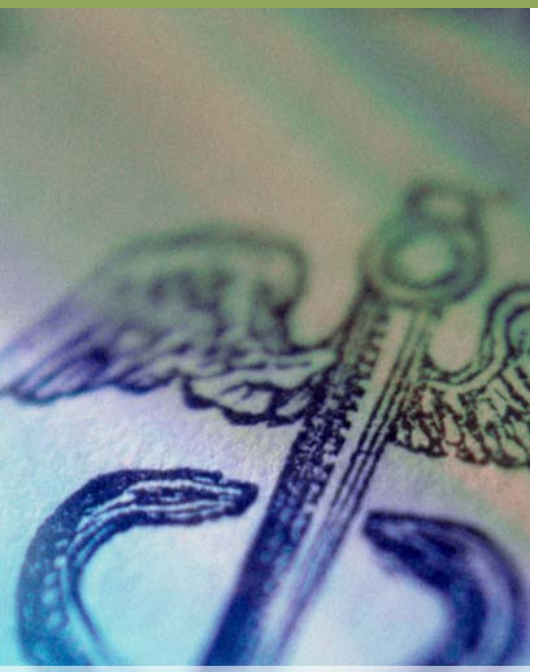

American Health Lawyers Association
2012 Annual Meeting and
In-House Counsel Program

Enterprise Risk Management and Conducting Peer Review in Evolving Health Systems

June 24-27, 2012

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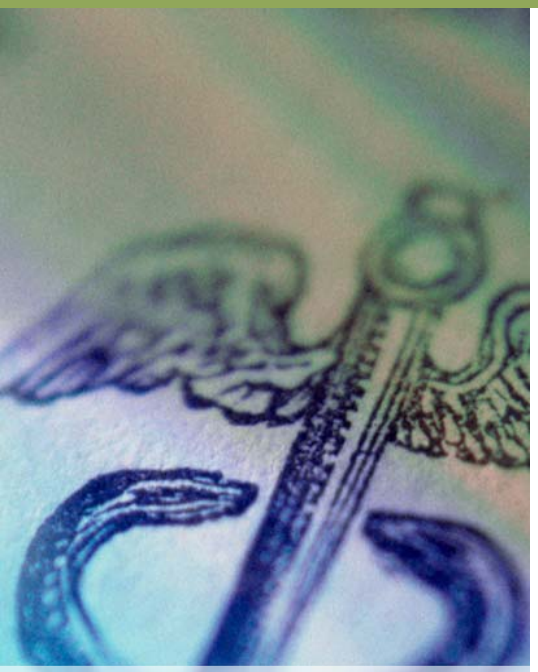

The Changing Healthcare Landscape and Quality Enforcement Initiatives

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The Changing Healthcare Landscape

- Consolidation of market
  - Hospital mergers
  - Practice acquisitions
- Provider margins are under attack
  - Reductions in Medicare/Medicaid reimbursement
  - Higher costs
  - Private payer reductions
- New models of provider integration are emerging
  - Co-management arrangements
  - Patient centered medical home
  - ACOs

The Changing Healthcare Landscape (cont'd)

- Shift from "Volume to Value" as a basis of reimbursement
  - Pay for performance
  - ACO quality metrics
  - Value Based Purchasing
  - Reduced or denied reimbursement for:
    - Hospital acquired conditions
    - Never events – (Billing Medicare for a never event is considered a false claim)

Examples of Quality Standards

- Never Events
  - Surgery on wrong body part
  - Surgery on wrong patient
  - Wrong surgery on a patient
  - Death/disability associated with use of contaminated drugs
  - Patient suicide or attempted suicide resulting in disability
  - Death/disability associated with medication error

Examples of Quality Standards (cont'd)

- Hospital Acquired Conditions
  - Foreign object left in patient after surgery
  - Death/disability associated with intravascular air embolism
  - Death/disability associated with incompatible blood
  - Stage 3 or 4 pressure ulcers after admission

Examples of Quality Standards (cont'd)

- Consistent with the overall purpose of the Affordable Care Act, the intent of the Shared Savings Program is to achieve high-quality health care for patients in a cost-effective manner. As part of CMS's goal to provide better care for individuals, defined as "safe, effective, patient-centered, timely, efficient, and equitable," the regulations propose:
  - Measures to assess the quality of care furnished by an ACO;
  - Requirements for data submission by ACOs;
  - Quality performance standards

Examples of Quality Standards (cont'd)

  - Incorporation of reporting requirements under the Physician Quality Reporting System; and
  - Requirements for public reporting by ACOs.
- ACOs that do not meet quality performance thresholds for all measures would not be eligible for shared savings, regardless of how much per capita costs were reduced.

Examples of Quality Standards (cont'd)

- ACO Quality measures are in four domains**:**
  - Patient/caregiver experience (7)
  - Care coordination/patient safety (6)
  - Preventive health (8) and,
  - At-risk populations (12): includes 6 measures for diabetes (5 scored as a single composite), 1 for hypertension, 2 for IVD, 1 for heart failure, and 2 for CAD
  - *EHR adoption by PCPs will be included as a quality measure in the Care Coordination/Patient Safety domain and will be given double weight in scoring*
- Changes over time:
  - CMS can specify higher standards and/or new measures to improve quality of care

Examples of Quality Standards (cont'd)

- Value Based Purchasing Program Measures
  - Starting in October, 2012, will reward hospitals based on the quality of inpatient acute care services provided and not just on the quality delivered.
  - Under the VBP Program, CMS will pay acute care inpatient prospective payment system (IPPS) hospitals value-based incentive payments for meeting minimum performance standards for certain quality measures with respect to a performance period designated for each fiscal year.

Examples of Quality Standards (cont'd)

- Clinical Process of Care Measures
  - Acute myocardial infarction
    - Primary PCI received within 90 minutes of hospital arrival
  - Heart Failure
    - Discharge Instructions
  - Pneumonia
    - Blood cultures performed in ED prior to initial antibiotic received in hospital

Examples of Quality Standards (cont'd)

- Survey Measures
  - Communication with Nurses
  - Communication with Doctors
  - Responsiveness of Hospital Staff
  - Pain Management
  - Communication About Medicines
  - Cleanliness and Quietness of Hospital Environment
  - Discharge Information
  - Overall Rating of Hospital

Examples of Quality Standards (cont'd)

- Other Criteria for FY 2014
  - Eight Hospital Acquired Condition Measures
    - Foreign object retained after surgery
  - AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs), and Composite Measures
  - Mortality measures

Corporate Responsibility in Health Care Quality

- In 2007 the OIG and AHLA collaborated on a publication titled "Resource for Health Care Boards of Directors on Corporate Responsibility and Health Care Quality"
- Was published "for the specific purpose of identifying the role and responsibility of corporate boards and management with respect to its fiduciary obligations to meet its charitable mission and legal responsibilities to provide health care quality services"
- Cites ten key questions reflective of standards against which hospital boards will be measured

Corporate Responsibility in Health Care Quality (cont'd)

- What are the goals of the organization's quality improvement program?
  - What metrics and benchmarks are used to measure progress towards each of the performance goals? How is each goals specifically linked to management accountability?
  - How does the organization measure and improve the quality of patient/resident care? Who are the key management and clinical leaders responsible for these quality and safety programs?
  - How are the organization's quality assessment and improvement processes integrated into overall corporate policies and operations? Are clinical quality standards supported by operational policies? How does management implement and enforce these policies? What internal controls exist to monitor and report on quality metrics?

Corporate Responsibility in Health Care Quality (cont'd)

- Does the board have a formal orientation and continuing education process that helps members appreciate external quality of patient safety requirements? Does the board include members with expertise in patient safety and quality improvement issues?
- What information is essential to the board's ability to understand and evaluate the organization's quality assessment and performance improvement programs? Once these performance metrics and benchmarks are established, how frequently does the board receive reports about the quality improvement effort?

Corporate Responsibility in Health Care Quality (cont'd)

- Are human and other resources adequate to support patient safety and clinical quality? How are proposed changes in resource allocation evaluated from the perspective of clinical quality and patient care? Are systems in place to provide adequate resources to account for differences in patient acuity and care needs?
- Do to the organization's competency assessment and training, credentialing and peer review processes adequately recognize the necessary focus on clinical quality and patient safety issues?
- How are these "adverse patient events" and other medical errors identified, analyzed, reported and incorporated into the organization's performance improvement activities? How do management and the board address quality deficiencies without unnecessarily increasing the organization's liability exposure?

Corporate Responsibility in Health Care Quality (cont'd)

- How are the organization's quality assessment and improvement processes coordinated with its corporate compliance program? How are quality of care and patient safety issues addressed in the organization's risk management and corrective action plans?
- What processes are in place to promote the reporting of quality concerns and medical errors and to protect those who ask questions and report programs? What guidelines exist for reporting quality and patient safety concerns to the board?

Examples of Quality Enforcement Efforts

- The OIG has identified that its principal enforcement tools include allegations of violations of the False Claims Act, use of corporate integrity agreements, including the use of external quality of care monitors, as well as civil fines and, in extreme circumstances, exclusion from the Medicare program
- The OIG has made the following statements:

  > "To hold responsible individuals accountable and to protect additional beneficiaries from harm, the OIG excludes from participation in federal health care programs individuals and entities whose conduct results in poor care. In enforcement actions against corporate entities, . . . OIG places particular emphasis on high level officials, such as owners and chief executive officers. . . ."

Examples of Quality Enforcement Efforts
(cont'd)

- **<u>Rogers v. Azmat</u> (2010)**
  - DOJ interviewed in a False Claims Act lawsuit alleging that Satilla Regional Medical Center and Dr. Najam Azmat submitted claims for medical substandard and unnecessary services to Medicare and Medicaid . The complaint alleges, among other things, that the defendants submitted claims for medical procedures performed by Dr. Azmat in Satilla's Heart Center that the physician was neither qualified nr properly credentialed to perform. As a result, at least one patient died and others were seriously injured.

Examples of Quality Enforcement Efforts
(cont'd)

- The complaint states that Satilla placed Dr. Azmat on staff even after learning that the hospital where he previously worked had restricted his privileges as a result of a high complication rate on his surgical procedures. The complaint also states that after Dr. Azmat joined the Satilla staff, the hospital management allowed him to perform endovascular procedures in the hospital's Heart Center even though he lacked experience in performing such procedures and did not have privileges to perform them.

Examples of Quality Enforcement Efforts
(cont'd)

- The complaint further states that the nurses in Satilla's Heart Center recognized that Dr. Azmat was incompetent to perform endovascular procedures and repeatedly raised concerns with hospital management. Despite the nurse's complaints and Dr. Azmat's high complication rate, Satilla's management continued to allow him to perform endovascular procedures and to bill federal health care programs for these services.

The Changing Healthcare Landscape (cont'd)

- Increased enforcement
  - 2012 OIG Work Plan
    - Reliability of hospital-reported quality measures data
    - Hospital admissions with conditions coded as "present-on-admission" and accuracy of "present on admissions" indicators
    - Review of Medicaid payments for HACs and never events
    - Acute-care inpatient transfers to inpatient hospice care
    - Safety and quality of surgeries and procedures in surgicenters and hospital outpatient departments

The Changing Healthcare Landscape (cont'd)

- Quality of care and safety of residents and quality of post-acute care for nursing homes
- Hospital reporting of adverse events
- Hospital same-day readmissions
- Hospitalizations and re-hospitalization of nursing home residents
- Review effectiveness of PSO programs

The Changing Healthcare Landscape (cont'd)

- January, 2012 OIG Report: "Hospital Incident Reporting Systems Do Not Capture Most Patient Harm"
  - All hospitals have incident reporting systems to capture events and are heavily relied on to identify problems
  - These systems provide incomplete information about how events occur
  - Of the events experienced by Medicare beneficiaries, hospital incident reporting systems only captured an estimated 14% due to events that staff did not perceive as reportable or were simply not reported
  - Accrediting bodies only review incident reports and outcomes but not the methods used to track errors and adverse events

So Now What?

- Compliance plans need to be updated or prepared which reflect the provider's commitment to improving quality as per the areas identified by the OIG
- Even if not seeking ACO certification at this time, hospital should review the ACO final rules as a future standard on which private and public reimbursement and standards of care will be based

So Now What? (cont'd)

- A failure to comply with ACO, VBP and other developing standards, including a pattern of HACs and Never Events, may also have a direct or indirect impact on provider responsibilities:
  - Accreditation standards
  - Doctrine of corporate negligence and related civil liability theories
  - DOJ/OIG expectations on board responsibility for delivering quality health care services which could trigger False Claims Act exposure (Azmat case)

So Now What? (cont'd)

- Remedial action plans need to be developed that are designed to assist providers in meeting standards but can include the ability to suspend or terminate participation
- Performance results should be taken into consideration at the time of appointment, reappointment and contract renewal, and some internal administrative process/fair hearing for participants who are excluded should be provided

So Now What? (cont'd)

- Health care providers should consider implementation of an Enterprise Risk Management Program which includes an assessment of identifying, measuring, monitoring and managing risk, including quality of care risks that may have an adverse impact on an organization.
- It is important that provider evaluate its processes and procedures, reports, analyses, etc., so as to maximize available confidentiality and immunity protections under state and federal law (e.g., participation in a Patient Safety Organization under Patient Safety and Quality Improvement Act of 2005).

Medical Staff Processes – One Healthcare System's Enterprise Risk Management Approach

Peggy Nakamura, RN, MBA, JD
Vice President, Chief Risk Officer and Associate Counsel

Adventist Health

Medical Staff Processes – One Healthcare System's Enterprise Risk Management Approach

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Adventist Health

What Is ERM and How Is It Different From Traditional Risk Management?

- ERM can be described as a risk-based approach to managing an enterprise, integrating concepts of strategic planning, operations management, and internal control. ERM provides a framework for management, which involves identifying particular events or circumstances relevant to the organization's objectives (risks and opportunities), assessing them in terms of likelihood and magnitude of impact, determining a response strategy, and monitoring progress.

What Is ERM and How Is It Different From Traditional Risk Management?

ERM		RM
Proactive	vs.	Reactive
Strategic	vs.	Incident-specific
Holistic	vs.	Singular risk
Upside of Risk	vs.	Downside of risk

AH Enterprise Risk Management-- Framework and Plan

- Statement: This enterprise risk management (ERM) framework and plan establishes a process for identifying, measuring, monitoring and managing risk that could have a material impact on Adventist Health and its operations.
- Objective: Utilizing the ERM framework and plan guides Adventist Health to:
  - Manage and identify significant risks to the enterprise
  - Align risk appetite with strategic objectives
  - Reduce the frequency and severity of operational losses and surprises
  - Seize and maximize opportunities with a risk aware attitude

AH Enterprise Risk Management-- Framework and Plan

- Structure and Process: The ERM framework and plan shall be presented to the AH Board annually for consideration and approval. SLT will function as the ERM oversight committee and provide overall direction for AH's ERM plan. SLT will, no less than annually, identify and prioritize risks that could impact achievement of system objectives. The ERM plan will include SLT's prioritized risks and accountable individuals to lead a multi-disciplinary team to address select risks. The ERM Risk Assessment Tool will be utilized as a method to comprehensively identify risks, develop loss mitigation strategies and report to SLT.

AH Enterprise Risk Management--Framework and Plan

Risk domains, commonly referred to as categories or areas of risk, are utilized in ERM processes and are listed on the ERM Risk Assessment Tool. The AH ERM framework and plan include the following risk domains:

- People
- Technology
- Strategic
- Financial
- Legal/Regulatory
- Operations

AH Enterprise Risk Management--Framework and Plan

- Monitoring and Control: The Chief Risk Officer (CRO) will, no less than semi-annually, report to SLT on the status of the various loss mitigation strategies and new or emerging risks to the enterprise for SLT's consideration. Specific accountability for implementation and monitoring of loss mitigation strategies will be set forth in the ERM Assessment Tool. The accountable team leader will report quarterly to SLT on approved measures or metrics.

Risk Domains (Category)

- People: The risks that relate to the organization's most valuable asset, the workforce. This area includes employee selection, retention, turnover, competency, compensation, absenteeism, termination and succession planning.
- Technology: The risks associated with the use of technology: hardware, equipment, devices, tools, techniques, systems and methods of organization.
- Strategic: The risks associated with brand, reputation, business strategy, market issues and customer (patient) satisfaction.

Risk Domains (Category)

- Financial**:** The risks that affect the profitability, cash position, access to capital, or external financial ratings through business relationships or the timing and recognition of revenue and expenses.
- Legal/Regulatory: The risks associated with licensure, accreditation, and federal and state statutes, standards and regulations.
- Operations: The risks related to the business operation and that result from inadequate, absent, or failed internal processes, people or systems.

ERM Risk Assessment Tool

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ERM Risk Assessment Tool

Issue/Initiative: _____ **Team Leader:** _____

Date: _____

Risk Domains (Category)	Identified Risk	Actions to Address Risk	Focus/Metrics	Accountability Individual/Department
I. People The risks that relate to the organization's most valuable asset, the workforce. This area includes employee selection, retention, turnover, competency, compensation, absenteeism, termination and succession planning.				
II. Technology The risks associated with the use of technology: hardware, equipment, devices, tools, techniques, systems and methods of organization.				

Adventist Health

ERM Risk Assessment Tool

III. Strategic The risks associated with brand, reputation, business strategy, market issues and customer (patient) satisfaction.				
IV. Financial The risks that affect the profitability, cash position, access to capital, or external financial ratings through business relationships or the timing and recognition of revenue and expenses.				
V. Legal/Regulatory The risks associated with licensure, accreditation, and federal and state statutes, standards and regulations.				
VI. Operations The risks related to the business operation and that result from inadequate, absent, or failed internal processes, people or systems.				

Adventist Health

So . . .

- The Greeley Company commissioned to conduct a comprehensive assessment of each hospital's medical staff peer review processes --
  - How effective are the existing processes?
  - Any facility specific opportunities?
  - Any system-wide opportunities to reduce risk through the adoption of best practices?

The Greeley Company

- Assessment Components
  1. Peer Review Program Process Assessment using the self-assessment rating tool with onsite validation by the consultant
  2. Case Review Effectiveness Assessment based on the data supplied by the facilities
  3. Medical Staff Culture Assessment based on the Greeley Culture Survey

The Greeley Company

- Peer Review Program Self Assessment with Onsite Validation
  - Process benchmarking: Criteria based tool
    - Best practice based criteria, not just regulatory compliance
    - Each criteria measures a single attribute
    - Three level scoring system to identify primary opportunities
    - Facility group score based on a 2 hour meeting
    - Consultant validation of facility criteria scoring

The Greeley Company

Category	Criteria
Structure	10
Leadership	10
Appoint/Reappointment	21
Case Review Process	20
Aggregate Measures	15
Performance Feedback	5
Manage Performance	7
Total Criteria	**88**

Challenges/Risks Identified in a Healthcare System's Medical Staff Processes

- Physician Competency Evaluation and Improvement
  - Insufficient time, resources, knowledge base
  - Inadequate technology to support best practices
  - Lack of a standardized approach to handling patient complaints/patient experience regarding physicians
  - Tension between revenue generation and quality
  - Lack of ability to do cost accounting (i.e., cost ratio)
  - Lack of best practice consistency and sustainability
  - Financial pressures result in inadequate resources to support peer review/OPPE

Challenges/Risks Identified in a Healthcare System's Medical Staff Processes

- Keeping current with legal/regulatory requirements--medical staff documents and knowledge base for medical staff leaders
- Lack of effective and integrated processes and consistent application
- Pressures on peer review: conflict of interest, economic impact, disregarding red flags
- Disconnect between contracting and credentialing
- Disconnect between recruiting and medical staff processes

Challenges/Risks Identified in a Healthcare System's Medical Staff Processes

- Physician Leadership
  - Inadequate skills/training, support, compensation, time, mentoring, empowerment, pool of candidates succession planning, standardization of expectations and best practices
  - Inadequate technology to support best practices and leadership
  - Lack of data regarding patient satisfaction, individual service line results

Challenges/Risks Identified in a Healthcare System's Medical Staff Processes

- Potential for disclosure of confidential documents when new technology is implemented or when leadership changes
- Lack of physician engagement in strategic planning
- Lack of alignment between organizational goals and medical staff goals
- Damage to organization's reputation due to poor/inadequate medical staff processes
- Lack of understanding financial information and financial planning processes

Challenges/Risks Identified in a Healthcare System's Medical Staff Processes

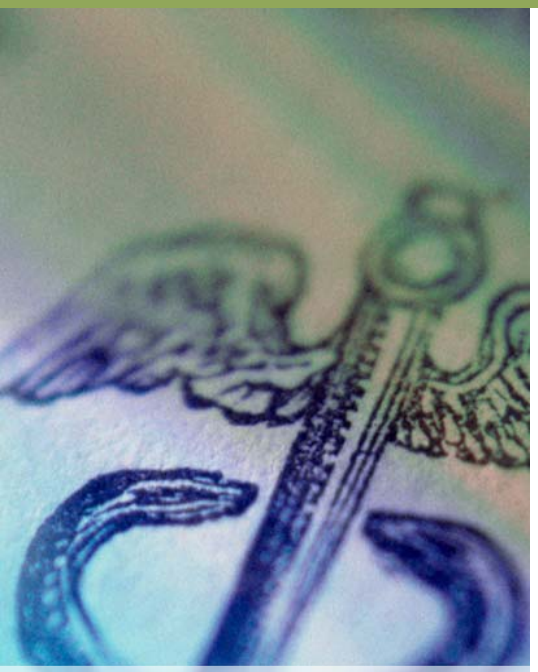
- Lack of standardization regarding physician compensation and medical staff dues
- Inadequate incentive alignment
- Inadequate relevant and real-time business intelligence metrics
- Poor execution of required duties
- Failure to adhere to existing medical staff policy and procedures, bylaws, rules and regulations
- Knowledge deficit in medical staff processes

System Opportunities

- Structure -- ↑ IT infrastructure, ↓committees
- Leadership -- Clear expectations, leadership training
- Appointment/Reappointment -- FPPE timeliness, integrating OPPE data into FPPE
- Case Review Process -- refining review criteria, defining thresholds for FPPE
- Aggregate Data -- Risk adjusted data, medical staff engagement
- Performance Feedback -- feedback on all cases
- Manage Performance -- well-designed intervention, leadership training

2012 Status

- Transitioning to multi-specialty peer review committees
- Medical Staff Processes Steering Committee
- Expanding to include all provider settings: acute care, outpatient, clinics, physician practices
- Developing professionalism policy
- Developing resources for medical staff processes best practices, tools, forms, policies and procedures
- Integrating recruitment activities with medical staff operations



Utilizing PSOs to Maximize Confidentiality and Privilege Protections

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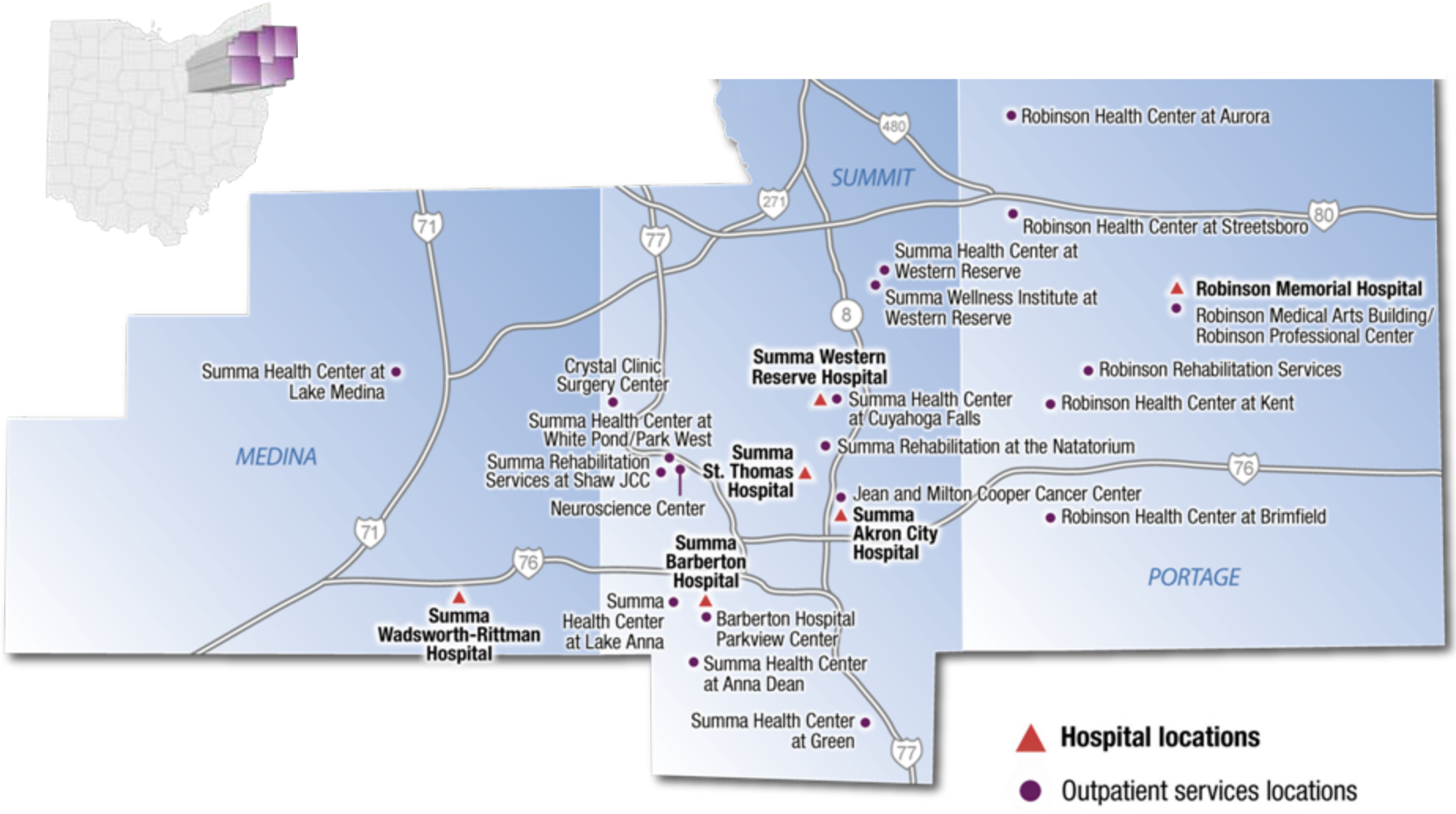
Summa's Service Area



The Integrated Delivery System

SUMMA Health System

Hospitals

Inpatient Facilities
- Tertiary/Academic Campus
- 4 Community Hospitals
- 1 Affiliate Community Hospital
- 2 JV Hospitals with Physicians

Outpatient Facilities
- Multiple ambulatory sites
- Locations in 3 Counties

Service Lines
- Cardiac, Oncology, Neurology, Ortho, Surgery, Behavioral Health, Women's, Emergency, Seniors

Key Statistics
- 2,000+ Licensed Beds
- 62,000 IP Admissions
- 45,000 Surgeries
- 660,000 OP Visits
- 229,000 ED Visits
- 5,000 Births
- Over 220 Residents

Physicians

Multiple Alignment Options
- Employment
- Joint Ventures
- EMR
- Clinical Integration
- Health Plan

Summa Physicians, Inc.
- 265 Employed Physician Multi-Specialty Group

Summa Health Network
- PHO with over 1,000 physician members
- EMR/Clinical Integration Program

Health Plan

Geographic Reach
- 17 Counties for Commercial
- 18 Counties for Medicare
- 55-hospital Commercial provider network
- 41-hospital Medicare provider network
- National Accounts in 2 States

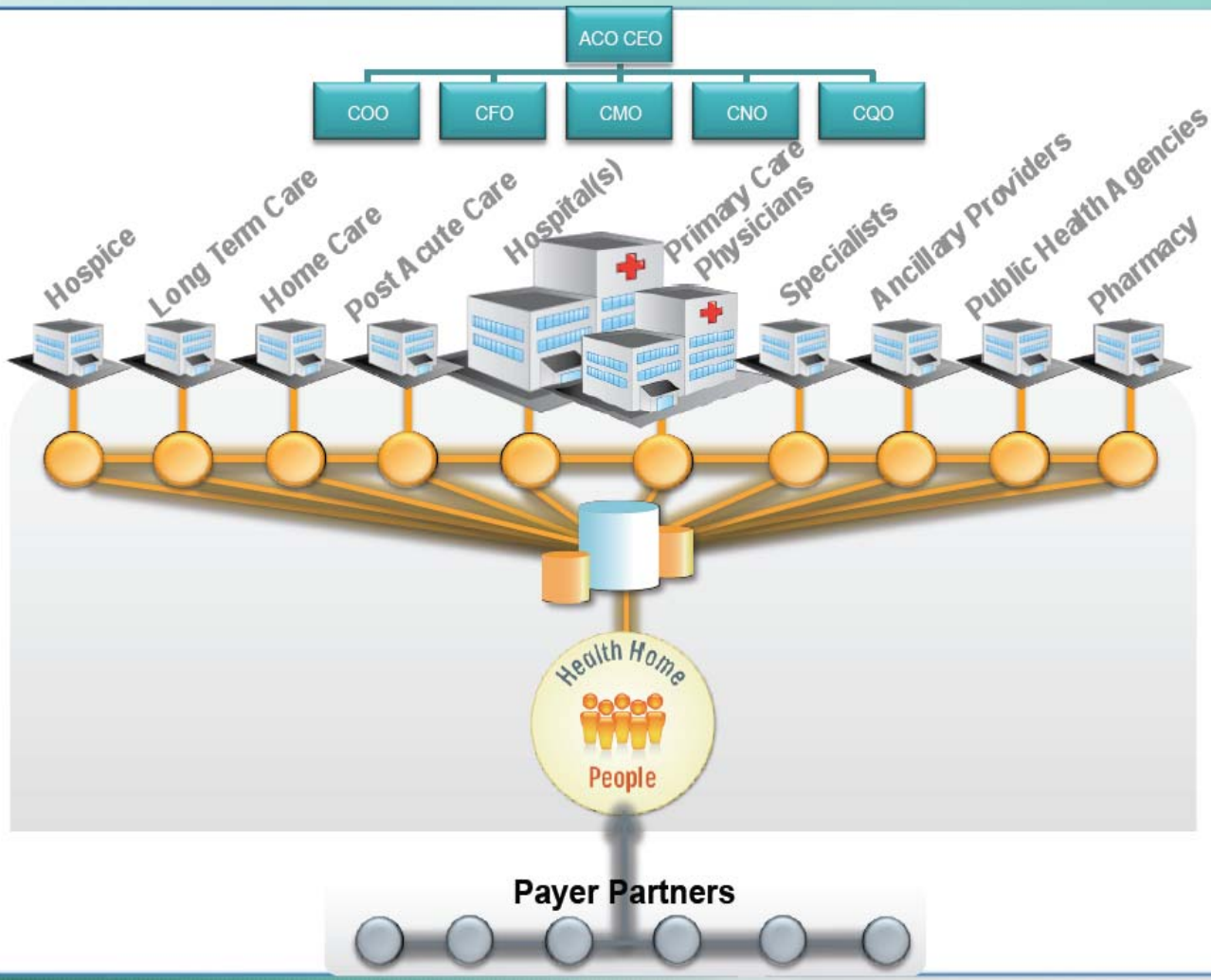
155,000 Total Members
- Commercial Self Insured
- Commercial Fully Insured
- Group BPO/PSN
- Medicare Advantage
- Individual PPO

Foundation

System Foundation Focused On:
- Development
- Education
- Research
- Innovation
- Community Benefit
- Diversity
- Government Relations
- Advocacy

Net Revenues: **Over $1.6 Billion**
Total Employees: **Nearly 11,000**

Complete view of an operational ACO



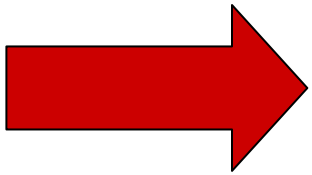
Patient Safety and Quality Improvement Act (PSQIA) Purpose

To encourage the expansion of voluntary, provider-driven initiatives to improve the quality and safety of health care; to promote rapid learning about the underlying causes of risks and harms in the delivery of health care; and to share those findings widely, thus speeding the pace of improvement.

- Strategy to Accomplish its Purpose
  - Encourage the development of PSOs
  - Establish strong Federal and greater confidentiality and privilege protections
  - Facilitate the aggregation of a sufficient number of events in a protected legal environment.

Long-Term Goals of the PSQIA

- **Encourage the development of PSOs**
- **Foster a culture of safety through strong Federal and State confidentiality and privilege protections**
- **Create the Network of Patient Safety Databases (NPSD) to provide an interactive, evidence-based management resource for providers that will receive, analyze, and report on de-identified and aggregated patient safety event information**

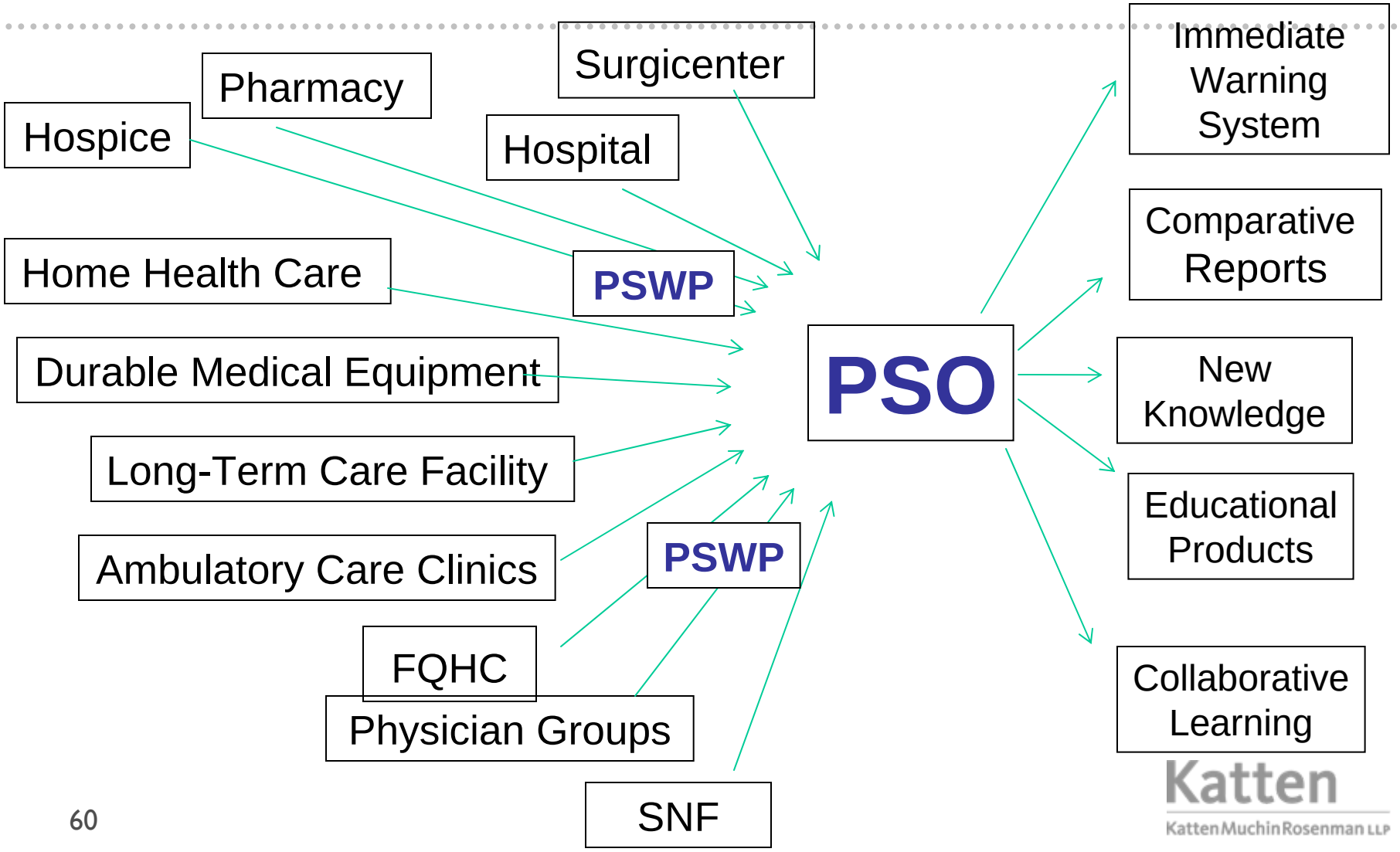


Further accelerating the speed with which solutions can be identified for the risks and hazards associated with patient care through the magnifying effect of data aggregation

Who or What Does the Act Cover?

- Provides uniform protections against certain disciplinary actions for all healthcare workers and medical staff members
- Protects Patient Safety Work Product (PSWP) submitted by Providers either directly or through their Patient Safety Evaluation System (PSES) to Patient Safety Organizations (PSOs)
- Protects PSWP collected on behalf of providers by PSOs, e.g., Root Cause Analysis, Proactive Risk Assessment

PSO Approach & Expected Results



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Essential Terms of the Patient Safety Act

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

Patient Safety Evaluation System (PSES)

PSES Definition

Body that manages the collection, management, or analysis of information for reporting to or by a PSO (CFR Part 3.20 (b)(2))

- Determines which data collected for the PSO is actually sent to the PSO and becomes Patient Safety Work Product (PSWP)
- PSES analysis to determine which data is sent to the PSO is protected from discovery as PSWP

Patient Safety Work Product (PSWP)

PSWP Definition

Any data, reports, records, memoranda, analyses (such as Root Cause Analyses (RCA)), or written or oral statements (or copies of any of this material) which could improve patient safety, health care quality, or health care outcomes;

And that:

- Are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a PSES for reporting to a PSO, and such documentation includes the date the information entered the PSES; or
- Are developed by a PSO for the conduct of patient safety activities; or
- Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES

What is NOT PSWP?

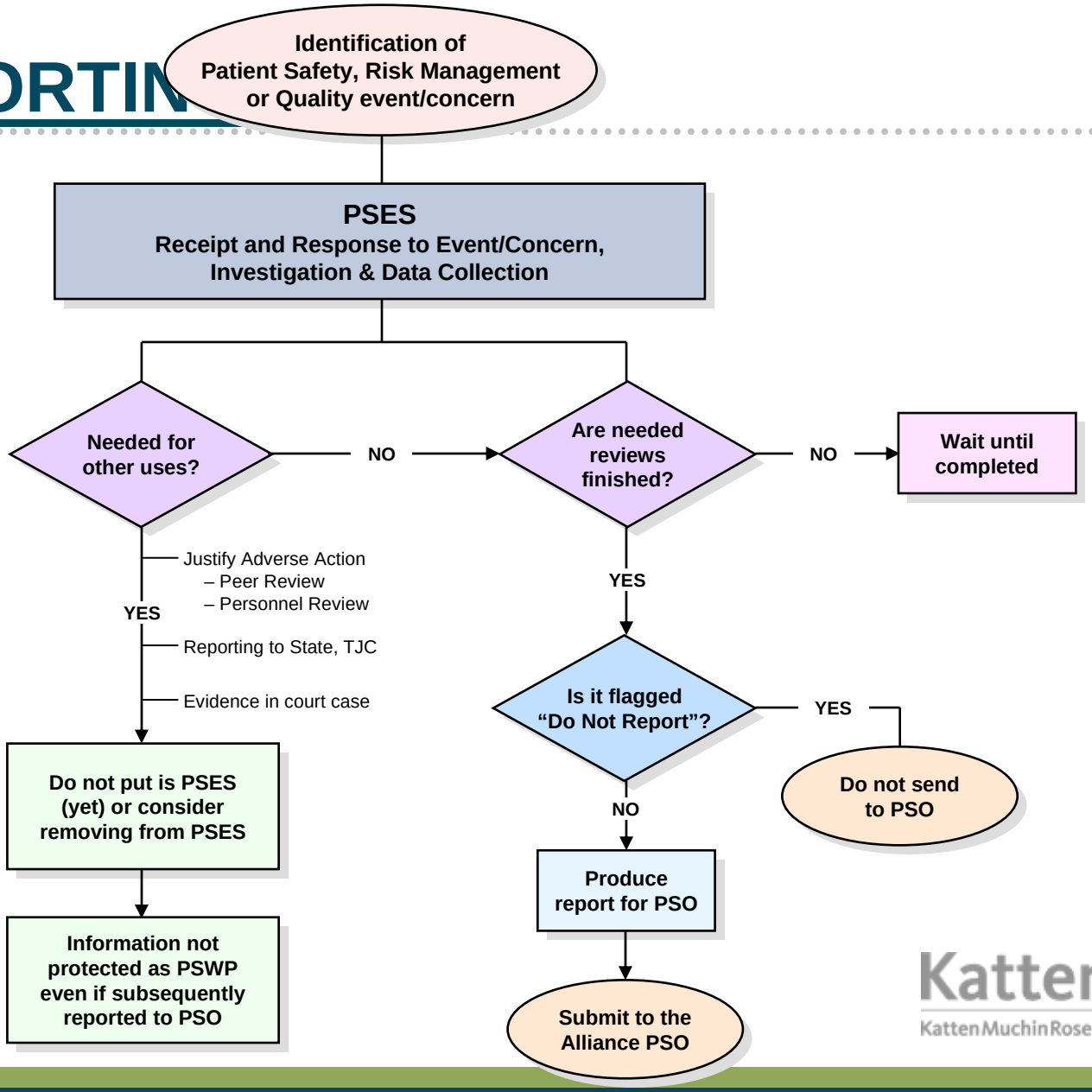
- Patient's medical record, billing and discharge information, or any other original patient or provider information
- Information that is collected, maintained, or developed separately, or exists separately, from a PSES. *Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered PSWP*
- PSWP assembled or developed by a provider for reporting to a PSO but removed from a PSES and no longer considered PSWP if:
  - Information has not yet been reported to a PSO; and
  - Provider documents the act and date of removal of such information from the PSES

What is Required?

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

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

PSO REPORTIN



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Designing Your PSES

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

Event/Incident Reporting Policy

- Modify existing policies as needed to reflect the purpose of internal event reporting is to …
  - Improve patient safety, healthcare quality and patient outcomes
  - Provide learning opportunity through reporting to a PSO
- Include a process (through the PSES) for the removal of incidents from PSES or separate system for …
  - Disciplinary action
  - Just culture
  - Mandatory state reporting
  - Independent/separate peer review

Questions To Answer When Developing PSES Policy

Who or What Committee(s)

- Collects data that will be reported to a PSO?
  - Single source or multiple sites?
  - Single department or organization wide event reporting?
- Analyzes data that will be reported to a PSO?
- Removes data from PSES prior to reporting to a PSO?
- Submits the data from the PSES to the PSO(s)?
  - Committee or individual authorized submission?

Questions To Answer When Developing PSES Policy

What data should be …

- Collected to report to a PSO?
  - Patient safety data, healthcare quality and outcomes data
    * Data cannot be used for adverse disciplinary, versus remedial, employment action, mandated state reporting
- Removed from PSES prior to reporting to a PSO?
  - Criteria based or subjective case-by-case decision making
  - Peer review information that could lead to disciplinary action
- When is data …
  - Reported to PSES?
  - Removed from PSES?
  - Reported to PSO?
    * Each date must be documented

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

Criteria-based Prioritization

Suggested criteria

- Promotes culture of safety/improves care
- Impressions/subjective data that is not available in the medical record
- Information that could be damaging during litigation
- Not required to report elsewhere
- Required to report elsewhere, but data for reporting could be obtained from medical record
- Data will not be used to make adverse employment decisions

Types of Data PSES May Collect and Report To The PSO

- Medical Error, FMEA or Proactive Risk Assessments, Root Cause Analysis
- Risk Management – incident reports, investigation notes, interview notes, RCA notes, notes rec'd phone calls or hallway conversations, notes from PS rounds
- Outcome/Quality—may be practitioner specific, sedation, complications, blood utilization etc.
- Peer Review
- Committee minutes–Safety, Quality, Quality and Safety Committee of the Board, Medication, Blood, Physician Peer Review

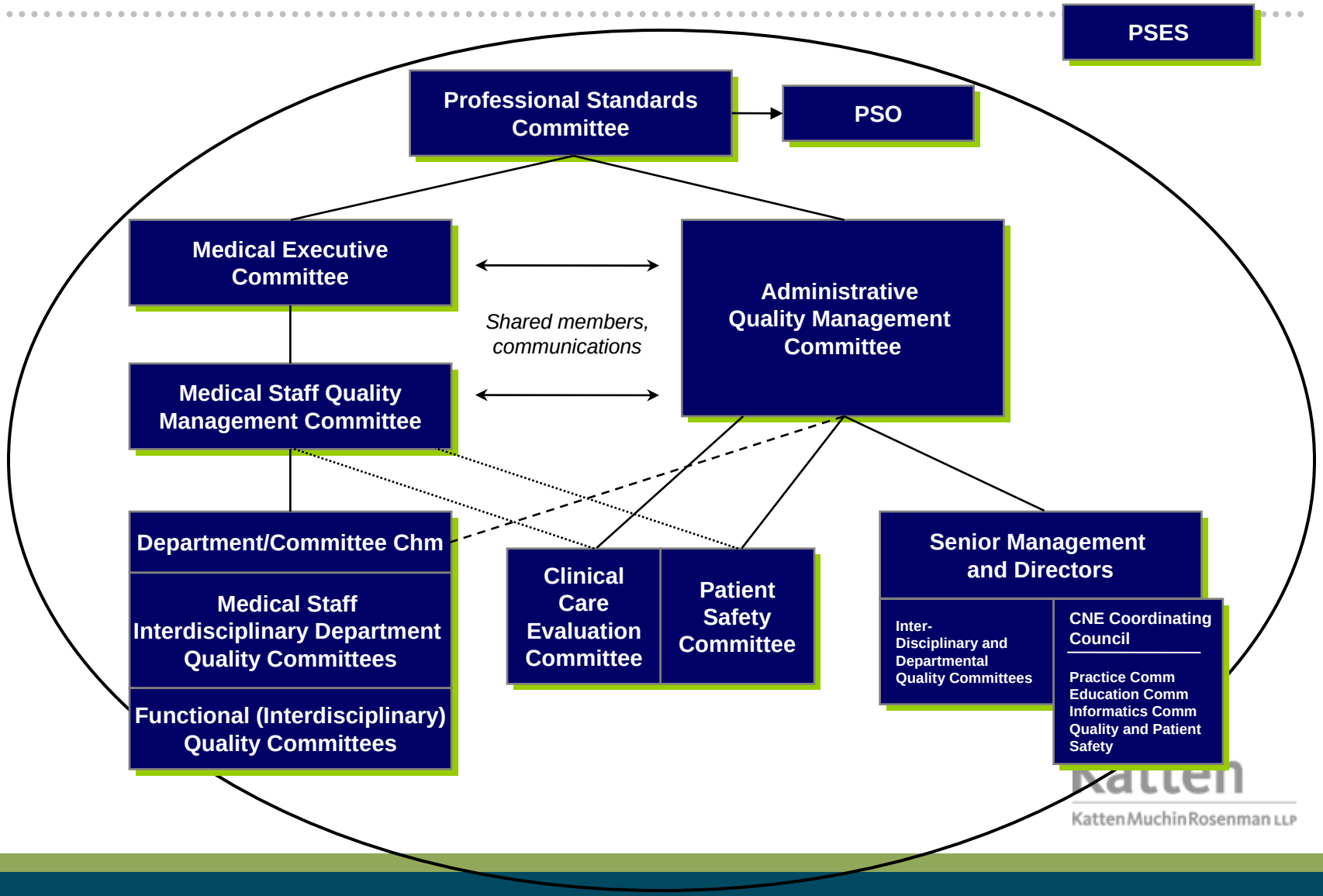
PA Patient Safety Authority: Reports Identify Trends

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

Steps to PSO Reporting

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

PSO Reporting Process



Confidentiality and Privilege Protections

Patient Safety Work Product

In order to optimize protection under the Act:

- Understand the protections afforded by the Act
- Inventory data from all sources to determine what can be protected
- Internally define your PSES
- Complete appropriate policies on collection, analysis and reporting
- Develop component PSO and/or select listed PSO

Patient Safety Work Product Privilege

PSWP is privileged and shall not be:

- Subject to a federal, state, local, Tribal, civil, criminal, or administrative subpoena or order, including a civil or administrative proceeding against a provider
- Subject to discovery
- Subject to FOIA or other similar law
- Admitted as evidence in any federal, state, local or Tribal governmental civil or criminal proceeding, administrative adjudicatory proceeding, including a proceeding against a provider
- Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law

Patient Safety Work Product

Exceptions:

- Disclosure of relevant PSWP for use in a criminal proceeding if a court determines, after an in camera inspection, that PSWP
  - Contains evidence of a criminal act
  - Is material to the proceeding
  - Not reasonably available from any other source
- Disclosure through a valid authorization if obtained from each provider prior to disclosure in writing, sufficiently in detail to fairly inform provider of nature and scope of disclosure

Patient Safety Work Product Confidentiality

Confidentiality:

PSWP is confidential and not subject to disclosure

Exceptions:

- 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 patent safety activities
- Disclosure to a contractor of a PSO or provider
- Disclosure among affiliated providers
- Disclosure to another PSO or provider if certain direct identifiers are removed
- Disclosure of non-identifiable PSWP
- Disclosure for research if by a HIPAA covered entity and contains PHI under some HIPAA exceptions
- Disclosure to FDA by provider or entity required to report to the FDA regarding quality, safety or effectiveness of a FDA-regulated product or activity or contractor acting on behalf of FDA

Patient Safety Work Product Confidentiality

Exceptions (cont'd):

- Voluntary disclosure to accrediting body by a provider of PSWP but if about a provider who is not making the disclosure provider agrees identifiers are removed
  - Accrediting body may nor further disclose
  - May not take any accrediting action against provider nor can it require provider to reveal PSO communications
- Disclosure for business operations to attorney, accountants and other professionals who cannot re-disclose
- Disclosure to law enforcement relating to an event that constitutes the commission of a crime or if disclosing person reasonably suspects constitutes commission of a crime and is necessary for criminal enforcement purposes

Enforcement

- Confidentiality
  - Office of Civil Rights
  - Compliance reviews will occur and penalties of up to $10,000 per incident may apply
- Privilege
  - Adjudicated in the courts