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Katten Muchin Rosenman LLP

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Effective Documentation of Peer Review Under Amendment 7

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Michael R. Callahan
Katten Muchin Rosenman LLP
525 West Monroe Street
Chicago, Illinois 60661
(312) 902-5634
michael.callahan@kattenlaw.com

Overview of Amendment 7

- "Patients' right to know about adverse incidents."
- "Patients have a right to have access to any records made or received in the course of business by a health care facility or provider relating to an adverse medical incident"
- "Adverse medical incident means:
  - medical negligence, intentional misconduct, and any neglect or default of a health care facility or provider;
  - that caused or could have caused injury to or death of a patient;

Overview of Amendment 7

  - including, but not limited to, incidents required to be reported to any governmental agency or body; and
  - incidents that are reported to or reviewed by any healthcare facility for review, risk management, quality assurance, credentials, or similar committee, or any representative of such committee.

- Records do not include “any documents or portions thereof which constitute, contain, or reflect any attorney-client communications or any other attorney-client work product.

Overview of Amendment 7

- Does not alter immunity protections or compel "testimony by, persons providing information or participating in any peer review panel, medical review community hospital committee, or other hospital board otherwise provided by law . . ."
- Amendment 7 was approved by Florida voters on November 2, 2004.
- Previously, this peer review information was strictly confidential and not subject to discovery or admissability into evidence.

Florida Supreme Court Decisions

- Florida Hospital Waterman, Inc. v. Buster (2008)
  Notami Hospital of Florida v. Bowen
  - These two cases were consolidated on appeal.
  - Buster involved an investigation of an adverse medical issue.
  - Notami involved the selection, retention and termination of a physician.
  - Court held that Amendment 7 was self executing, meaning that no additional legislation was necessary in order for the law to be implemented.

Florida Supreme Court Decisions

- Court also held that the Amendment could be applied retroactively to all existing medical incident reports including that records created prior to the effective date of the Amendment.
- Amendment 7 gave patients an immediate right of access.
- Clear intent of Amendment was to override previous restriction.

Florida Supreme Court Decisions

- Current law requires a witness testifying before a peer review committee to testify as to matters within his knowledge about the medical incident in question.
- Hospitals have no vested right in maintaining confidentiality of adverse medical incidents.

Related Florida Court Decisions

- Florida Eye Clinic v. G. Mach (5th Dist. Court of Appeal) (2009) .
  - Litigation involved a request by the Plaintiff to seek production of documents regarding incident reports concerning complaints of infections and related investigations at the clinic over a four-year period.

Related Florida Court Decisions

- Clinic refused to produce the requested incident reports arguing that they were protected under the attorney work-product doctrine and the attorney-client privilege because the reports were created in anticipation of litigation so that accurate information would be available to defense counsel in the event that a lawsuit arose and was designed to provide information concerning an ongoing investigation to be utilized with counsel in the defense of a lawsuit.

Related Florida Court Decisions

- Trial court ordered production of documents holding that the privileges no longer existed after Amendment 7 and the Florida Supreme Court case in Buster.
- The Appellate Court makes a distinction between “fact work product”, meaning factual information which pertains to a clients case and is prepared or gathered in a connection with anticipated litigation, and “opinion work product”, which reflects the attorney’s mental impressions, conclusions, opinions or theories.

Related Florida Court Decisions

- In the Court's opinion, the requested incident reports were never reviewed by counsel and were created "in anticipation of litigation" to be made "available to defense counsel in the event of a lawsuit is filed arising out of the wound infection chronicled".
- Consequently, this information is "fact work product" which, in the opinion of the Court, was expressly overturned or eliminated by Amendment 7 as a basis of seeking confidentiality.

Related Florida Court Decisions

  - The Court comments that Amendment 7 would not seem to require production of "opinion at work product" although those are not the facts of this particular case.

- Baldwin v. Shands Teaching Hospital and Clinics (1st Dist. Court of Appeals) (2010)
  - Lawsuit involves a request brought by a Plaintiff patient to compel the Hospital to produce its risk management incident report and peer review forms relating to a perforation of his hypopharynx while being intibated for general anesthesia before a scheduled appendectomy.

Related Florida Court Decisions

- Hospital argued that because its own internal review concluded that the incident did not involve negligence it therefore was not an adverse medical incident that otherwise would require disclosure under Amendment 7.
- While the Hospital acknowledges its responsibilities under state law to initiate internal reviews involving unusual outcomes, it contends that the Plaintiff failed to show that the medical incident in question was “adverse”.

Related Florida Court Decisions

- Record was unclear as to how the Hospital determines which incident reports are subject to peer review and risk management and which ones are not.
- The Court held that the Hospital should not be the sole arbiter in determining whether a medical incident was or was not "adverse" for purposes of complying with a production request. Such is the role of the Court particularly in the light of the broad coverage of Amendment 7.

Related Florida Court Decisions

- The term “adverse medical incident” is not limited to “medical negligence” but it instead refers to a specific incident involving a specific patient that caused or could have caused injury to or death of the patient whether by a negligent act or omission as long as connected to the patient and which was the cause or near-cause of an injury or death.
- Court ordered the production of the requested information.

Available Options for Maintaining Confidential Protections After Amendment 7

- Work with legal counsel to determine scope of available work product and attorney-client protections such as having attorney present at various root cause analysis, peer review and related meetings.
- Consider minimizing the use of written communications.
- Closely review all written minutes, reports and other materials so as to reduce or eliminate information which may increase exposure of hospital physician under investigation.

Available Options for Maintaining Confidential Protections After Amendment 7

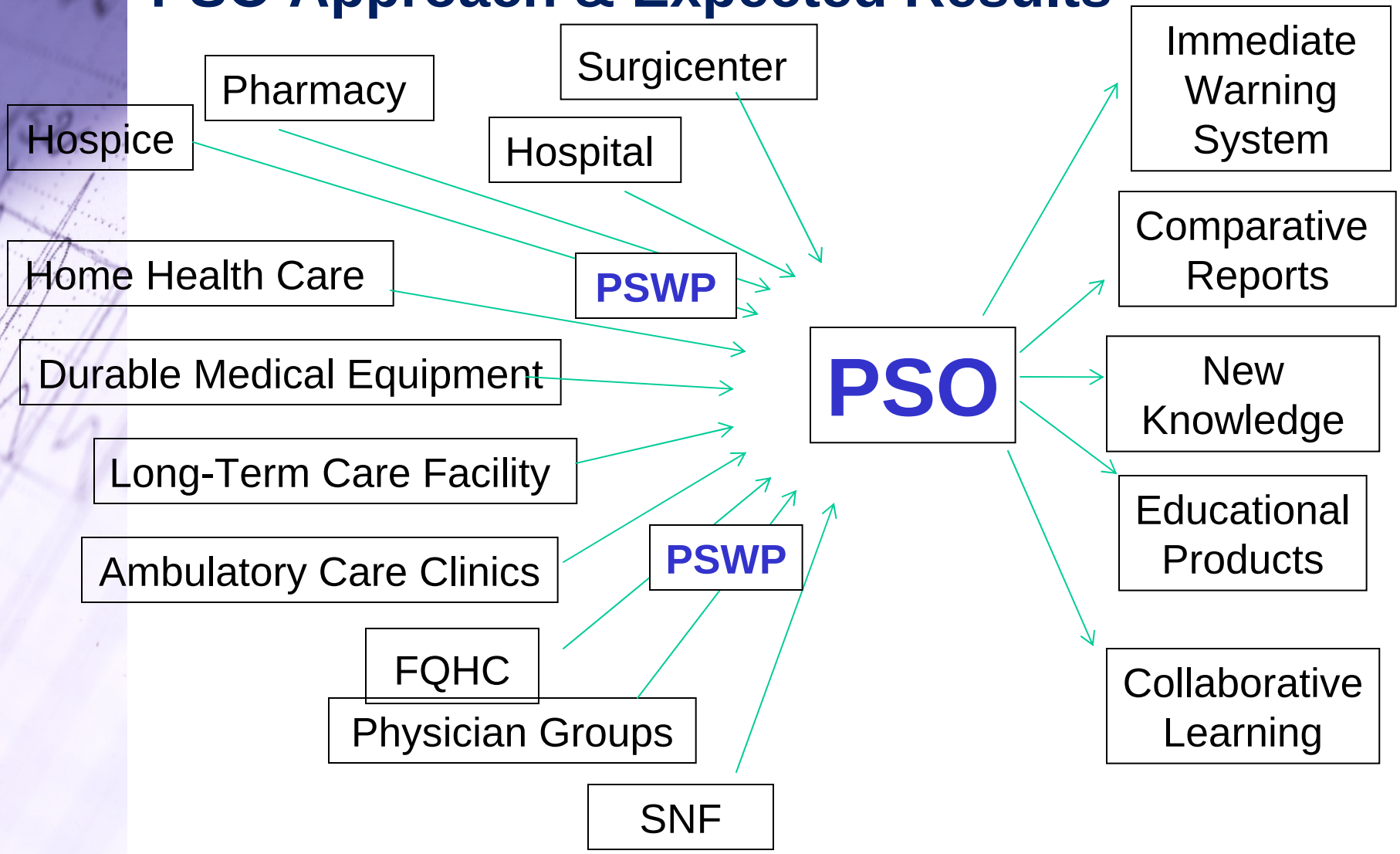
- Make sure to document decisions, conclusions and actions taken as a result of the reviews.
- Consider participation in a Patient Safety Organization.

Patient Safety Organizations Under The Patient Safety Act

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

Patient Safety Work Product (PSWP)

- 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*

What is NOT 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?

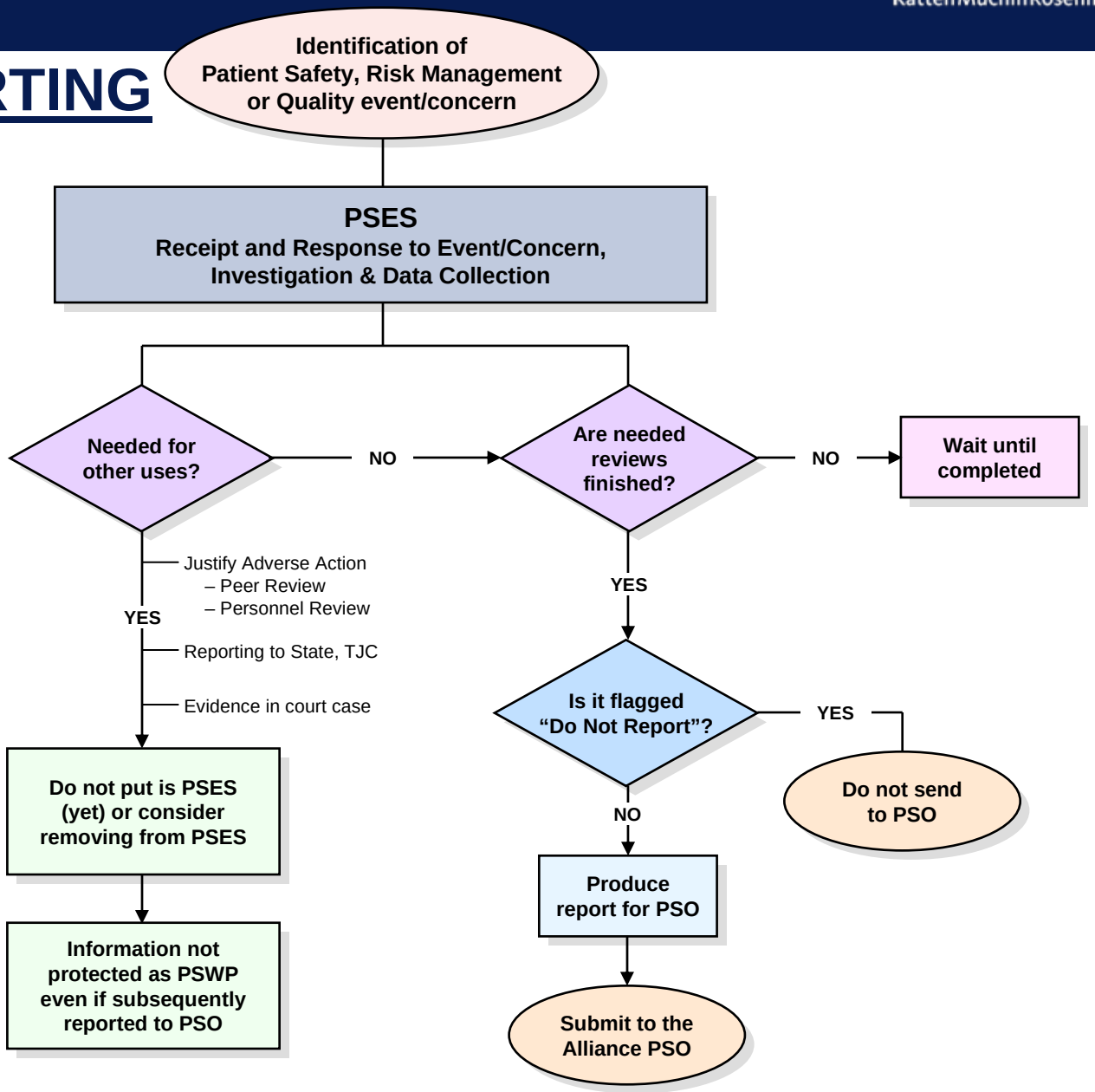
Establish and Implement a Patient Safety Evaluation System (PSES), that:

- 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

What is Required?

- 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

Designing Your PSES

- 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

Event/Incident Reporting Policy

- 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

Questions To Answer When Developing PSES Policy

- 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

How Does a Provider Determine Which Data Should Be Reported To A PSO?

- 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.

Types of Data PSES May Collect and Report To The PSO

- Peer Review
- Committee minutes–Safety, Quality, Quality and Safety Committee of the Board, Medication, Blood, Physician Peer Review

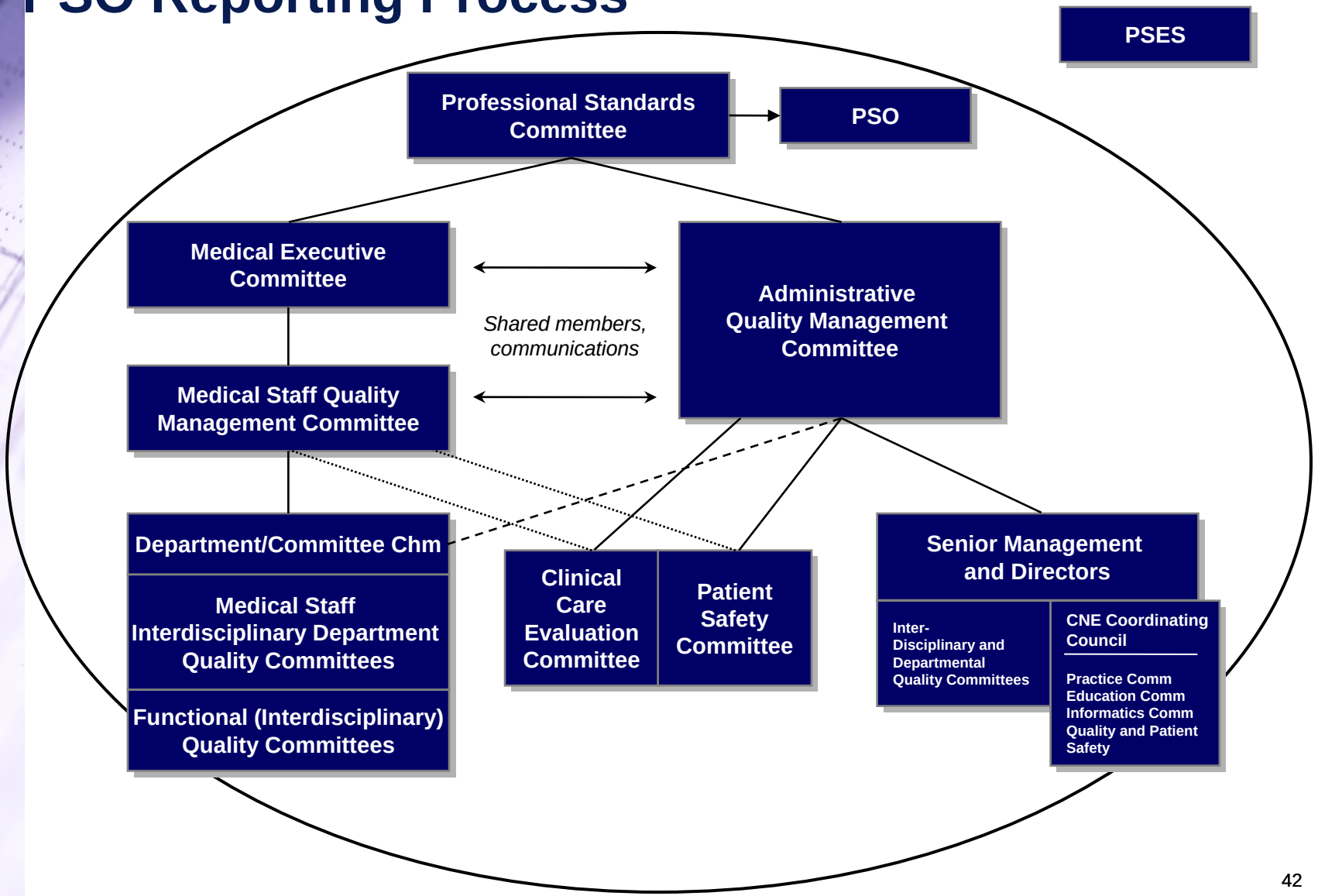
Steps to PSO Reporting

- 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

Steps to PSO Reporting

  - Agree to the processes that the PSES will follow to determine PSWP
- Create appropriate policies: Event Reporting; PSES, PSO Reporting

PSO Reporting Process



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

Patient Safety Work Product Privilege

- 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

Patient Safety Work Product Confidentiality

Exceptions (cont'd):

- 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
- 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

Patient Safety Work Product Confidentiality

Exceptions (cont'd):

- 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
- 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

Patient Safety Work Product Confidentiality

  - 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

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

Hypothetical: Post Op Infections

- Review also discloses member of targeted ortho group as having other identified issues including:
  - Total shoulder procedures in elderly patients
  - Questionable total ankle procedures
  - Untimely response to post op infections
- Issues identified are significant enough to trigger 3rd party review

Hypothetical: Post Op Infections

- 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