

New Federal Patient Safety Act:
**How to Expand Existing Peer Review
Protections, Obtain Active Physician
Participation and Comply with
Joint Commission Standards**

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1 pm – 3 pm CDT



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Clarity Group, Inc.

Clarity's mission is to enable healthcare providers to execute on their vision for excellence through consultative and technology solutions that assist them in ...

- Effectively managing the risk, quality, and safety of their healthcare services, and ...
- Effectively managing the financial and professional liability risk exposure associated with the delivery of their healthcare services.



Clarity PSO, A Division of Clarity Group Inc.

- Certification listed by AHRQ – November 2008
- Quarterly comparative reports, evidence based recommendations
- In-depth statistical analysis for improvement opportunities
- Education and resource development
- Healthcare 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



Goals for Today's Program

- Learn how the Patient Safety Act confidentiality and privilege protections exceed those provided under state law
- Design your Patient Safety Evaluation System to maximize legal protections and to comply with the Joint Commission Ongoing Professional Practice Evaluation (OPPE) and Focused Professional Practice Evaluation (FPPE) standards

Goals for Today's Program (cont'd)

- Find out about how the Act encourages greater medical staff participation in improvement activities through creation of accountability and limitation on use of peer review for discipline
- Meet the Joint Commission Medical Staff Requirements for OPPE and FPPE

Panel of Experts

Moderator

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Panel

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Introduction and Overview

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The Patient Safety Act

- Background
- Purpose
- Who is covered under the Act and What is Required
- Opportunity for physician performance improvement and sharing best practices

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 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 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 confidentiality and privilege protections
 - ✓ Facilitate the aggregation of a sufficient number of events in a protected legal environment.

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

Who or What Does the Act Cover?

- Limits the use of patient safety information in criminal, civil, and administrative proceedings and imposes monetary penalties for violations of confidentiality or privilege protections
- Provides uniform protections for all healthcare workers

Who or What Does the Act Cover?

(cont'd)

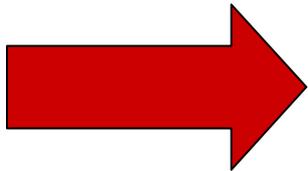
- Protects Patient Safety Work Product (PSWP) submitted by Providers either directly or through their Patient Safety Evaluation System (PSES) to PSOs
- Protects PSWP collected on behalf of providers by PSOs, e.g. Root Cause Analysis, Proactive Risk Assessment

The Patient Safety Act Does Not

- Mandate provider participation in a PSO
- Make significant error reporting mandatory—defers to states
- 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



Opportunity PSOs Present Related to Medical Care Evaluation

- CMS and Joint Commission require an assessment of competence prior to the granting, renewal, or restriction of privileges
- CMS and JCAHO require an in-depth assessment when concern arises about a practitioner's performance or there is no current data on the practitioner's performance
- Effective Ongoing Professional Practice Evaluation (OPPE) and Focused Professional Practice Evaluation (FPPE) processes could help an organization assure patients, payors and regulators that competent physicians, PAs and NPs practice in their organization and that the organization is meeting their regulatory, legal and ethical duty

Opportunity PSOs Present Related to Medical Care Evaluation (cont'd)

- Maintaining OPPE and FPPE outside of a PSO supports a culture of accountability while reporting individual medical care evaluation to a PSO builds a learning culture

Opportunity PSOs Present Related to Medical Care Evaluation (cont'd)

- Competency (OPPE/FPPE)
 - Required by CMS and Joint Commission
 - May be protected from discovery by state laws
 - Guides the organization's decision to grant, renew or restrict privileges
 - Creates a culture of accountability
- Medical Care Evaluation
 - If collected for reporting to a PSO and reported
 - ✓ Federal privilege and confidentiality protections
 - ✓ Cannot be used for disciplinary actions
 - ✓ Promotes a learning culture and sharing of best practices
 - Requires clear criteria of events that will not be sent to a PSO to support the culture of accountability

The Joint Commissions New Approach to Assessing Physician Performance

*Stephen M. Dorman, MD
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Stephen M. Dorman MD

The Joint Commissions New Approach to Assessing Physician Performance

Thou Shalt Measure
Thou Shalt Analyze
Thou Shalt Take Action

Why?

- Lack of previous success of physicians rigorously dealing with issues related to colleague performance.
- Lack of valid data when difficult decisions needed to be made related to physician performance.
- Threat of litigation real in light of lack of substantial performance documentation.

Why? (cont'd)

- Peer recommendations were essentially useless.
- Physicians would never provide objective references if they knew that substandard performance would be reported.
- “Credentialing” always focused on documents.
- NPDB only listed most serious issues.

Why? (cont'd)

- Databank reports were not timely.
- Physicians were allowed to resign when under the threat of or under actual investigation.
- Interruption of referral patterns.
- Interference with friendships.
- Accusations of financial motivations for competition.

Measurement Part I

- In the early 90s with the advent of performance improvement, a physician “profile” was to be maintained and used at reappointment every two years.
- Areas for measurement have not actually changed much since then.
- Compliance was spotty, but not often scored.

Measurement Part I (cont'd)

- Subject to surveyor variability.
- Many physician surveyors were not comfortable with the measurement standards and did not understand them.
- Most of the data collection at that time was manual.
- Profiles frequently indicated “0” for lack of quality issues despite poor performance.

Measurement Part II

- With a change in Joint Commission leadership, it became apparent that these standards were never scored and were essentially meaningless.
- Physician “thinkers” at the Joint Commission became instrumental in changing the approach (and some prodding by CMS).

Measurement Part II (cont'd)

- First things first: render the current standards meaningful.
- Implement physician performance measures that were rate based so that they could be compared with peer performance (early 2000).
- Comparisons were to be meaningful (meaning statistically analyzed).

Measurement Part II (cont'd)

- Profiles slowly became more meaningful
- Hospitals elected to participate in national measurement venues (Care Science, Premier Data, STS, ACC databases etc)
- Though data became available, still no action was taken on bad performance data

Measurement Part II (cont'd)

- There was a paralysis because of lack of benchmark data.
- Hospitals did not understand that it was acceptable to compare performance to “peer group”
- External data was not available because of peer review protection
- Low volume providers were not measured

Measurement Part III

- It became apparent that even though suboptimal performance could be detected at the two year reappointment period, what was being done in advance of that date?
- Why wasn't poor performance identified because it became "too late" or the reappointment was due and had to be done on less than desirable performance data?

Measurement Part IV

➤ ONGOING REVIEW

- The time frame for the review of physician performance data was discussed.
- To be “ongoing”, it was determined that every 2 years was insufficient, and in fact, that every year was insufficient.
- TJC stated that ongoing review should be conducted every 6-9 months unless “trigger” events have occurred.

Measurement Part IV (cont'd)

- Ongoing review dependent on those performance measures that primarily depend on the performance of an individual provider.
- These concepts apply not only to physicians, but also others who are credentialed and privileged.

Measurement Part IV (cont'd)

- It also became apparent that privileges that were granted were not based on evidenced-based criteria or any other criteria for that matter.
- Now the tie is between measured performance and privileges is clear.
- No data – no privileges.
- No use of external data.

Measurement Part IV (cont'd)

- CMS requires that each privilege granted be based on the assessment of the competence of the physician to exercise that privilege.
- The move to Core Privileges (assuming that competence is common to the group as defined).
- Special request privileges must be individually evaluated.
- “Laundry lists” are still highly problematic for all the reasons stated.

The Standard: MS.05.01.01: CLINICAL

- The organized medical staff has a leadership role in organization performance improvement activities to improve quality of care, treatment, and services and [patient] safety.
- Relevant information developed from the following processes is integrated into performance improvement initiatives and consistent with [organization] preservation of confidentiality and privilege of information.

The Standard: MS.05.01.01

- 1: The organized medical staff provides leadership for measuring, assessing, and improving processes that **primarily depend on the activities of one or more licensed independent practitioners**, and other practitioners credentialed and privileged through the medical staff process. (See also PI.03.01.01, EPs 1-4)

The Standard: MS.05.01.01

- 2: The medical staff is **actively involved** in the measurement, assessment, and improvement of the following: **Medical assessment and treatment of patients.** (See also PI.03.01.01, EPs 1-4)

The Standard: MS.05.01.01

- 3: The medical staff is actively involved in the measurement, assessment, and improvement of the following: Use of **information about adverse privileging decisions** for any practitioner privileged through the medical staff process.

The Standard: MS.05.01.01

- 4: The medical staff is actively involved in the measurement, assessment, and improvement of the following: **Use of medications**

The Standard: MS.05.01.01

- 5: The medical staff is actively involved in the measurement, assessment, and improvement of the following: **Use of blood and blood components**

The Standard: MS.05.01.01

- 6: The medical staff is actively involved in the measurement, assessment, and improvement of the following: **Operative and other procedure(s)**
 - Judgment (decision making)
 - Clinical and Technical Skills

The Standard: MS.05.01.01

- 7: The medical staff is actively involved in the measurement, assessment, and improvement of the following: **Appropriateness of clinical practice patterns.**
 - **Utilization Review (LOS, Avoidable days, denials)**

The Standard: MS.05.01.01

- 8: The medical staff is actively involved in the measurement, assessment, and improvement of the following: **Significant departures from established patterns of clinical practice.**
 - **All other departments: Pathology, radiology, anesthesiology, ER**

The Standard: MS.05.01.01

- 9: The medical staff is actively involved in the measurement, assessment, and improvement of the following: **The use of developed criteria for autopsies. (CMS REQUIREMENT)**

The Standard: MS.05.01.01

- 10: Information used as part of the performance improvement mechanisms, measurement, or assessment includes the following: **Sentinel event data.**

The Standard: MS.05.01.01

- 11: Information used as part of the performance improvement mechanisms, measurement, or assessment includes the following: **Patient safety data.**

The Standard: MS.05.01.03: CITIZENSHIP

- 1: The organized medical staff participates in the following activities: **Education of patients and families.**

The Standard: MS.05.01.03: CITIZENSHIP

- 2: The organized medical staff participates in the following activities: **Coordination of care, treatment, and services with other practitioners and hospital personnel, as relevant to the care, treatment, and services of an individual patient.**

The Standard: MS.05.01.03: CITIZENSHIP

- 3: The organized medical staff participates in the following activities: **Accurate, timely, and legible completion of patient's medical records.**

The Standard: MS.05.01.03: CITIZENSHIP

- 4: The organized medical staff participates in the following activities: **Review of findings of the assessment process that are relevant to an individual's performance. The organized medical staff is responsible for determining the use of this information in the ongoing evaluations of a practitioner's competence.**

The Standard: MS.05.01.03: CITIZENSHIP

- 5: The organized medical staff participates in the following activities: Communication of findings, conclusions, recommendations, and actions to improve performance to appropriate staff members and the **governing body**.

The Standard: MS.08.01.03

- Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privilege(s), or to revoke an existing privilege prior to or at the time of renewal.

The Standard: MS.08.01.03

- 1: The process for the ongoing professional practice evaluation includes the following: **There is a clearly defined process** in place that facilitates the evaluation of each practitioner's professional practice. (D means there must be a policy)

The Standard: MS.08.01.03

- 2: The process for the ongoing professional practice evaluation includes the following: The **type of data** to be collected is determined by individual **departments and approved by the organized medical staff.** (Performance measures must be defined for CMS in a Medical Staff Plan).

The Standard: MS.08.01.03

- 3: The process for the ongoing professional practice evaluation includes the following: Information resulting from the ongoing professional practice evaluation is **used to determine whether to continue, limit, or revoke any existing privilege(s).**

FOCUSED REVIEW

- While it was a good thing to evaluate providers after they had already been working 6 months, it was apparent that there was real risk in the “unknown”.
- Peer Recommendations could not be trusted.
- Harm could come to patients soon after practice began.

FOCUSED REVIEW (cont'd)

- There were analogous standards in the Human Resources chapter for an “initial assessment of competency” before hospital staff could carry out job responsibilities independent.

FOCUSED REVIEW (cont'd)

- It was clear that something was needed on the “front end.”
- Next it was determined that in classic “peer review”, cases simply fell off and issues were never closed or capriciously investigated. There was no accountability for closure of many significant issues.

FOCUSED REVIEW (cont'd)

➤ The purpose:

- Initially assessment competence of all new physicians or new privileges regardless of experience.
- Conduct intensive, planned and “focused” investigations when adverse events occurred (trigger events).
- Conduct intensive, planned and “focused” investigations when ongoing performance measurement indicated undesirable performance.

Focused Review: New Privileges (cont'd)

- Goal: To be conducted as rapidly as possible.
- “Volume” of review defined by the medical staff and departments.
- Individual plans should be developed to allow the medical staff when review has concluded.
- Each provider may warrant a tailored plan.
- Some departments are completely uniform.

Focused Review: New Privileges (cont'd)

- Should be conducted in a time frame that is too short for rate based performance measurement: data collection would not be statistically significant for short term.
- Evaluation of privilege must be realistic: chart review versus direct observation.
- All requirements defined in a plan.
- TOP Medical Staff Standard RFI in 2009.

The Standard: MS.08.01.01

- The organized medical staff defines the circumstances requiring monitoring and evaluation of a practitioner's professional performance.
 - Initial Appointment (new privileges)
 - New mid-cycle privilege
 - Trigger events
 - Variant data

The Standard: MS.08.01.01 (cont'd)

- The focused evaluation process is defined by the organized medical staff. The time period of the evaluation can be extended, and/or a different type of evaluation process assigned. Information for focused professional practice evaluation may include chart review, monitoring clinical practice patterns, simulation, proctoring, external peer review, and discussion with other individuals involved in the care of each patient (e.g., consulting physicians, assistants at surgery, nursing or administrative personnel).

The Standard: MS.08.01.01 (cont'd)

- Relevant information resulting from the focused evaluation process is integrated into performance improvement activities, consistent with the organization's policies and procedures that are intended to preserve confidentiality and privilege of information.

The Standard: MS.08.01.01

- 1: A period of focused professional practice evaluation is implemented for all initially requested privileges.

The Standard: MS.08.01.01

- 2: The organized medical staff develops criteria to be used for evaluating the performance of practitioners when issues affecting the provision of safe, high quality patient care are identified. (D means Plan)

The Standard: MS.08.01.01

- 3: The performance monitoring process is clearly defined and includes each of the following elements:
 - Criteria for conducting performance monitoring
 - Method for establishing a monitoring **plan** specific to the requested privilege
 - Method for determining the duration of performance monitoring
 - Circumstances under which monitoring by an external source is required

The Standard: MS.08.01.01

- 4: Focused professional practice evaluation is **consistently implemented** in accordance with the criteria and requirements defined by the organized medical staff.

The Standard: MS.08.01.01

- 5: The **triggers** that indicate the need for performance monitoring are clearly defined.
 - Note: Triggers can be single incidents or evidence of a clinical practice trend.

The Standard: MS.08.01.01

- 6: The decision to assign a period of performance monitoring to **further assess** current competence is based on the evaluation of a practitioner's current clinical competence, practice behavior, and ability to perform the requested privilege.
 - Note: Other existing privileges in good standing should not be affected by this decision.

The Standard: MS.08.01.01

- 7: Criteria are developed that determine the type of monitoring to be conducted. (D means this has to be in the plan).

The Standard: MS.08.01.01

- 8: The measures employed to resolve performance issues are clearly defined. (D means it must be in the plan).

The Standard: MS.08.01.01

- 9: The measures employed to resolve performance issues are consistently implemented.

Scoring

- All of the medical staff standards on these issues are “A” meaning 100% compliance is required.
- Focused Review: 16% of hospitals cited.
- Ongoing Review: 15% of hospitals cited.
- Problems with no or low volume providers
- Changes to privileges based to data

Credentialing and Privileging Process

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The Tort of Negligence

- Plaintiff must be able to establish:
- Existence of duty owed to the patient
 - That the duty was breached
 - That the breach caused the patient's injury
 - The injury resulted in compensable damages

Duty - Doctrine of Corporate Negligence

- Hospital, along with its medical staff, is required to exercise reasonable care to make sure that physicians applying to the medical staff or seeking reappointment are competent and qualified to exercise the requested clinical privileges. If the hospital knew or should have known that a physician is not qualified and the physician injures a patient through an act of negligence, the hospital can be found separately liable for the negligent credentialing of this physician

Duty - Doctrine of Corporate Negligence (cont'd)

- Doctrine also applies to managed care organizations such as PHOs and IPAs
- Restatement of this Doctrine and duty is found in:
 - Case law, i.e., Darling v. Charleston Community Hospital
 - State hospital licensing standards
 - Accreditation standards, i.e., Joint Commission and Healthcare Facilities Accreditation Program, NAMSS
 - Medical staff bylaws, rules and regulations, department and hospital policies, corporate bylaws and policies

Duty - Doctrine of Corporate Negligence (cont'd)

- Some questions associated with this duty:
 - How are core privileges determined?
 - Based on what criteria does hospital grant more specialized privileges?
 - Are hospital practices and standards consistent with those of peer hospitals?
 - Were any exceptions to criteria made and, if so, on what basis?

Duty - Doctrine of Corporate Negligence (cont'd)

- Were physicians to whom the exemption applied “grandfathered” and, if so, why?
- Did you really scrutinize the privilege card of Dr. Callahan who is up for reappointment but has not actively practiced at the Hospital for the last six years?
- Has each of your department’s adopted criteria which they are measuring as part of FPPE or OPPE obligations such as length of stay patterns or morbidity and mortality data?

Breach of Duty

- The hospital breached its duty because:
- It failed to adopt or follow state licensing requirements
 - It failed to adopt or follow accreditation standards, i.e., FPPE and OPPE
 - It failed to adopt or follow its medical staff bylaws, rules and regulations, policies, core privileging criteria, etc.
 - It reappointed physicians without taking into account their accumulated quality or performance improvement files

Breach of Duty (cont'd)

- It reappointed physicians even though they have not performed any procedures at hospital over the past two years and/or never produced adequate documentation that the procedures were performed successfully elsewhere
- It failed to require physicians to establish that they obtained additional or continuing medical education consistent with requirement to exercise specialized procedures

Breach of Duty (cont'd)

- It appointed/reappointed physician without any restrictions even though they had a history of malpractice settlements/judgments, disciplinary actions, insurance gaps, licensure problems, pattern of substandard care which has not improved despite medical staff intervention, current history or evidence of impairment, etc.
- It failed to grandfather or provide written explanation as to why physician, who did not meet or satisfy credentialing criteria, was otherwise given certain clinical privileges
- It required physician to take ED call even though he clearly was not qualified to exercise certain privileges
- Violated critical pathways, ACOG, ACR standards

Causation

- The hospital's breach of its duty caused the patient's injury because:
- If the hospital had uniformly applied its credentialing criteria, physician would not have received the privileges which he negligently exercised and which directly caused the patient's injury
 - History of malpractice suits since last reappointment should have forced hospital to further investigate and to consider or impose some form of remedial or corrective action, including reduction or termination of privileges, and such failure led to patient's injury

Causation (cont'd)

- Causation is probably the most difficult element for a plaintiff to prove because plaintiff eventually has to establish that if hospital had met its duty, physician would not have been given the privileges that led to the patient's injury
- Plaintiff also must prove that the physician was negligent. If physician was not negligent, then hospital cannot be found negligent

Examples of Negligent Credentialing Cases

- Darling v. Charleston Community Memorial Hospital (1965)
- First case in the country to apply the Doctrine of Corporate Negligence
 - Case involved a teenage athlete who had a broken leg with complications and was treated by a family practitioner
 - Leg was not set properly and patient suffered permanent injury
 - Hospital claimed no responsibility over the patient care provided by its staff physician

Examples of Negligent Credentialing Cases (cont'd)

- Court rejected this position as well as the charitable immunity protections previously provided to hospitals
- Part of the basis for the decision was the fact that hospital was accredited by the Joint Commission and had incorporated the Commission's credentialing standards into its corporate and medical staff bylaws

Examples of Negligent Credentialing Cases (cont'd)

- These standards reflected an obligation by the medical staff and hospital to make sure physicians were qualified to exercise the privileges granted to them
- Physician was found to be negligent
- The medical staff and hospital's decision to give privileges to treat patients with complicated injuries to an unqualified practitioner directly caused the patient's permanent injuries. Therefore, the hospital was held liable for the damages

Examples of Negligent Credentialing Cases (cont'd)

➤ **Frigo v. Silver Cross Hospital (2007)**

- Frigo involved a lawsuit against a podiatrist and Silver Cross
- Patient alleged that podiatrist's negligence in performing a bunionectomy on an ulcerated foot resulted in osteomyelitis and the subsequent amputation of the foot in 1998

Examples of Negligent Credentialing Cases (cont'd)

- The podiatrist was granted Level II surgical privileges to perform these procedures even though he did not have the required additional post-graduate surgical training required in the Bylaws as evidenced by completion of an approved surgical residency program or board eligibility or certification by the American Board of Podiatric Surgery at the time of his initial appointment in 1992

Examples of Negligent Credentialing Cases (cont'd)

- At the time of his reappointment, the standard was changed to require a completed 12 month podiatric surgical residency training program, successful completion of the written eligibility exam and documentation of having completed 30 Level II operative procedures
- Podiatrist never met these standards and was never grandfathered. In 1998, when the alleged negligence occurred, he had only performed six Level II procedures and none of them at Silver Cross

Examples of Negligent Credentialing Cases (cont'd)

- Frigo argued that because the podiatrist did not meet the required standard, he should have never been given the privileges to perform the surgery
- She further maintained that the granting of privileges to an unqualified practitioner who was never grandfathered was a violation of the hospital's duty to make sure that only qualified physicians are to be given surgical privileges. The hospital's breach of this duty caused her amputation because of podiatrist's negligence

Examples of Negligent Credentialing Cases (cont'd)

- Jury reached a verdict of \$7,775,668.02 against Silver Cross
- Podiatrist had previously settled for \$900,000.00
- Hospital had argued that its criteria did not establish nor was there an industry-wide standard governing the issuance of surgical privileges to podiatrists
- Hospital also maintained that there were no adverse outcomes or complaints that otherwise would have justified non-reappointment in 1998

Examples of Negligent Credentialing Cases (cont'd)

- Court disagreed and held that the jury acted properly because the hospital's bylaws and the 1992 and 1993 credentialing requirements created an internal standard of care against which the hospital's decision to grant privileges could be measured
- Court noted that Dr. Kirchner had not been grandfathered and that there was sufficient evidence to support a finding that the hospital had breached its own standard, and hence, its duty to the patient

Examples of Negligent Credentialing Cases (cont'd)

- This finding, coupled with the jury's determination that Dr. Kirchner's negligence in treatment and follow up care of Frigo caused the amputation, supported jury's finding that her injury would not have been caused had the hospital not issued privileges to Dr. Kirchner in violation of its standards

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

(cont'd)

- 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

Patient Safety Work Product Privilege

(cont'd)

- Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law

Patient Safety Work Product Privilege

(cont'd)

➤ 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 (cont'd)

➤ Exceptions:

- 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 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

Patient Safety Work Product Confidentiality (cont'd)

➤ Exceptions:

- 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
- Disclosure for business operations to attorney, accountants and other professionals who cannot re-disclose

Patient Safety Work Product Confidentiality (cont'd)

➤ Exceptions:

- 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 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 (cont'd)

➤ 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

Interaction with HIPAA Privacy Regulations (cont'd)

➤ PSWP vs PHI (cont'd)

- 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

Interaction of PSO Protections with State Peer Review Activities and Protections

- 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 Activities and Protections (cont'd)

- 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

Interaction of PSO Protections with State Peer Review Activities and Protections (cont'd)

- 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
- Remember that once it is removed and used for other purposes it cannot be later reported and treated as PSWP

Interaction of PSO Protections with State Peer Review Activities and Protections (cont'd)

- 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

Interaction of PSO Protections with State Peer Review Activities and Protections (cont'd)

- Also, keep in mind that PSWP reported to a PSO cannot be used to defend in a negligent credentialing action (Frigo case) or other legal action

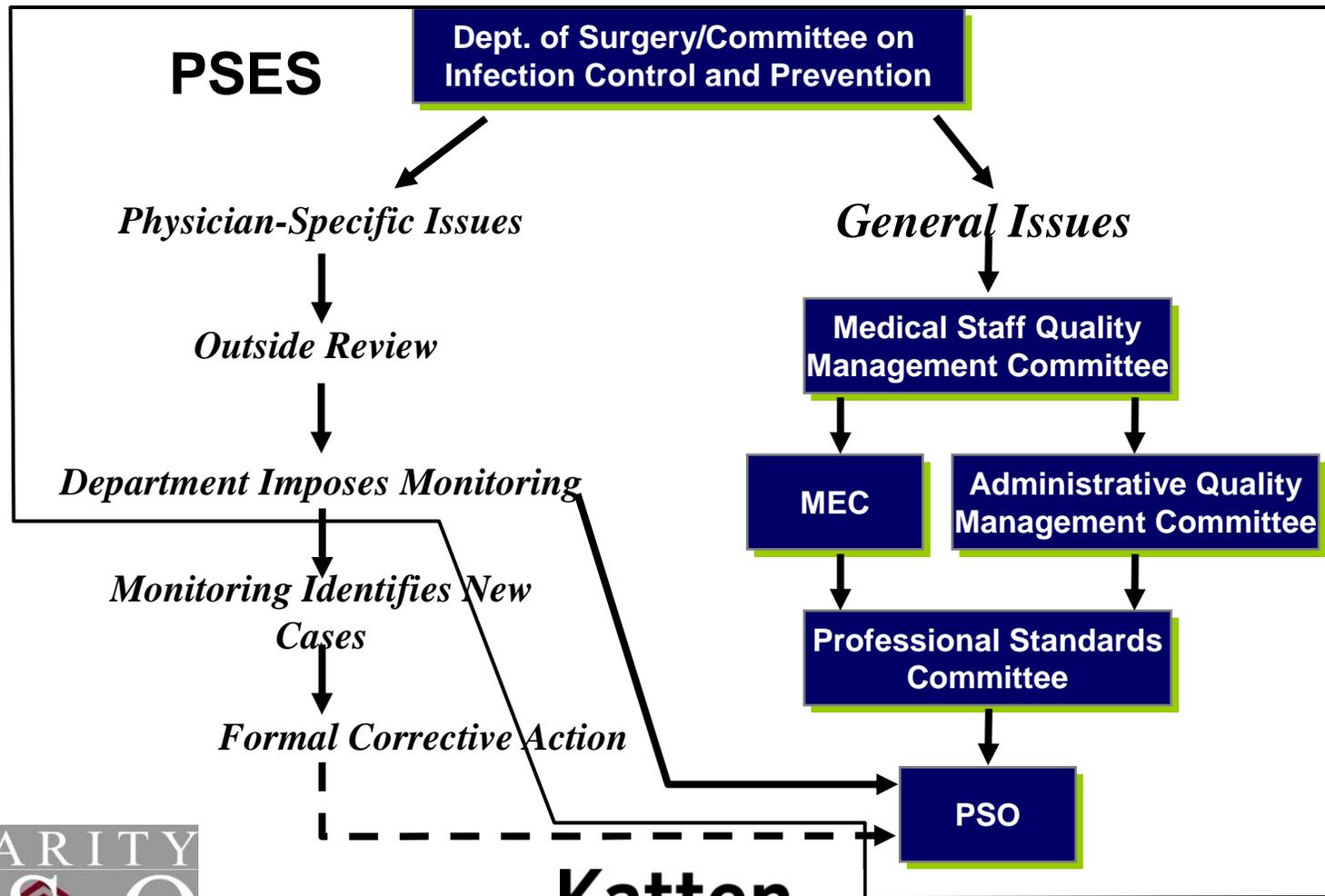
Peer Review Hypothetical: Post Op Infections

- 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

Peer Review Hypothetical: Post Op Infections (cont'd)

- Review identifies a number of questionable practices generally, which are not consistent with established infection control protocols
 - Data and analysis and recommendations eventually reported to PSO
- Review also discloses member of targeted ortho group as having other identified issues including:
 - Total shoulder procedures in elderly patients
 - Questionable total ankle procedures
 - Untimely response to post op infections
- Issues identified are significant enough to trigger 3rd party review

Peer Review Hypothetical: Post Op Infections (cont'd)



How OPPE, FPPE and PSO Reporting Support a Culture of Safety

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



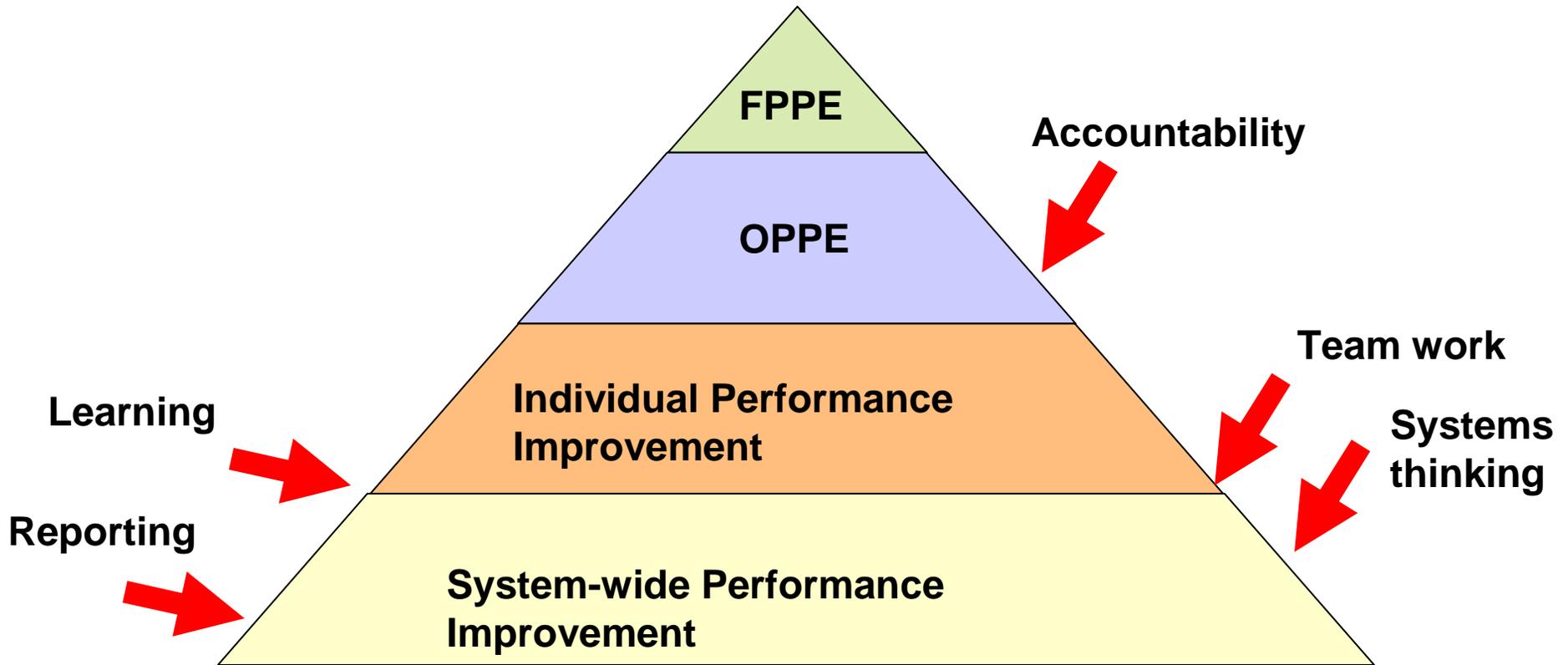
Attributes of a Culture of Safety

- Reporting
- Learning/Improvement
- Systems Thinking
- Accountability
- Team Work
- Leadership support

Attributes of a Culture of Accountability

- Recognition of fairness related to the identification and resolution of human performance problems
- Distinction between honest mistakes and intentional shortcuts with respect to discipline
- Free flow of information across all levels of an organization
- High level of self reporting (www.hanford.gov)

How OPPE, FPPE and PSO Reporting Support a Culture of Safety



Physician Performance Evaluation Versus Physician Performance Improvement

Possible state
law protection



OPPE/
FPPE

Competency
Assessment



Transparency

PSA
protected



Learning

Teamwork

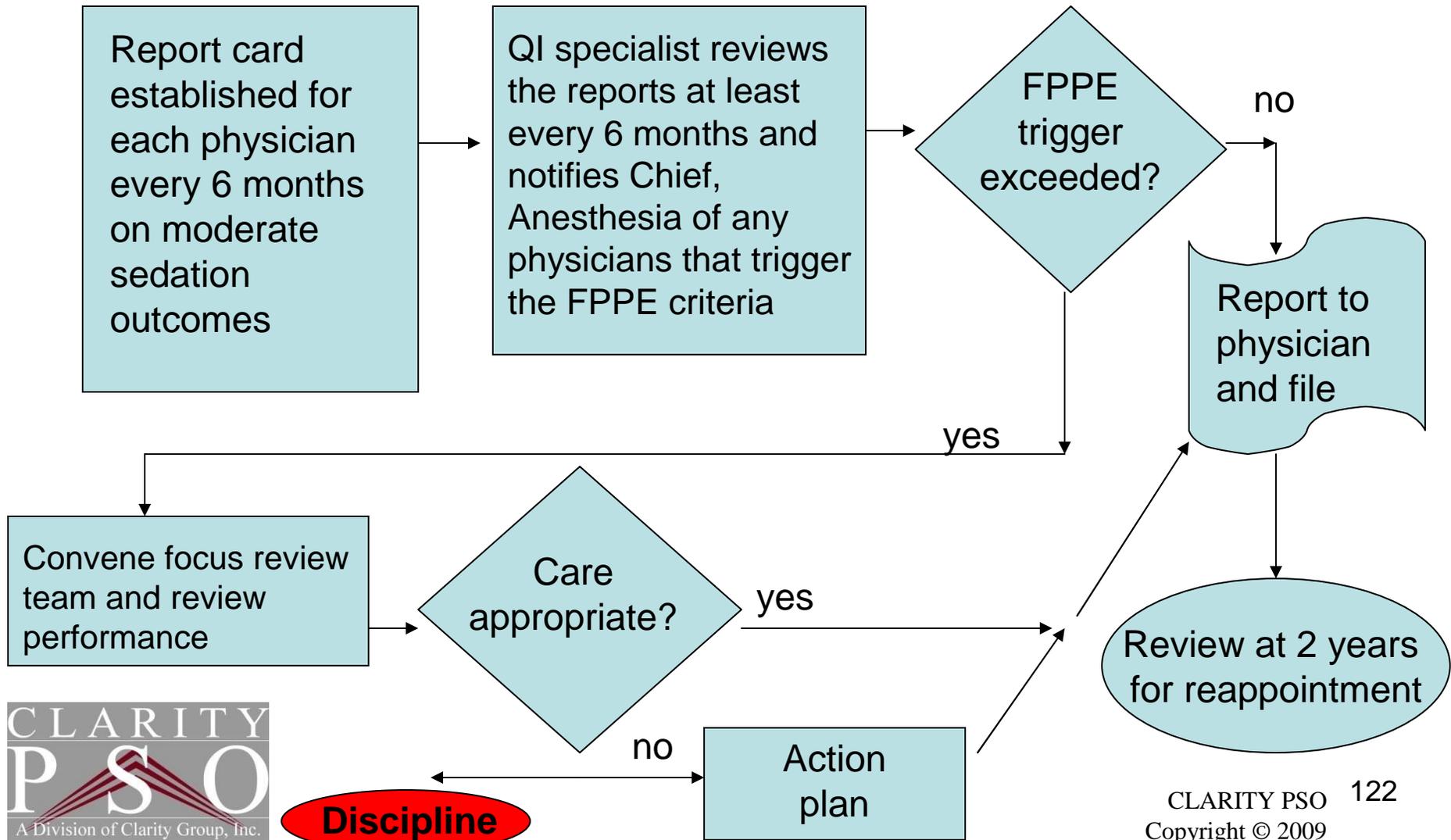
Sharing
Best
Practices



System
improvements

OPPE/FPPE Process

Moderate Sedation Hypothetical



Competence (OPPE/FPPE) vs. Medical Care Evaluation

➤ OPPE

- Systematic
- Objective e.g. rate based
- Source data should be medical record or administrative data
- May lead to disciplinary actions

➤ FPPE

- Assessment of an outlier physician's performance when rate exceeded
- Source data should be medical record data
- May lead to disciplinary actions

➤ Medical Care Evaluation

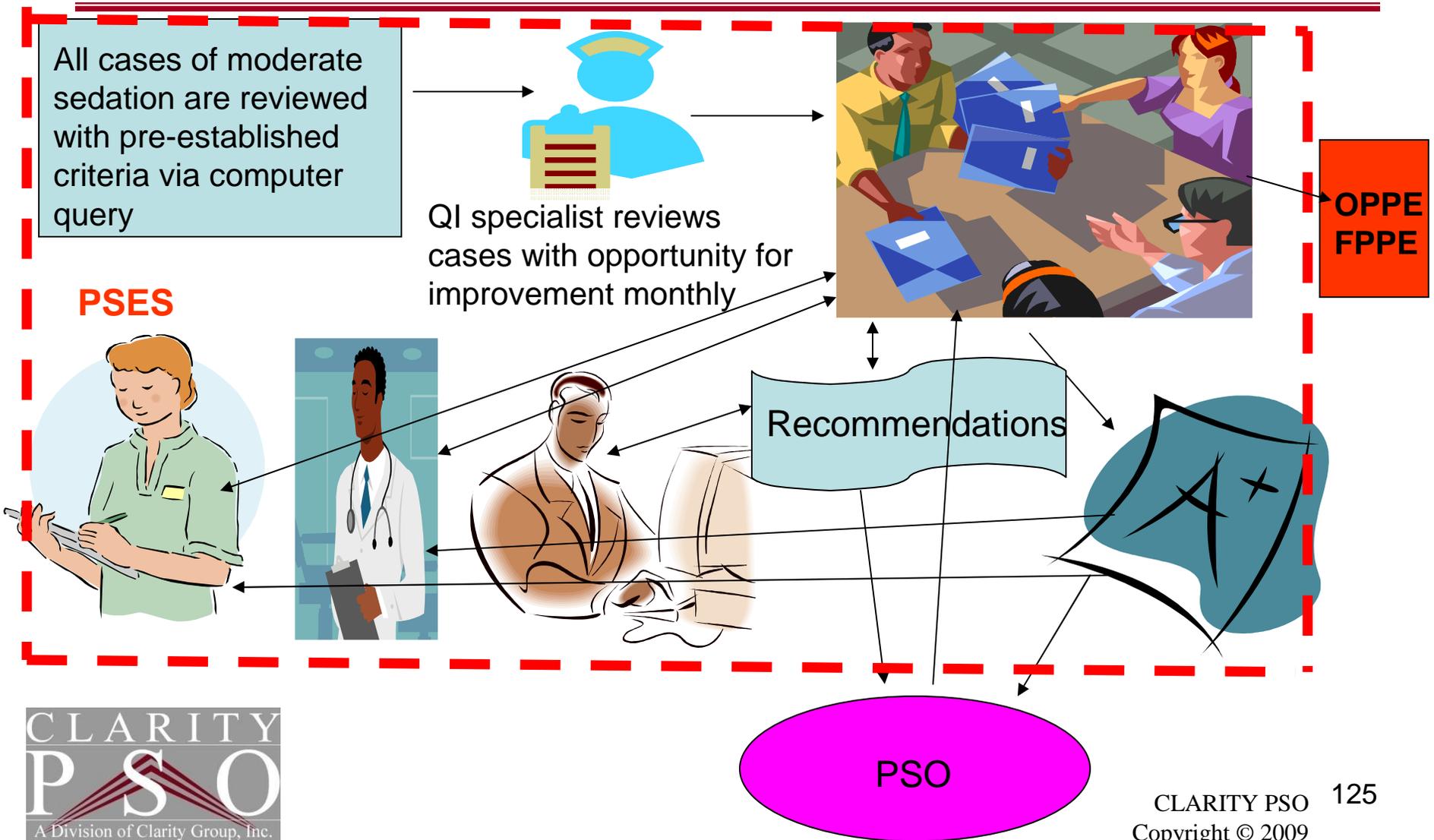
- PSWP e.g., common format incident reports, subjective data and Copies of PSWP
- Reviews looking for improvement opportunity vs. outlier data
- Opportunity to benchmark and share learning beyond 1 organization
- Evidence based recommendations
 - ✓ Recommendation may be to add a new OPPE indicator or modify FPPE indicator
- Federal privilege and confidentiality protections allows data to be broadly shared to support improvement

Competence (OPPE/FPPE) vs. Medical Care Evaluation

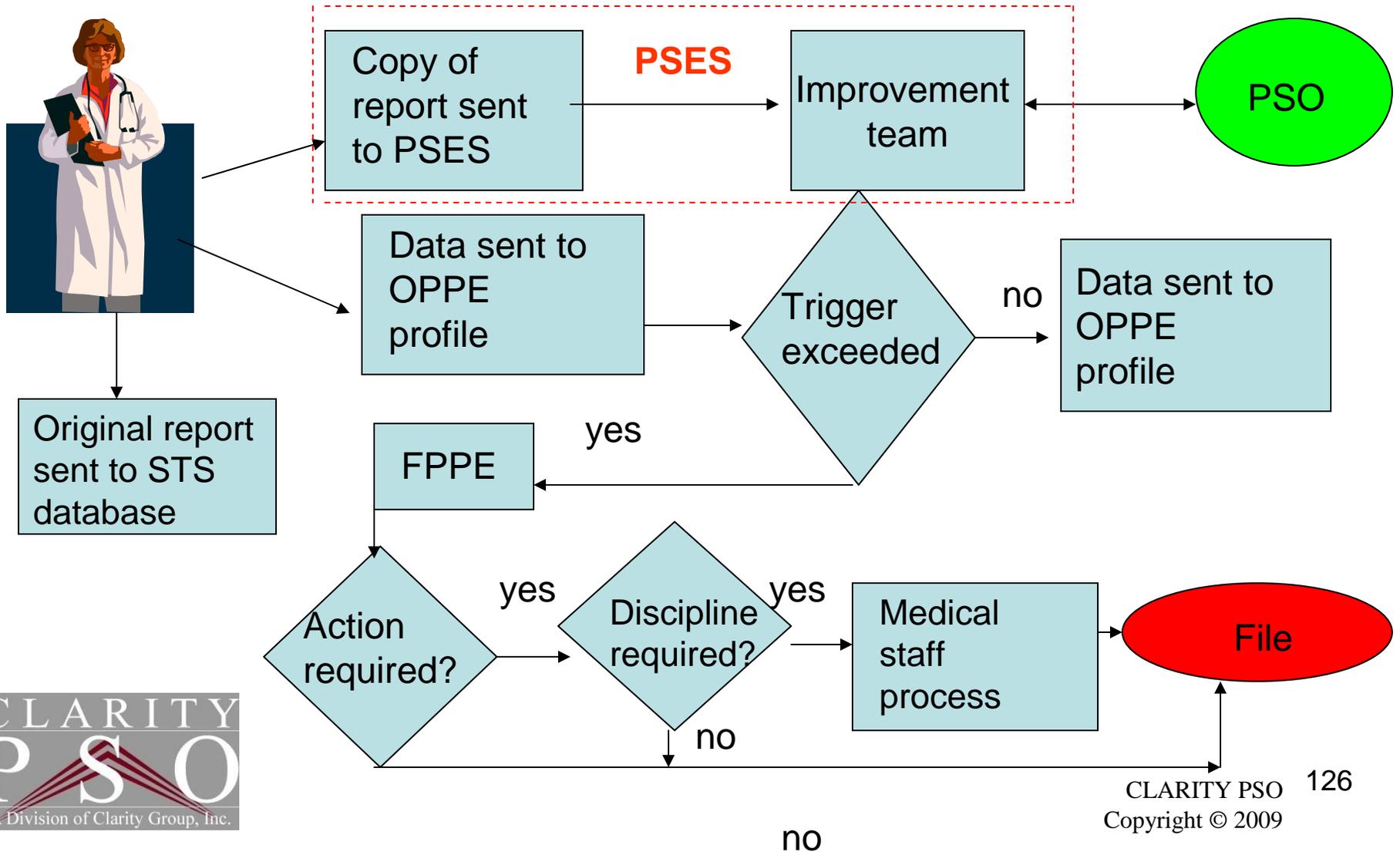
- OPPE/FPPE to renew moderate sedation privileges
 - Patient care
 - ✓ Customer satisfaction with services
 - Medical/Clinical
 - ✓ Moderate sedation test passed
 - Practice Based Learning
 - ✓ Number of Cases
 - ✓ Percent of cases with reversal agents used
 - ✓ Percent of cases that required unplanned transfer to ICU post procedure
 - ✓ Percent of cases with an adverse outcome (see definition)
 - Interpersonal skills
 - ✓ Complaints

- Moderate Sedation PSO PI Project
 - 100% sedation cases where the patient received a reversal agent, experienced an adverse outcome, or an unplanned transfer to critical care are reviewed by a nurse with pre-established criteria
 - Cases that do not meet criteria are reviewed and discussed by the multidisciplinary sedation committee and recommendations are given on an as needed basis
 - Quarterly, each nurse, physician, PA and NP involved in the process receives a report card with recommendations
 - All data submitted to PSO
 - PSO compares data with like providers and offers evidence based recommendations
 - Lessons learned are shared broadly within the organization

PSA Moderate Sedation Improvement



Cardiac Surgery Performance Improvement



Example Department of Surgery OPPE Profile

- Patient Care
 - Patient satisfaction
 - Complaint
- Medical Knowledge
 - Appropriate indication for Procedures
 - Major diagnosis/tissue discrepancies
 - Appropriate blood use
 - Antibiotic prior to incision
- Practice Based Learning and Improvement
 - Unplanned return to OR
 - Unplanned transfer to critical care
 - Complication ratio to Department/National
 - Infection ratio to Department/National
 - Mortality ratio to Department/National
- Interpersonal and Communication Skills
 - Peer recommendations
- Professionalism
 - Complaints from other healthcare providers
 - Adherence to Universal Protocol
 - Meeting attendance
 - Medical Staff responsibility compliance
- Systems Based Practice
 - ALOS Ratio to Department ALOS
 - Appropriate utilization of MRI/CT
 - C/T ratio

Physician Evaluation Scenario

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

Not PSWP

Provider investigates claim under Attorney-Client Privilege

Is this an isolated incident or a pattern/trend?

Provider collects outcome data on tonsillectomies for reporting to PSO

PSWP

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

Not PSWP

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

Benefits Of Using a PSO for Medical Care Evaluation

- Federal level privilege and confidentiality
- Learning culture
- Ability to share information broadly within the organization
- Early identification of opportunities for improvement and intervention to prevent patient harm
- Hopefully opportunities improved before any trend requiring FPPE

Questions?

Thank You!

➤ For More Information, please contact:

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Please take a few minutes to provide us with your evaluation of today's program ~ Thank you!



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