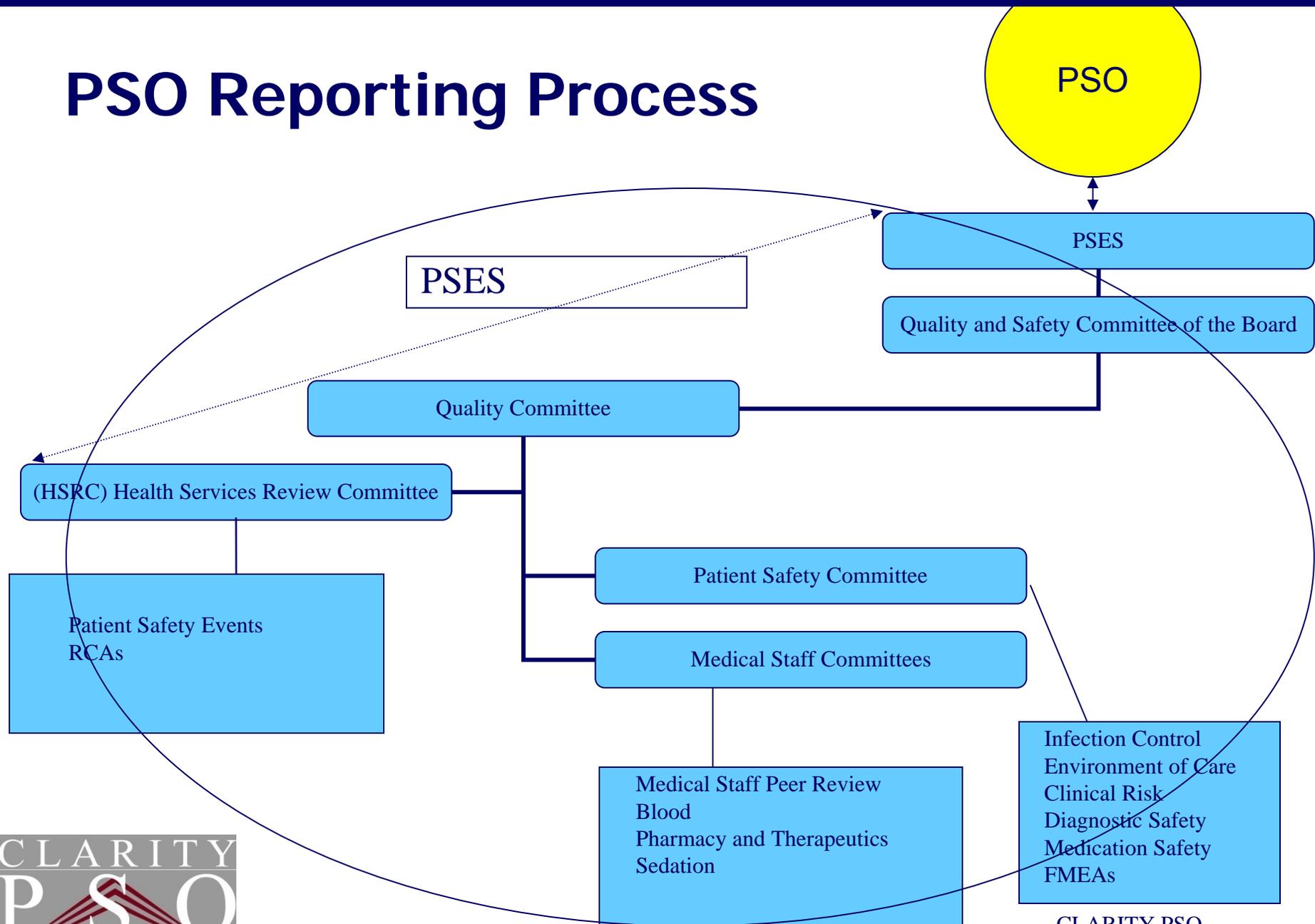
PSO Reporting Policy

- Who is authorized to report?
- When does reporting occur?
- When is PSWP vs. Copy sent?
- What is the process for the documentation of reporting or removal prior to reporting to a PSO?

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

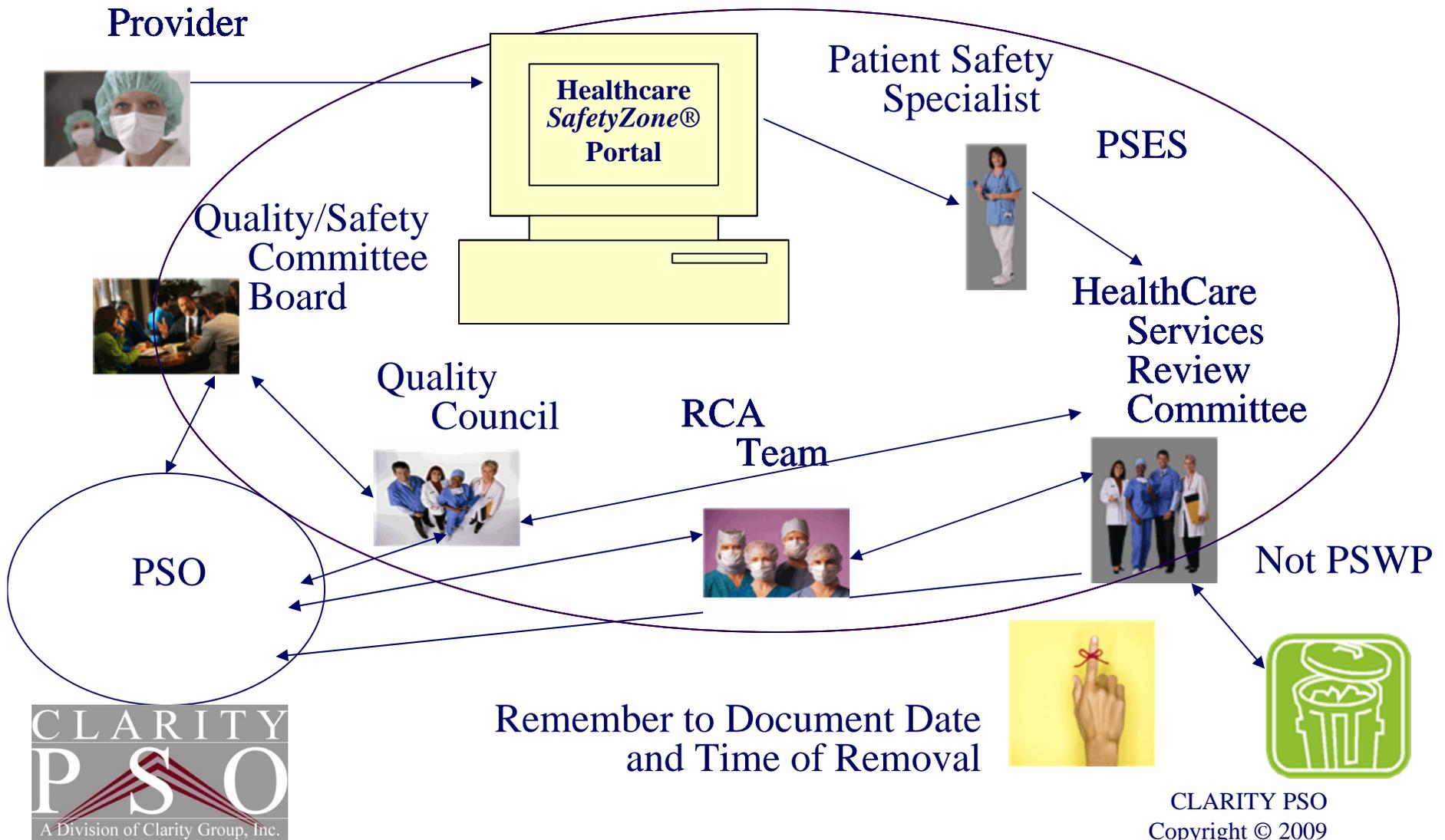
PSO Reporting Process



Incorporating Protection under the Act with Common Activities

- Reporting to State Agencies (external sources requiring patient specific data)
- Reporting and Disclosure of Medical Error
- Medical Staff Evaluation / Peer Review

Patient Safety Event Reporting



Structure Your 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

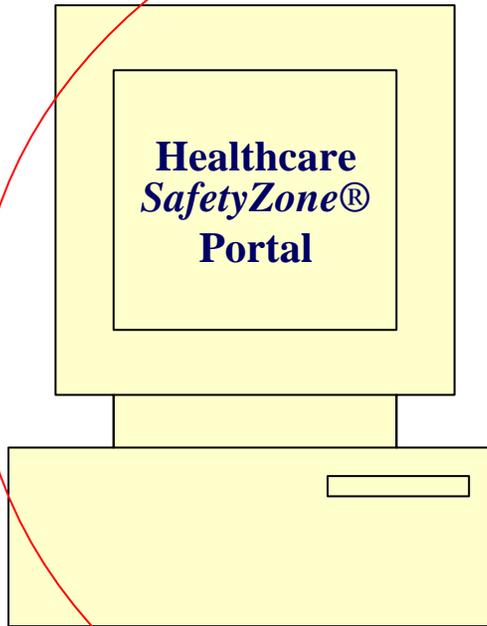
Disclosure of Medical Errors

Nurse identifies medication error that harmed patient

Nurse takes actions needed to mitigate harm

Nurse notifies MD and Risk Manager

Nurse documents the objective facts about the event in the medical record



Safety Manager reviews event

Safety Manager works with HSRC to identify immediate steps to prevent future harm

HSRC determines whether PSWP and reports PSWP or a copy of the report to PSO

If appropriate RCA conducted and reported to PSO

PSES

Objective facts disclosed to patient/ family



Action	Date Completed	Responsible party	Status
Remove Heparin 10,000 U from Room 1234	12/15/09	Mary Smith	Closed
Add Heparin to the High alert drug list	01/10/10	John Jones	Open



CLARITY PSO
Copyright © 2009

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

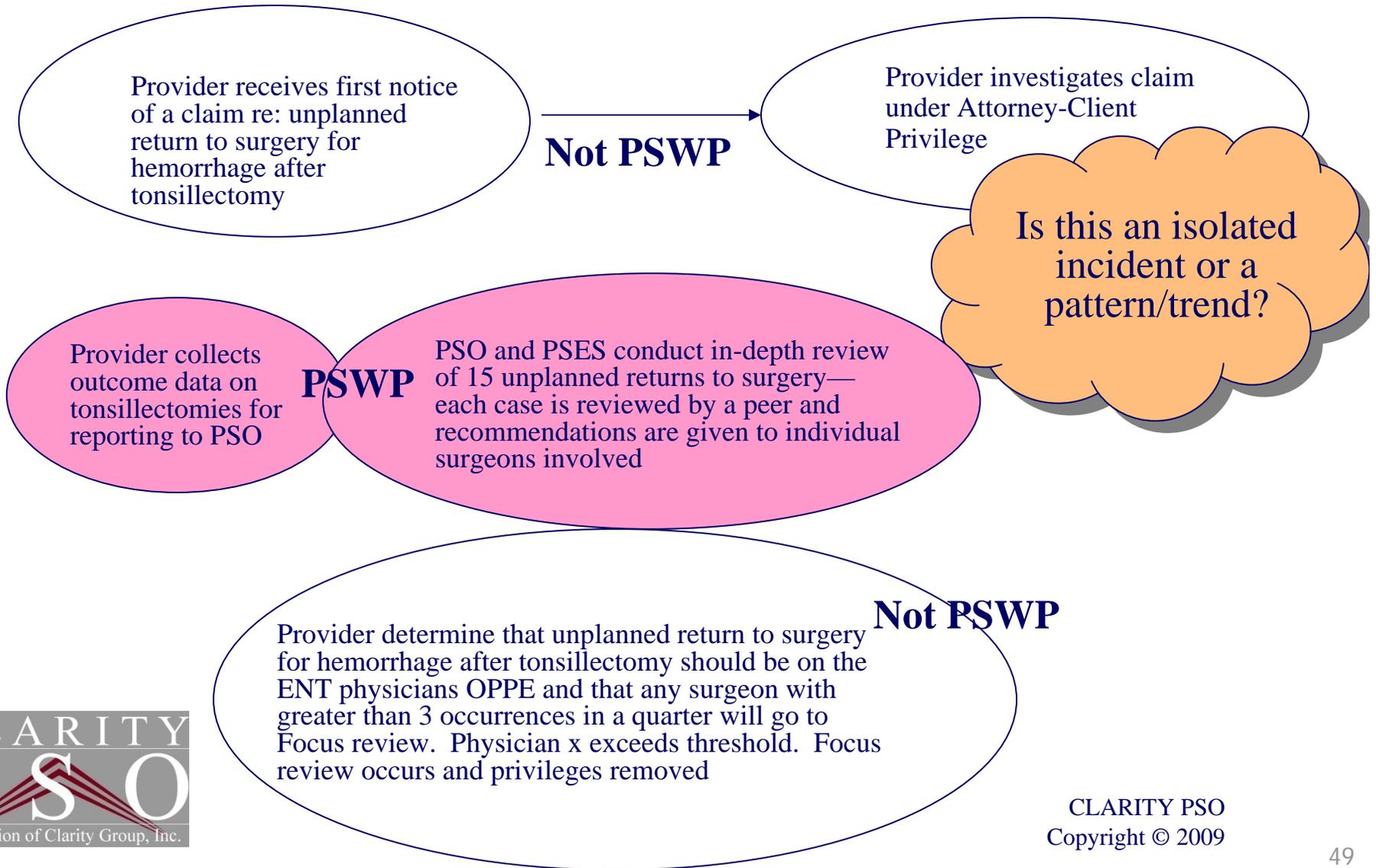
- Report to PSO
 - Event report that contains staffs impressions on why this event may have happen
 - Additional analyses to determine why the event happen
 - RCA recommendations

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
 - Focused Evaluation
 - Physician specific reports

Physician Evaluation Scenario



PSES Peer Review

PSES collects physician specific data whenever blood administered with hgb >7

Physicians receive letter with clinical recommendations from a peer whenever case does not meet criteria

Physician allowed to respond with clinical justification

Determination made by PSES with additional information provided by physician

Each physician receives a report that shows % blood administered appropriately vs. Peers

Goal is Learning/Performance Improvement



Joint Commission OPPE/FPPE

Medical Executive
Committee
approves OPPE
criteria and
threshold:

blood does not
meet criteria

>3 cases

Medical Executive
Committee
conducts FPPE
because Dr. X
exceeded
threshold

Physician X
instructed that
she may not
order blood
without approval
of assigned
physician

**Purpose of the review
is to evaluate
whether to renew
privileges**



In Summary ...

Summary of the Process



Event Data Collection



Copyright 2009, Clarity Group, Inc.

Makes determination of PSWP

Patient Safety Evaluation System

Not Patient Safety Work Product

PSWP

Copy of Info.

Investigation and study may be protected

PSO

- Benchmarking
- Education
- Resources



CLARITY PSO
Copyright © 2009

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
- Select Listed PSO



**Use Information to Enhance
Safety, Quality and Healthcare
Outcomes**

PSO Eligibility

- Eligible organizations:
 - Any public or private entity / component
 - Any for-profit or not-for-profit / component
- Ineligible organizations:
 - Health insurance issuers or their component entities
 - Accrediting & licensing bodies
 - Entities that regulate providers, including their agents (e.g., QIOs)
 - Mandatory public reporting systems



PSO Types

- Independent stand-alone entity
 - Regional, State or National
- Component PSO
 - A parent organization with controlling or majority interest or authority to manage the work of the PSO
 - Additional certification requirements
 - Must be a division or separate legal entity to ensure firewall protections of PSWP from the parent organization
 - Because the single mission of the PSO must be IMPROVEMENT, there are some hurdles to overcome for component PSOs



What Will the PSO Do?

- Receive reports voluntarily from providers for the purpose of analysis of patient safety events
- PSOs will aggregate and analyze the data from multiple providers
- Permits the identification of patterns that could suggest underlying or systemic solutions



Some Certified PSOs

- California Hospital Patient Safety Organization
- ECRI Institute PSO
- Clarity PSO
- Florida Patient Safety Corporation
- Coalition for Quality and Patient Safety of Chicagoland
- Institute for Safe Medication Practices (ISMP)
- Kentucky Institute for Patient Safety and Quality
- Quantros Patient Safety Center
- University Healthsystem Consortium



HHS Predictions

- 50-100 organizations will be certified as PSOs within the first 3 years
- 60% of hospitals will participate in a PSO
- Hospitals will report about 1 event/near miss/unsafe condition per bed per month
- Some hospitals, health systems, nursing homes, and other providers will establish their own component PSOs to review their patient safety events in a protected legal environment
 - Same IT system can be used if sufficient safeguards to maintain PSWP firewall



Provider Implications

- There is no limit to the number of PSOs in which a provider can participate
- Employers may require employees report to the PSO but no actions can be taken against an employee for reporting
- Need to choose for yourself the scope of your program



PSO Services: Requirements

- Must be an agreement in place between the PSO and providers that articulates the relationship in order to receive the protections
- Within 45 days of entering into a contract with a provider, the PSO must disclose this to HHS as well as any "other relationships" with a contracted Provider—information will be made publicly available
- A functional reporting system can exist between PSO and provider to minimize data transport challenges i.e. shared server
- HIPAA compliance and business associate obligations
- Documentation of the provider's PSES (structure, operation, functional reporting)



PSO Services: Requirements

- PSOs are required to collect information that allows comparison of “similar events among similar providers”
- “Common Formats” have been made available by AHRQ, acting for the Secretary of HHS, to assist PSOs to meet this requirement
- Permits PSOs to share data with other PSOs or other providers reporting to the PSO as long as they remove any identifiers of a particular provider or reporter from data in the PSWP



PSO Services: Requirements

- Must notify providers of security breaches or disclosures
- Certification for three years,
- If recertification paperwork not submitted, listing as PSO will automatically terminate
- PSO status can be revoked in an expedited fashion if breeches occur
- Every 24 months PSOs must attest that they are contracted with at least two different providers
- At recertification, PSOs will be required to state how they meet the requirements



PSO Services: Data Aggregation

- Aggregation will occur at several levels
 - Provider (e.g., hospital, long-term care facility, physician practice)
 - Patient Safety Organization
 - National Patient Safety Database



PSO Services

- Comparative reports
- New knowledge and insights
- Educational products
- Collaborative Learning



PSO Services

- HHS requires PSOs to provide direct feedback and assistance to providers to minimize patient risk
- Purposely designed to mitigate incentives to use the PSO as a legal protection vehicle
- Any recommendations that the PSO develops for the provider after analysis of the event or information remain protected
- There is no regulatory requirement for the provider to follow the PSO's recommendations
- Actual changes that the provider implements to improve patient care—including changes in organizational management, the care environment, or processes—are not protected



Long-Term PSA Goals

- Patient safety events, near misses and unsafe conditions are all included in the Common Formats
- 0.1 Beta Version
 - Scope limited to safety: preventing harm to patients from the delivery of health care
 - Limited to hospital setting
- Common Formats to be developed for additional settings, e.g., long-term care, ambulatory surgery center, physician offices
- Voluntary, spontaneous reporting
- Numerator data only



Common Formats: Types of Forms

- Healthcare Event Reporting Form (HERF)
 - Identity, date, time, location, reporter, narrative, links to other forms
- Patient Information Form (PIF)
 - Demographics, harm, mitigating actions, interventions
- Final Assessment Form (FAF)
 - Assessment of preventability, final narrative
- Event-Specific Forms



Currently Available Common Format Event-Specific Forms

- Anesthesia
- Blood, Tissue, Organ Transplantation or Gene Therapy
- Device & Medical or Surgical Supply
- Falls
- Healthcare-Associated Infection
- Medication & Other Substances
- Perinatal
- Pressure Ulcers
- Surgical & Other Invasive Procedures (except Perinatal)



AHRQ Future Plans

- Common Formats Version 1.0 to be released Summer 2009
- Expanded & enhanced versions based on user feedback
 - Expansion to other settings
 - Expansion to other topic areas of patient safety events
 - Complete remaining phases of quality cycle (e.g., root cause analysis)
- Annual updates & revisions



Overview of PSO Confidentiality and Privilege Protections

Michael R. Callahan
Katten Muchin Rosenman LLP
525 W. Monroe • Chicago, Illinois
312.902.5634
michael.callahan@kattenlaw.com

Sheila M. Sokolowski
Katten Muchin Rosenman LLP
525 W. Monroe • Chicago, Illinois
312.902.5456
sheila.sokolowski@kattenlaw.com

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.

Documents and Analyses

- Analyze corporate structure issues
- Analyze interaction with other state and federal law
- Draft policies and procedures
- Draft service agreements
- Draft form provider authorization for disclosure of PSWP

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.

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

- 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.

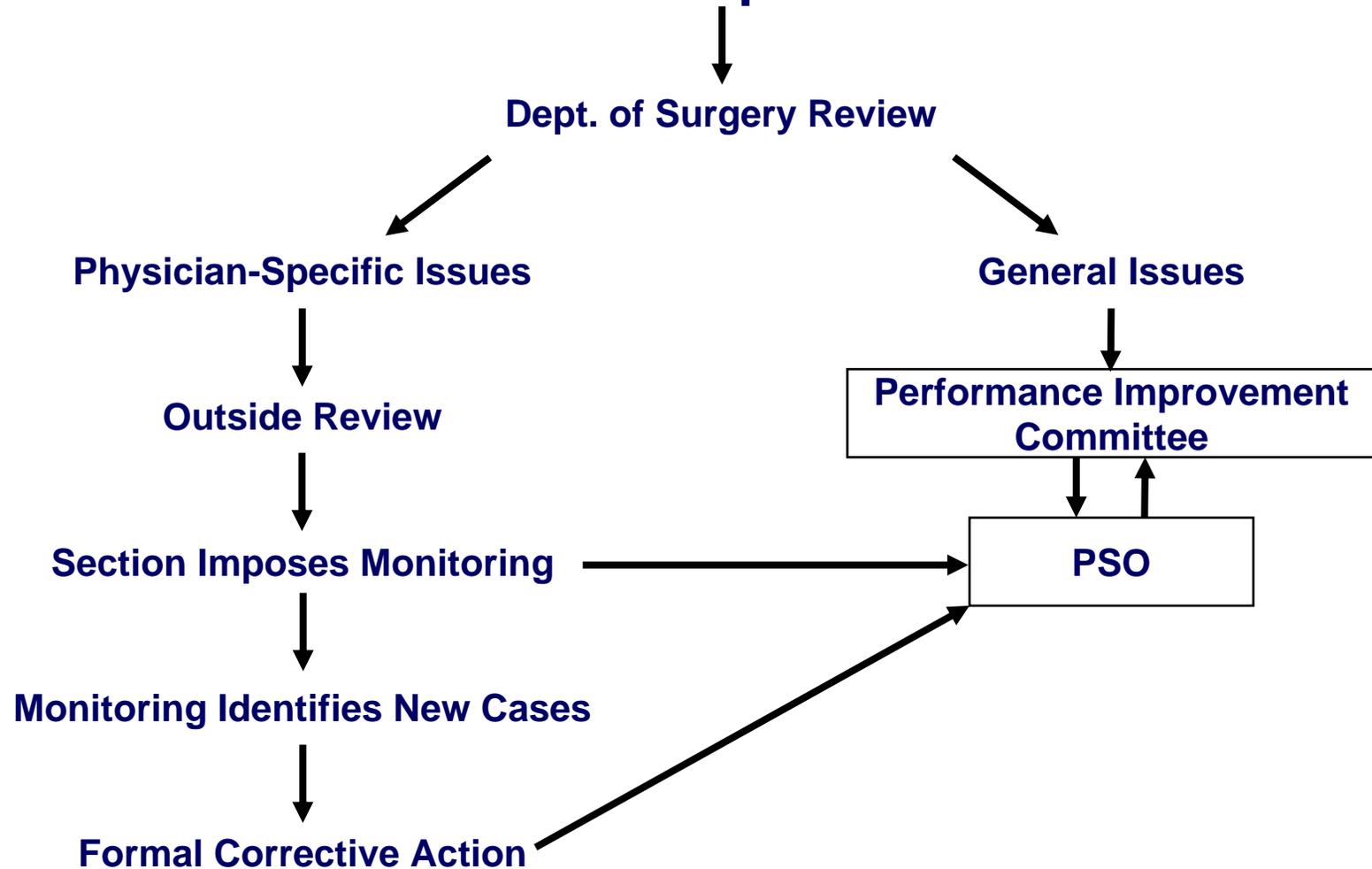
Hypothetical - Post Op Infections

- 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.
- Review 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.
- Department Chair recommends formal corrective action.

Ortho Post Op Infections



Maximizing Protections Under PSO and State Laws

- PSO
 - Remember that PSO protections apply in both state and federal proceedings.
 - PSO protections supersede state law unless state is more protective.
 - Need to compare PSO rules and state statutes and caselaw.
 - Need to identify patient safety work product.
 - 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.
 - Within a PSES.

Maximizing Protections Under PSO and State Laws

- Date the info was entered into the PSES
- Are developed by a PSO for the conduct of patient safety activities.
 - Efforts to improve patient safety and quality of delivery.
 - Collection and analysis of PSWP.
 - Development and dissemination of info with respect to improving patient safety (recommendations, protocols, or info on best practices).
 - Utilization of PSWP for the purpose of encouraging a culture of safety and providing feedback and assistance to minimize patient risk.
 - Maintenance of procedures to preserve confidentiality.

Maximizing Protections Under PSO and State Laws

- Provision of appropriate security measures.
- Utilization of qualified staff.
- Activities related to PSES and feedback to participants,
 - Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to a PSES.
 - Not all information reported to a PSO will be protected unless it meets definition and purposes.
 - PSWP that is disclosed impermissibly is still privileged and confidential.

Maximizing Protections Under PSO and State Laws

- State Law
 - Medical Studies Act – Illinois
 - Information, reports, minutes, analysis used for the purpose of reducing morbidity or mortality for improving patient care not subject to discoverability or admissibility as evidence.
 - Information has to be requested by and/or generated by a peer review committee or designee.
 - Does not apply to medical records or publicly available information.
 - Can be used for disciplinary purposes.
 - Physician can obtain access for purposes of defending himself at hearing.
 - Improper disclosure not subject to waiver.

Maximizing Protections Under PSO and State Laws

- The relevant provisions of the Medical Studies Act are as follows:
 - All information, interviews, reports, statements, memoranda, recommendations, letters of reference or other third party confidential assessments of a health care practitioner's professional competence, or other data of health maintenance organizations, medical organizations under contract with health maintenance organizations or with insurance or other health care delivery entities or facilities, physician-owned insurance companies and their agents, committees of ambulatory surgical treatment centers or post-surgical recovery centers or their medical staffs, or committees of licensed or accredited hospitals or their medical staffs, including Patient Care Audit Committees, Medical Care Evaluation Committees, Utilization Review Committees, Credential Committees and Executive Committees, or their designees (but not the medical records pertaining to the patient), used in the course of internal quality control or of medical study for the purpose or reducing morbidity or mortality, or for

Maximizing Protections Under PSO and State Laws

- improving patient care or increasing organ and tissue donation, shall be privileged, strictly confidential and shall be used only for medical research, the evaluation and improvement of quality care, or grating, limiting or revoking staff privileges or agreements for services, except that in any health maintenance organization proceeding to decide upon a physician's services or any hospital or ambulatory surgical treatment center proceeding to decide upon a physician's staff privileges, or in any judicial review of either, the claim of confidentiality shall not be invoked to deny such physician access to or use of data upon which such a decision was based. (Source: P.A. 92-644, eff. 1-1-03.)
- Such information, records, reports, statements, notes, memoranda, or other data, shall not be admissible as evidence, nor discoverable in any action of any kind in any court or before any tribunal, board, agency or person. The disclosure of any such information or data, whether proper, or improper, shall not waive or have any effect upon its confidentiality, nondiscoverability, or nonadmissibility

Maximizing Protections Under PSO and State Laws

- It is important for all to know the language and interpretation of your state peer review statute and PSO rules.
- As a general rule, courts do not like confidentiality and privileges statutes which effectively deny access to information.
- Although appellate courts have upheld state protections, trial courts especially look for ways to potentially limit application and will strictly interpret these laws.

Maximizing Protections Under PSO and State Laws

- The courts have criticized attorneys for simply asserting the protections without attempting to educate the court about what credentiality and peer review is or explaining why the information in question should be treated as privileged and confidential.
- One effective means of improving the hospital and medical staffs odds is to adopt a medical staff bylaw provision or policy which defines “peer review” and “peer review committee” in an expansive manner while still consistent with the language of the state statute. Examples are set forth below:

Peer Review

- “Peer Review” refers to any and all activities and conduct which involve efforts to reduce morbidity and mortality, improve patient care or engage in professional discipline. These activities and conduct include, but are not limited to: the evaluation of medical care, the making of recommendations in credentiality and delineation of privileges for Physicians, LIPs or AHPs seeking or holding such Clinical Privileges at a Medical Center facility, addressing the quality of care provided to patients, the evaluation of appointment and reappointment provided to patients, the evaluation of appointment and reappointment applications and qualifications of Physicians, LIPs or AHPs, the evaluations of complaints, incidents and other similar communications filed against members of the Medical Staff and others granted clinical Privileges. They also include the receipt, review, analysis, acting on and issuance of incident reports, quality and utilization review functions, and other functions and activities related thereto or referenced or described in any Peer Review policy, as may be performed by the Medical Staff or the Governing Board directly or on their behalf and by those assisting the Medical Staff and Board in its Peer Review activities and conduct including, without limitation, employees, designees, representatives, agents, attorneys, consultants, investigators, experts, assistants, clerks, staff and any other person or organization who assist in performing Peer review functions, conduct or activities.

Peer Review Committee

- “Peer Review Committee” means a Committee, Section, Division, Department of the Medical Staff or the Governing Board as well as the Medical Staff and the Governing Board as a whole that participates in any Peer Review function, conduct or activity as defined in these Bylaws. Included are those serving as members of the Peer Review committee or their employees, designees, representatives, agents, attorneys, consultants, investigators, experts, assistants, clerks, staff and any other person or organization, whether internal or external, who assist the Peer Review Committee in performing its Peer Review functions, conduct or activities. All reports, studies, analyses, recommendations, and other similar communications which are authorized, requested or reviewed by a Peer Review Committee or persons acting on behalf of a Peer Review Committee shall be treated as strictly confidential and not subject to discovery nor admissible as evidence consistent with those protections afforded under the Medical Studies Act. If a Peer Review Committee deems appropriate, it may seek assistance from other Peer Review Committees or other committees or individuals inside or outside the Medical Center. As an example, a Peer review Committee shall include, without limitation: the MEC, all clinical Departments and Divisions, the Credentials Committee, the Performance Improvement/Risk Management Committee, Infection Control Committee, the Physician’s Assistance Committee, the Governing Board and all other Committees when performing Peer Review functions, conduct or activities.

Maximizing Protections

- Another concept to keep in mind is that Appellate Courts have held that information which is normally generated within the hospital or medical staff which is not clearly treated as a “peer review document” cannot be kept confidential by simply submitting it to a Peer Review Committee for review and action. Therefore, the hospital and medical staff should consider identifying those kinds of reports, such as incident reports, quality assurance reports, etc., as being requested by or authorized by a qualified Peer Review Committee. Same goes for PSWP.
- Unilateral vs. committee action should be avoided
- Self-serving language such as “privileged and confidential under state and federal law: document cannot be admissible or subject to discovery” should be placed at the top or bottom of Peer Review/PSWP materials.

Maximizing Protections

- If there is a challenge as to whether the documents are protected, hospital and medical staff should prepare appropriate affidavits, or other testimonials which effectively educate the court as to why these materials should be considered privileged and confidential.
- If a physician or plaintiff cannot admit protected information into evidence, it can effectively foreclose one or more causes of action because the plaintiff will not be able to introduce proof to substantiate the claim.

Additional Steps to Ensure that Data Collected and Reports Prepared are Treated as Privileged and Confidential

- Goal is to maximize efforts to keep performance monitoring, quality and utilization data and reports (PSWP) and peer review records as privileged and confidential from discovery or admissibility in litigation proceedings
- Need to identify the following:
 - List all relevant reports, studies, forms, reports, analyses, etc., which are utilized by the hospital and medical staff
 - Profiling data and reports
 - Comparative data
 - Utilization studies
 - Outcomes standards and comparisons by physicians
 - Incident reports
 - Quality assurance reports
 - Medical errors

Additional Steps to Ensure that Data Collected and Reports Prepared are Treated as Privileged and Confidential

- Patient complaints
- Cost per patient visit, ALOS, number of refunds and consultants used, etc.
 - Identify which reports and info, if discoverable, could lead to hospital/physician liability for professional malpractice/corporate negligence
 - Identify all applicable state and federal confidentiality statutes and relevant case law
- Peer review confidentiality statute
- Physician-patient confidentiality
- Medical Records
- PSO

Additional Steps to Ensure that Data Collected and Reports Prepared are Treated as Privileged and Confidential

- Attorney-client communications
- Business records
- Records, reports prepared in anticipation of litigation
- HIPAA
- Drug, alcohol, mental health statutes
- Identify scope of protections afforded by these statutes, and steps needed to maintain confidentiality, to list of reports to determine what are and are not practiced
- Can steps be taken to improve or maximize protection?

Additional Steps to Ensure that Data Collected and Reports Prepared are Treated as Privileged and Confidential

- What documents are left and how sensitive is the information in the reports?
- If sensitive information remains, can it be moved to or consolidated with a confidential report?
- Can information be de-identified or aggregated while not minimizing its effectiveness?
- Adopt self-serving policies, bylaws, etc, which identify these materials as confidential documents — need to be realistic. A document is not confidential because you say it is.
 - Need to consult with your legal counsel before finalizing your plan
 - Plan needs to be updated as forms and law changes

Application of PSO to Other Settings

- “Clinical Integration” in managed care setting.
 - In order to maximize flexibility in contract negotiations so as to avoid strict adherence to the “messenger model” methodology, FTC/DOJ require that the IPA/PHO either be “financially integrated”, i.e., true at risk contracts such as HMO, and/or “clinically integrated”, i.e., adoption of quality and utilization standards and protocols, penalties for non-compliance, strict membership requirements.
 - Not yet clear whether IPAs/PHOs would be considered providers under the rules.
 - IPA/PHO could certainly create a component PSO.
 - Participation could be a factor used by the FTC/DOJ to determine whether managed care entity is clinically integrated.

Application of PSO to Other Settings

- Compliance and Providing “Medically Necessary” Services
 - OIG is becoming more aggressive in investigating and denying coverage and payment for health care services in which there has been an adverse result, i.e., “never events”, or which were unnecessary, i.e., over-utilization.
 - Hospitals may be better positioned from a compliance and defense standpoint if they are actively participating in a robust program of reviewing quality and utilization, including a provider arrangement with one or more PSOs.
- Accreditation and Board Fiduciary Responsibilities.
 - Participation in a PSO is good evidence of meeting accreditation requirements regarding FPPE and OPPE.