PSO 101: Overview of Patient Safety Act

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Michael's peers regard him as "one of the top guys […] for credentialing—he's got a wealth of experience" (Chambers USA). Additionally, his clients describe him as "always responsive and timely with assistance," and say he is "informed, professional and extremely helpful" and "would recommend him without reservation" (Chambers USA). Michael's clients also commend his versatility, and say "He is willing to put on the hat of an executive or entrepreneur while still giving legal advice," according to Chambers USA.

He is a frequent speaker on topics including ACOs, health care reform, PSOs, health care liability and peer review matters. He has presented around the country before organizations such as the American Health Lawyers Association, the American Medical Association, the American Hospital Association, the American Bar Association, the American College of Healthcare Executives, the National Association Medical Staff Services, the National Association for Healthcare Quality and the American Society for Healthcare Risk Management.

Michael was recently appointed as chair of the Medical Staff Credentialing and Peer Review Practice Group of the American Health Lawyers Association. He also was appointed as the public member representative on the board of directors of the National Association Medical Staff Services.

He was an adjunct professor in DePaul University's Master of Laws in Health Law Program, where he taught a course on managed care. After law school, he served as a law clerk to Justice Daniel P. Ward of the Illinois Supreme Court.
Speaker Bios

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Ellen Flynn RN, MBA, JD is currently the AVP, Patient Safety and Accreditation Programs for the UHC Safety Intelligence® PSO. Previously, she held the position of Director of Quality at UHC. Ellen has over 30 years of healthcare experience and managed quality, safety, and patient experience departments in large academic medical centers and health systems including Rush System for Health, Children’s Hospital of Wisconsin, and Universal Health Services. Prior to returning to UHC, Ellen was the Manager, Health Industries Advisory Services at PricewaterhouseCoopers LLP. Ellen has a Juris Doctor degree from Loyola University School of Law, an MBA, Management Information System from DePaul University and a Bachelor of Science in Nursing from Loyola University.

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Mr. Pavkovic brings a diverse background to his current role as the Senior Director of Patient Safety at Vizient the nation’s largest member-owned health care company. While working as an operating room nurse and manager, he earned advanced degrees in public health and law. His legal career included defending healthcare providers from claims of professional malpractice, working for county government as a health law attorney and practicing as a healthcare risk manager at an academic medical center. At Vizient, he draws on these professional experiences to assist members in identifying patient safety improvement and loss control opportunities. He is a frequent national presenter and published author on a variety of risk management and patient safety topics.
Disclaimer

- The opinions expressed in this presentation do not reflect the official position of the Agency for Healthcare Research and Quality (AHRQ) or the Office of Civil Rights (OCR).
- This information is not being offered as legal or medical advice.
PSO 101: Overview of Patient Safety Act

The purpose of this program is to provide an overview of the Patient Safety Act and the fundamental principles and requirements under the Act. It is designed for hospitals and other licensed health care providers and facilities considering whether to participate in a PSO as well as to serve as a refresher course for current PSO participants. Topics to be discussed including the following:

- Overview of Patient Safety Act
- What is a Patient Safety Evaluation System (PSES) and how is it formed?
What information can be considered privileged and confidential patient Safety Work Product (PSWP), which is not subject to discovery or admissibility into evidence?

What patient safety activity benefits can a PSO provide?

Do the protections apply to all state and federal proceedings?

What is “functional reporting” to a PSO?

How can a clinically integrated network participate in a PSO?
Based on the basic principles and requirements described in the PSO 101 presentation, this program will review a number of patient safety scenarios involving adverse events, patient injuries, peer review issues and malpractice litigation. Among the areas to be addressed are the following:

- What information can be collected within a PSES and shared internally and externally?
- What if the state, CMS or The Joint Commission come knocking? Do I have to turn over my PSWP?
- Can peer review information be included in a PSES? What are the pros and cons?
PSO 201: PSO Standards Applied to Real-World Scenarios (cont’d)

- How is patient safety information collected in the PSES and actually reported to a PSO?
- Can PSWP be shared with third parties? If so, how?
- Are the protections ever waived?
- What are the disclosure exceptions?
One of the reasons providers have been reluctant to participate in PSOs is because there have been very few reported trial and appellate court decisions which have interpreted the Patient Safety Act. Most challenges to date have involved malpractice plaintiffs who have sought to discover PSWP including incident reports, peer review and other quality improvement information.

The purpose of this program is as follows:

- Review of some of the key appellate court cases, including:
  - *Tibbs v. Bunnell*, currently before the US Supreme Court
PSO 301: Discussion of PSO Court Cases and the Litigation Lessons Learned (cont’d)

- **Walgreen v. Illinois Department of Financial and Professional Services**
- **Charles v. Southern Baptist Medical Center**

- What are the litigation lessons learned?
- What arguments are plaintiffs making to gain access to PSWP?
- What steps do providers need to take in anticipation of these arguments?
- What are the best ways to educate courts when contesting a discovery request?
Health Care Reform and PSOs

- Medicare/Medicaid and private payers are now reimbursing providers based on documented compliance with established quality metrics and outcome measures.

- Examples of this shift from volume to value as a condition of payment include:
  - Medicare Shared Savings ACOs
  - Value-based purchasing outcome standards
  - Pay for performance standards
  - Readmission rate penalties
  - Hospital acquired condition/Infection penalties
  - HHS has set a goal of tying 85% of all of its traditional Medicare payments to quality or value metrics
Health Care Reform and PSOs (cont’d)

- In order to meet these ever evolving standards, clinically integrated networks, hospitals and other providers will need to implement these standards into their appointment, reappointment, ongoing monitoring and similar processes in order to track performance and implement remedial measures, including disciplinary action for non-compliance not only because of the potential adverse impact on patients but also because it will result in reduced reimbursement.

- The result of these efforts will be the creation of very sensitive quality, risk and peer review analyses, reports, studies, and other information, most of which may not be protected under existing state laws.
Health Care Reform and PSOs (cont’d)

- As will be discussed during this presentation, participation in PSOs therefore play a very important role in being able to conduct these patient safety, quality and risk activities in a protected space in order to continue to improve patient care services.
Background

Congress enacted the Patient Safety and Quality Improvement Act of 2005 in response to the IOM report “To Err is Human” to address national concerns over number of preventable errors that were occurring.

By granting privilege and confidentiality protections to providers who work with a federally-listed Patient Safety Organization (PSO), the Act was intended to nationally enhance health care quality and safety.

AHRQ created the Common Formats to help providers uniformly report to PSOs patient safety event for aggregation and analysis.

PSOs are required to collect and analyze data in a standardized manner using the AHRQ Common Formats to identify safety improvement opportunities, and share learnings widely.
Background

Legislative History:

- Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act)
- Signed into law July 29, 2005
- Final rule released November 21, 2008
- Rule took effect January 19, 2009
- CMS issued final regulations for Sec. 1311 of the Affordable Care Act in March of 2014

  - All hospitals > 50 beds are required to have a Patient Safety Evaluation System (PSES), which may mean a relationship with a PSO, to be part of a qualified health plan (QHP) participating in a Health Insurance Exchange (HIE). There is a two-year phase-in period: Jan 1, 2015 to Jan 1, 2017.
Background (cont’d)

- CMS issued a proposed regulation which affirms the January 1, 2017 but would allow a QHP to enter into a hospital provider agreement if it has a PSES or participates in a Health Enterprise Network (HEN) or has a contract with a Quality Improvement Organization (QIO).

- The privilege and confidentiality protections, however, are only afforded to licensed providers which participate in a PSO and not those which only are in a HEN or a QIO arrangement.
The Patient Safety and Quality Improvement Act of 2005

- The goal of the Act was to improve patient safety by encouraging voluntary and confidential reporting of health care events that adversely affect patients. To implement the Patient Safety Act, the Department of Health and Human Services issued the Patient Safety and Quality Improvement Rule (Patient Safety Rule).

- The Patient Safety Act and the Patient Safety Rule authorize the creation of PSOs to improve quality and safety through the collection and analysis of aggregated, confidential data on patient safety events. This process enables PSOs to more quickly identify patterns of failures and develop strategies to eliminate patient safety risks and hazards.
The Patient Safety and Quality Improvement Act of 2005 (cont’d)

- Provides privilege & confidentiality protections for information when providers work with Federally listed PSOs to improve quality, safety and healthcare outcomes
- Authorizes establishment of “Common Formats” for reporting patient safety events
- Establishes “Network of Patient Safety Databases” (NPSD)
- Requires reporting of findings annually in AHRQ’s National Health Quality / Disparities Reports
Patient Safety Act

- Facilitates development of a safe and protected learning space where providers focus on improving care versus legal or disciplinary implications of findings.
- Allows provider organizations to maintain a “Just” culture of accountability with deliberate PSES set-up.

- Enables all licensed providers to receive equal protections.
- Supports new healthcare models that place more and more responsibility on non-physician healthcare providers and corporate parent organizations.

- Enables healthcare providers to collaborate and learn from quality, safety and healthcare outcome initiatives that cross state lines without legal ramifications.
Patient Safety Act

- **Early recognition**
  • Supports risk mitigation by creating awareness of provider opportunities that can be gleaned by a PSO that aggregates large volumes of event data across many similar providers.

- **Meaningful comparison**
  • Encourages data collection, aggregation and analysis amongst similar providers in a common format to allow for meaningful comparisons and easier identification of improvement opportunities.

- **Flexible Participation**
  • Allows providers to negotiate with PSOs about the quantity and type of data reported and the type of analysis and feedback provided by the PSO.
Key Components of Patient Safety Act

- **PSOs** – Almost any entity can be or have a PSO. PSOs serve as independent, external experts who can collect, analyze, and aggregate Patient Safety Work Product to develop insights into the underlying causes of quality and patient safety events.
- **Providers** – An individual or entity licensed or otherwise authorized under State law to provide health care services and/or a parent organization of one or more entities licensed or otherwise authorized to provide health care services.
- **Patient Safety Events** – Incidents or near misses or unsafe conditions
- **Any type of event that adversely affects healthcare quality, patient safety or healthcare outcomes**
- **Common Formats** – Provide a uniform way to measure patient safety events clinically & electronically and to permit aggregation & analysis locally, regionally, & nationally.
Patient Safety Activities

- Efforts to improve patient safety and the quality of health care delivery;
- The collection and analysis of patient safety work product;
- The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
- The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
Patient Safety Activities (cont’d)

- The maintenance of procedures to preserve confidentiality with respect to patient safety work product;
- The provision of appropriate security measures with respect to patient safety work product;
- The utilization of qualified staff; and
- Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.
What is Patient Safety Work Product (PSWP)?

**Requirements**

- Data which could improve patient safety, health care quality, or health care outcomes
  - Data assembled or developed by a provider for reporting to a PSO and are reported to a PSO
  - Data developed by a PSO to conduct of patient safety activities

**Must be created in PSES**

Deliberation and Analysis

Reports

Oral and Written Statement

Data

Memoranda

Records

Key dates must be documented

PSWP

Analysis and deliberations conducted within a PSES
What is Not PSWP?

- Data removed from PSES
- Medical record
- Not PSWP
- Data collected for another reason
- Billing
- Other original record

Requirements

- Information collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system.

- Data removed from a patient safety evaluation system

- Data collected for another reason
The collection, management, or analysis of information for reporting to or by a PSO. A provider's PSES is an important determinant of what can, and cannot, become patient safety work product.
PSES Operations

Establish and Implement Your PSES to:

- **Collect** data to improve patient safety, healthcare quality and healthcare outcomes
- **Review** data and takes action when needed to mitigate harm or improve care
- **Analyze** data and makes recommendations to continuously improve patient safety, healthcare quality and healthcare outcomes
- Conduct RCAs, Proactive Risk Assessments, in-depth reviews, and aggregate RCAs
- Determine which data will/will not be reported to the PSO
- **Report to PSO**
- Conduct auditing procedures
PSES Operations (cont’d)

Examples in PSES for collecting and reporting to a PSO:

- Medical Error investigations, FMEA or Proactive Risk Assessments, Root Cause Analysis
- Risk Management - incident reports, investigation notes, interview notes, RCA notes, notes from risk recommendations via phone calls or conversations, notes from PS rounds which relate to identified patient safety activities
- Outcome/Quality - may be practitioner specific, sedation, complications, blood utilization etc.
- Peer Review
- Committee minutes – Those portions of Safety, Quality, Quality and Safety Committee of the Board, Medication, Blood, Physician Peer Review relating to identified patient safety activities
Steps to documenting a provider PSES

**PSES means the collection, management, or analysis of information for reporting to or by a PSO**

- **Goals**: Define Goals for working with a PSO
- **Workforce**: Identify staff that will support PSES activities
- **Workspace and Equipment**: Define PSES workspace and equipment
- **Data collection, analysis and deliberation**: Define and prioritize data collection, analysis and deliberation
- **Communication**: Identify PSWP use and communication with PSO and within provider
- **Revise Policies**: Review and revise pertinent policies and procedures
- **Evaluate**: Evaluate impact of PSO participation
PSES Consideration Checklist

PSES participation decisions – preparing to assert privilege and confidentiality protections generates from consistency in practice
- Internal communication
  - Involving other clinical departments
- External communication
  - Involving your defense counsel
- How to assert a claim of privilege and confidentiality
- Handout available
Prioritizing Data for PSO Reporting

**High** = subjective or judgmental information, event contributing factors, recommendations for improvement  
**Medium** = additional facts that clarify understanding about the event  
**Low** = basic facts that may be available in the medical record (original not PSWP)

<table>
<thead>
<tr>
<th>Data</th>
<th>Main Purpose</th>
<th>Other Uses</th>
<th>Priority for Reporting</th>
<th>Type</th>
<th>Report to PSO</th>
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<tr>
<td>System peer review</td>
<td>Patient safety, healthcare quality and outcomes</td>
<td>None</td>
<td>High</td>
<td>PSWP</td>
<td>Yes - original</td>
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<tr>
<td>System patient safety committee</td>
<td>Patient safety</td>
<td>None</td>
<td>High</td>
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<td>Yes - original</td>
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<tr>
<td>Completed actions</td>
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<td>Patient safety</td>
<td>Medium</td>
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<td>Yes - copy</td>
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<tr>
<td>RCA conducted within PSES</td>
<td>Patient safety</td>
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<td>High</td>
<td>PSWP</td>
<td>Yes - original</td>
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<tr>
<td>Hospital OPPE</td>
<td>Reappoint physicians</td>
<td>Patient safety</td>
<td>Medium</td>
<td>Not PSWP</td>
<td>Yes - copy</td>
</tr>
</tbody>
</table>
Prioritizing PSO Submission Activities

This graph displays one way to prioritize those activities that will be reported to a PSO. This grid should be created based upon results of data inventory. The x axis shows data that may be problem prone, the y axis displays the probability this data would be discoverable without the PSO privilege and confidentiality protections or ineligible for protections. The color identifies the primary purpose and the size of the bubble identifies the frequency of the activity.
Functional reporting

What is it?

Reporting of information to a PSO for the purposes of creating patient safety work product may include authorizing PSO access, pursuant to a contract or equivalent agreement between a provider and a PSO, to specific information in a patient safety evaluation system and authority to process and analyze that information, e.g., comparable to the authority a PSO would have if the information were physically transmitted to the PSO.

Considerations:

• How is it maintained by Provider within PSES
• How can the PSO retain the same responsibilities for privacy and security
Functional reporting (cont’d)

- What type of Functional Reporting agreement with PSO is necessary that describes how PSO will access to the data and utilize the data to identify quality, patient safety and healthcare outcome improvements.
- Must decide how and when functional reporting has taken place and must document same.

If PSWP Is Functionally Reported, PSO Must Have Access
Drop-Out Provision

The Patient Safety Rule provides a limited opportunity for a provider to remove PSWP protections from information that the provider entered into its PSES for reporting to a PSO.

The drop-out provision can be used for any reason, provided the information that the provider had placed in its PSES has not been reported to a PSO and the provider documents the action and its date.

Upon removal, the information is no longer protected. The drop-out provision cannot be used if the information has been reported to a PSO and it does not apply to information that describes or constitutes the deliberations or analyses of a PSES.
Maintain JUST Culture when Removing Data From PSES Before Reporting to PSO

Provider Operations

**Pre**
- Set expectations for reporting and use of data

**After Removal**
- Take disciplinary action
- Report to external agencies
- Use for another purpose

**Use of PSWP**
- Share data within organization to improve patient safety, healthcare quality and outcomes

PSES Operations

- Review data
- Remove data before reporting, document, and date
- Conduct patient safety activities, document, and date
- Report data to PSO, document and date
- Receive PSWP from PSO

PSO Operations

- Conduct Deliberations
- Conduct analysis
- Collect additional data
- Provide PSWP feedback
- Offer Evidence based recommendations

NPSD

- Receive PSWP
- Offer evidence based recommendations
PSO Participation Schematic

WORKING WITH A PSO: ONE APPROACH

Patient Safety and Quality Information

Information Triage by Provider

Information Eligible to Become PSWP
- Could improve safety, quality, or outcomes of health care, and
- Assembled or developed solely for reporting to PSO (not for other purposes)

Information not Eligible to Become PSWP
- Excluded by definition of PSWP (1); or
- Collected or developed for purposes other than reporting to a PSO, such as:
  - Corporate and external recordkeeping requirements
  - Inspection, survey, or external reporting requirements (Federal or State)
  - Other business purposes, such as claims, etc.

Provider PSES
- Date and document incoming information upon entry
- Analyze or deliberate (3)
- **Option:** Remove incoming information before reporting to the PSO (4)
- Prepare and report incoming information to PSO

Provider may enter a copy of "ineligible" information into its PSEF (2)

Information reported to the PSO or accessible by the PSO, pursuant to functional reporting, is PSWP (5)

PSO PSES
- Conduct required patient safety activities
- Provide feedback to provider PSES
- Prepare data to submit to PSOPPC

**Nonidentifiable Patient Safety Event Data**

Feedback to provider by PSO is PSWP

Abbreviations
- PSO = Patient Safety Organization
- PSWP = Patient Safety Work Product
- PSEF = Patient Safety Evaluation System
- PSOPPC = PSO Privacy Protection Center
- NPSD = Network of Patient Safety Databases

Footnotes:
1. Paragraph (2)(i) of the PSWP definition under the Patient Safety Rule (42 CFR§3.20) lists types of information that are not eligible to become PSWP.
2. Never report to the PSO, as PSWP, originals of ineligible information. Only copies of ineligible information or information dropped out of the PSEF can be reported to the PSO.
3. When analyses and deliberations are conducted in the PSES, PSWP protections will apply immediately; the drop-out provision does not apply.
4. Verify that incoming information is eligible to be PSWP before reporting to the PSO. The drop-out provision applies only to incoming information that has not yet been reported to a PSO. The provider must document the date and act of removing incoming information from the PSEF.
5. The drop-out provision cannot be applied to information that has been actually or functionally reported.
PSWP is Privileged:

**Not Subject to:**
- subpoenas or court order
- discovery
- FOIA or other similar law
- requests from accrediting bodies or CMS

**Not Admissible in:**
- any state, federal or other legal proceeding
- state licensure proceedings
- hospital peer review disciplinary proceedings
Patient Safety Act Privilege and Confidentiality Prevail Over State Law Protections

The privileged and confidentiality protections and restriction of disciplinary activity supports development of a Just Learning Culture

State Peer Review

- Limited in scope of covered activities and in scope of covered entities
- State law protections do not apply in federal claims
- State laws usually do not protect information when shared outside the institution – considered waived

Patient Safety Act

- Consistent national standard
- Applies in all state and federal proceedings
- Scope of covered activities and providers is broader
- Protections can never be waived
- PSWP can be more freely shared throughout a health care system
- PSES can include non-provider corporate parent

Working with a PSO must be implemented in a way that facilitates a Just Learning Environment while taking advantage of privilege and confidentiality protections.
PSWP is confidential and not subject to disclosure with limited exceptions.
Centralized PSES Model

PSES Role-PSWP
- Deliberations
- Analysis
- Recommendations
- Additional data collection

Regulatory Committee- not PSWP
- Completed actions
- Review of factual data
- Review of state, CMS and TJC required data

- Pharmacy and Therapeutics Committee
- Security EOC Committee
- Infection Control Committee
- Medical Executive Committee
- Grievance Committee
- OPPE
- FPPE
- QA PI Safety Committee
- PSES - PSWP Patient Safety Committee
Decentralized PSES Model

Information Eligible to Become PSWP
- Data aggregation, deliberations and analysis of PSWP and non-PSWP
- Review of specific actual and near miss event reports developed solely for reporting to PSO
- Activities initiated with the goal of learning, improving and enhancing patient safety and quality of care

Information NOT Eligible to Become PSWP
Collected/developed for purposes other than for reporting to PSO
- Claims, medical records
- Accreditation/regulatory survey information
- State regulatory record keeping requirements

Pharmacy & Therapeutics Committee

Agenda / Meeting Minutes

Standard Reports:
- Formulary recommendations
- Number of actual events
- Number of adverse-drug-event reports
- Medication-error prevention literature review
- Actions: Medication Protocols, Policy & Procedure changes etc.

Executive Session for Medication Safety Review in PSES
- Review of specific case: MR XX44321
- Analysis of Root Cause Analysis Action / Monitoring Plan in response to near miss
- Recommended actions
**Healthcare Systems Data Sharing**

- Patient safety rule allows healthcare systems to share data within a protected legal environment, both within and across states, without the threat that the information will be used against the subject providers.

- These protections do not relieve a provider from its obligation to comply with other Federal, State, or local laws pertaining to information that is not privileged or confidential under the Patient Safety Act.

- The Patient Safety Act is clear that it is not intended to interfere with the implementation of any provision of the HIPAA Privacy Rule.
Healthcare Systems Data Sharing (cont’d)

- Health System may require facilities and/or providers to report to a designated PSO.
- A patient safety event reporting requirement can be consistent with the statutory goal of encouraging organizational providers to develop a protected confidential sphere for examination of patient safety issues.
Healthcare Systems Data Sharing (cont’d)

- Affiliated providers may disclose identifiable PSWP.
- Certain provider entities with a common corporate affiliation, such as integrated health systems, may have a need, just as a single legal entity, to share identifiable and non-anonymized patient safety work product among the various provider affiliates and their parent organization for patient safety activities. Provider entities can choose not to use this disclosure mechanism if they believe that doing so would adversely affect provider participation, given that patient safety work product would be shared more broadly across the affiliated entities.
Patient Safety Evaluation System (PSES)

- Patient Safety Final Rule permits the establishment of a single patient safety evaluation system.
Or permits the sharing of patient safety work product as a patient safety activity among affiliated providers.

Will Sharing PSWP across affiliated providers inhibit learning culture?
Centralized PSES Model

- Information not required by regulators
- Corporate activity may fall within Patient Safety Final Rule

![Diagram showing Centralized PSES Model with various committees and their interactions.](image-url)

**Key Committees**:
- Health System PSES - PSWP
- Patient Safety Committee
- Pharmacy
- Grievance
- Medical Executive
- Security
- Infection Control
- QA PI Safety Committee
- OPPE
- FPPE

**Corporate Activity**:
Information not required by regulators. Corporate activity may fall within Patient Safety Final Rule.
How to Structure Health Care Systems, Clinically Integrated Networks and Other Affiliated Providers in Order to Benefit From Patient Safety Act Protections
Key Steps, Terms and Requirements

- Identify and implement your PSES
  - Create list of all peer review, quality, risk management and other patient safety activities
  - Identify the committee, reports and analyses related to these activities that you want to collect in the PSES for reporting to a PSO
- Identify individuals who need to access and work with PSWP as part of their jobs or responsibilities – these people are your Work Force members
- Identify what PSWP information you want to collect and share within your health care system/CIN
Key Steps, Terms and Requirements (cont’d)

- Identify the affiliated providers, unaffiliated providers, joint venture entities and other licensed entities you want to include in your PSES or to participate in the PSO
  - Identifiable or non-identifiable?

- Do you intend to use attorneys, accountants and/or contractors to assist you in furthering identified PSES patient safety activities?
  - You will need appropriate BAAs, confidentiality agreements and contracts
Key Steps, Terms and Requirements (cont’d)

Definitions

- Provider

  “An individual or entity licensed or otherwise authorized under state law to provide health care services. . .”

  “A parent organization of one or more [licensed providers] that manages or controls one or more [licensed providers]”

- Provider examples include:
  - Hospitals
  - Physicians and physician groups
  - Nursing facilities
Key Steps, Terms and Requirements (cont’d)

- Patient centered medical homes
- Surgicenters
- Pharmacies
- APNs, PAs, SAs

- Parent Organization

“Owns a controlling interest or a majority interest in a component organization; or

Has the authority to control or manage agenda setting, project management, or day-to-day operations;

Or authority to review and override decisions of a component organization.

The component organization may be a provider.”
Key Steps, Terms and Requirements (cont’d)

- **Component Organization**
  - “Is a unit or division of a legal entity (including a corporation, partnership, or a Federal, State, local or Tribal agency or organization);” or
  - “Is owned, managed, or controlled by one or more separate organizations”

- **Affiliated Provider**
  - “With respect to a provider, a legally separate provider that is the parent organization of the provider, is under common ownership, management or control of the provider, or is owned, managed, or controlled by the provider.”
Quality Committee Structure

*Programs such as Transplant and Departments such as Radiology, Pharmacy, Nursing, Environmental Services.

**Potential issue(s) in LIP practice identified during interdisciplinary review of clinical activities are referred to the Medical Executive Quality Review Committee for evaluation.
QUALITY AND PATIENT SAFETY
Organizational Chart
**Health System Corporate Structure**

**ACUTE CARE PLATFORM**

- Memorial Hospital Inc.
- ABC Community Memorial Hospital
- ABC Community Outpatient Health Svcs Inc.

**PROVIDER PLATFORM**

- DEF Community Hospital
- DEF Surgery Center, LLC

**Joint Venture and Member Relationships**

- **Cardiology Joint Venture, LLC**
  - 40%
- **Sports Training LLC**
  - 51%
- **Rehab, LLC**
  - 60%
- **Fitness Development LLC**
  - 40%
- **Midwest Dialysis, LLC**
  - 15%
- **Surgery Center, LLC**
  - 50%
- **Renal Care Group, LLC**
  - 35%
- **Home Care & Hospice, Inc.**
  - 50%
- **Integrated Health Network**
  - 16.7%
- **Diagnostic Imaging, LLC**
  - 40%
- **Clinical Imaging, Inc.**
  - 10%
- **Real Estate Ventures, LLC**
  - 50%
- **Regional Medical Center, Inc.**
  - Member
- **Medical CyberKnife, LLC**
  - 7.5%

*Consolidated LLC’s & Corporations in green (>50% governance and/or economic control)*
*Members of the obligated group in blue (excluded from the obligated group = FSC, COHS, WBSC, PPN and CP)*
*Non-controlled entities in red*
Key Take Aways

- PSWP can be shared within the provider among Work Force members for internal patient safety activities
- PSWP can be shared among affiliated providers
  - If disclosing identities of providers, incorporate written authorization for identified purposes within PSO agreement or other agreement/resolution
  - If wanting to disclose identity of other providers, i.e., physicians, you will need their written authorization which can be built into the appointment/reappointment application and/or employment agreement
Key Take Aways (cont’d)

- Need to be mindful of HIPAA implications if PSWP contains PHI. Is system organized as an OHCA or are providers considered affiliated covered entities under HIPAA?
- Non-provider parent organization can be included in PSES and obtain access to PSWP
- If the health care system has a component PSO then PSWP can only be disclosed by the PSO to the parent if you meet one of the disclosure exceptions
- IPAs, PHOs and other managed care arrangements are not considered providers under the Act – but check state law if they are authorized to provider health care services
Key Take Aways (cont’d)

- Component PSOs in health care systems tend to be more scrutinized by AHRQ in terms of access to and disclosure of PHI

- With respect to non-affiliated providers you need to determine if they fall under definition of owned, controlled or managed

- Make sure you meet one of the disclosure exceptions if releasing to a thirty party
QUESTIONS
Katten’s Health Care Practice

- **Katten** offers one of the largest health care practices in the nation—both in terms of the number of practitioners and the scope of representation.

- The integrated nature of our practice allows us to provide timely, practical and strategic advice in virtually all areas of law affecting the health care industry.

- Our experience encompasses regulatory compliance, fraud and abuse counseling, tax exemption issues, antitrust, financings for taxable and tax-exempt entities, reimbursement, and a variety of other issues specific to the health care industry.

- We also advise on transactions of all types, including mergers and affiliations, the development of clinically integrated networks, physician practice acquisition and compensation matters.

- To view other Health Care presentations by Katten, please [click here](#).
UHC Safety Intelligence® PSO – Fast Facts

- National patient safety leader since 2001
- Listed as PSO in 2008 by AHRQ and Certified through 2017
- National PSO Membership model
- AHRQ Common Formats (v1.1) based taxonomy
- Additional proprietary and customized taxonomy items
- Integrated submission with UHC SI Event reporting module
- National leadership role in PSO and Patient Safety activities
- Regular NPSD submissions via PSOPPC
- Multiple participation models
- Consistent ongoing feedback, comparative data, ongoing collaboration with other PSOs and members via Safe Tables, in person meetings, and webinars
- [Click here](#) to view the PSES Checklist
# Katten Muchin Rosenman LLP Locations

<table>
<thead>
<tr>
<th>Location</th>
<th>Address</th>
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