CHRMS: “PEARLS OF WISDOM”

Patient Safety Organizations
To Participate or Not: That is the Question

April 30, 2010

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

Monica C. Berry
Executive Director
Midwest Alliance for Patient Safety
222 South Riverside Plaza
Chicago, Illinois  60606
mberry@mchc.com
Objectives

• Discuss the advantages/disadvantages of participating in a PSO
• Articulate the confidentiality and privilege provisions
• Review hypothetical scenarios on how PSO protections can be applied
• Examine what risk management work product materials would and would not be eligible for protection
• Describe other quality of care benefits achieved through PSO participation
The Patient Safety Act

- Background
- Purpose
- Who is Covered under the Act and What is Required
- The PSES and Reporting to a PSO
- Confidentiality and Privilege Protections
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 existing federal protections
• Data reported within an organization is insufficient, viewed in isolation and not in a standard format
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.
Why Participate in a PSO?

- Regulatory mandates
- Employer and payer demands
- Just Culture – Joint Commission Sentinel Alert
- It’s good business
Why Participate in a PSO?

Regulatory Mandates

Illinois Health Care Adverse Event Reporting Law

- Implementation in 2010
- Calls for reporting of twenty-four specific “never” events to the state, along with root cause analysis and corrective action plans
- PSO participation will enable learning from experience of others and consultation in developing these mandatory resources
- PSO provides protection for supporting documents but not the RCA and action plan submitted to state (unless re-created)
Why Participate in a PSO? Employer and Payer Demands

Leapfrog Group challenge to all providers: adopt a four-pronged transparency strategy with patients when a “never” event occurs, including:

- Apology
- Internal root cause analysis
- Waiver of related charges
- Reporting for learning - can best be met through a PSO

Denial or reduction of reimbursement by payers and PHP initiatives
Why Participate in a PSO?  
TJC Sentinel Event Alert

• Leadership Committed to Safety
  – “A safe clinical environment is strengthened when work processes allow leaders and staff to discuss and learn about safety issues together.”
  – “A thorough and appropriate evaluation of adverse events is necessary to help prevent future occurrences.”
  – Suggested Actions:
    • “….hold open discussions …that focus on learning and improvement…..”
Why Participate in a PSO? It’s Good Business

- Consumer groups and advocates have called for substantially more engagement of the patient and the public in improving healthcare systems.
- Better and safer care should be more efficient care which costs less in dollars as well as in patient suffering, clinician frustration and unhappiness.
- Healthcare providers want to provide the best possible care, but at times the fear of disciplinary action and/or liability prevents this. PSO provides a safe environment where providers can learn.
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

Immediate Warning System
Comparative Reports
New Knowledge Educational Products
Collaborative Learning

PSO

Immediate Warning System
Comparative Reports
New Knowledge Educational Products
Collaborative Learning

PSO

Hospice
Pharmacy
Surgicenter
Hospice
Hospital
PSWP
PSWP

Home Health Care
Durable Medical Equipment
Long-Term Care Facility
Ambulatory Care Clinics
FQHC
Physician Groups
SNF

Hospice
Pharmacy
Surgicenter
Hospice
Hospital
PSWP
PSWP

Home Health Care
Durable Medical Equipment
Long-Term Care Facility
Ambulatory Care Clinics
FQHC
Physician Groups
SNF
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 REPORTING

Identification of Patient Safety, Risk Management or Quality event/concern

PSES
Receipt and Response to Event/Concern, Investigation & Data Collection

Needed for other uses? NO

Are needed reviews finished? NO

Wait until completed

YES

Justify Adverse Action
- Peer Review
- Personnel Review

Reporting to State, TJC

Evidence in court case

Do not put is PSES (yet) or consider removing from PSES

Is it flagged “Do Not Report”? YES

NO

Do not send to PSO

PRODUCE report for PSO

Information not protected as PSWP even if subsequently reported to PSO

Submit to the Alliance PSO
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
Risk Management & Patient Safety Events Flow

Patient Relations

Incident Reports

Calls and Walk-ins

QA Screens

Legal-Claims

Patient Safety - Risk Management

Initial Review of Facts

Quality Committee

Analytical Review

FMEA

Sentinel Event RCA

Closed

Best Practices/Safety Alerts

Monitoring
PA Patient Safety Authority: Why report? It provides useful information

- About 200,000 reports/year in PA-PSRS, and 97% are near misses or no-harm events
- The things that make adverse event reports useful are the same things that make near miss reports useful
- Purpose of both is the same: to identify the problems that need your attention
- The purpose is not to collect reports
Reporting provides information that is meaningful to others

- Resulted in dozens of articles in the Patient Safety Advisory: www.psa.state.pa.us
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
PA Patient Safety Authority: Reports provide useful information

• Examples:
  – One misunderstood colored wristband led to regional standardization
  – A hospital had a “sandbag” fly into the MRI core & screened their other sandbags throughout the facility
  – A report from a behavioral health unit of patients getting implements of self-harm in the ED
Learning lessons the easy way

• Examples:
  – Insulin given to the wrong patient
  – Wrong patient taken to the OR/procedure room
  – Patient with pacemaker scheduled for MRI
  – Patients found with multiple fentanyl patches
  – Neonates or infants given excessive doses of heparin
  – Wrong tissue type
Don’t limit focus to outcomes

- What types of near miss reports would have predicted your last Sentinel Event?

**NEAR MISSES**
- Wrong infant taken to mother’s bedside
- Unlabeled bag of donor blood found in blood bank
- Sites not being marked
- Pain medication given too soon

**SENTINEL EVENTS**
- Infant discharged to wrong family
- Transfusion-related death from ABO incompatibility
- Surgery on wrong body part
- Death from opiate/narcotic overdose
Steps to PSO Reporting

- **Inventory Data Currently Collected**
  - Patient safety, quality of care, healthcare outcomes

- **Prioritize Data that will be submitted to a PSO and become PSWP; what data will do the most to support improving the culture of safety**

- **Establish a system for data collection and review**
  - Standardized data collection will both enhance benchmarking comparisons and ultimately comply with AHRQ’s mandate for PSOs to collect standardized data; AHRQ’s “Common Formats” or another common format
  - Agree to the processes that the PSES will follow to determine PSWP

- **Create appropriate policies: Event Reporting; PSES, PSO Reporting**
## Inventory of Data to Improve Patient Safety, Healthcare Quality or Outcomes

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data Source</th>
<th>Data Collected by</th>
<th>Reported to</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allegation of abuse</td>
<td>Incident reports</td>
<td>Staff witness or aware</td>
<td>VP Nursing, If confirmed State Board of Nursing</td>
<td>Upon occurrence and 3 reports per year</td>
</tr>
<tr>
<td>Medication errors</td>
<td>Incident reports, Medical Record</td>
<td>Provider that made the error, Staff witness or aware</td>
<td>Risk Management, RM committee, Patient safety officer, Medication Safety Committee, Harm score I – State adverse event reporting</td>
<td>200 per month</td>
</tr>
<tr>
<td>Unplanned Returns to Surgery</td>
<td>Surgery log, Peer Review worksheets, Medical Record</td>
<td>QI Specialist</td>
<td>Risk Management, Patient safety officer, RM committee, Quality committee, MEC, Surgery Peer Review Committee, National Surgical Outcome Project If due to Retained Foreign Object, State adverse reporting</td>
<td>10 per month</td>
</tr>
</tbody>
</table>
PSO Reporting Process

- Professional Standards Committee
- Medical Executive Committee
- Medical Staff Quality Management Committee
- Department/Committee Chm
- Medical Staff Interdisciplinary Department Quality Committees
- Functional (Interdisciplinary) Quality Committees
- Administrative Quality Management Committee
- Clinical Care Evaluation Committee
- Patient Safety Committee
- Senior Management and Directors
- Inter-Disciplinary and Departmental Quality Committees
- CNE Coordinating Council
- Practice Comm Education Comm Informatics Comm
- Quality and Patient Safety

Shared members, communications

PSES
Mandatory Reporting to State Agencies

Providers have flexibility in defining and structuring their PSES, as well as determining what information is to become PSWP and, thus, protected from disclosure

- Use information that is not PSWP to fulfill mandatory reporting obligations e.g., Medical Records, Surgery Logs, etc.
- Report subjective incident report data to PSO for protections
  - Investigation notes, interview notes, forensics, etc.
Disclosure of Medical Errors

Disclose to Patient/Family

- Objective facts that are also documented in the medical record
- Actions taken to prevent harm to another patient

Report to PSO

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

Learning and Quality Improvement

Report to PSO:

- Physician specific reports
- Findings, Conclusions, Recommendations from individual case peer review

Reappointment/Renewal of Privileges

- Do not report to PSO:
- Ongoing professional practice evaluation (OPPE)
- Focused Evaluation (FPPE)
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, including an adjudicatory proceeding, including a proceeding against a provider
- Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law
Patient Safety Work Product

Exceptions:

– Disclosure of relevant PSWP for use in a criminal proceeding if a court determines, after an in camera inspection, that PSWP
  • Contains evidence of a criminal act
  • Is material to the proceeding
  • Not reasonably available from any other source

– Disclosure through a valid authorization if obtained from each provider prior to disclosure in writing, sufficiently in detail to fairly inform provider of nature and scope of disclosure
Patient Safety Work Product Confidentiality

Confidentiality:

PSWP is confidential and not subject to disclosure

Exceptions:

– Disclosure of relevant PSWP for use in a criminal proceeding if a court determines after an in camera inspection that PSWP
  • Contains evidence of a criminal act
  • Is material to the proceeding
  • Not reasonably available from any other source

– Disclosure through a valid authorization if obtained from each provider prior to disclosure in writing, sufficiently in detail to fairly inform provider of nature and scope of disclosure
Patient Safety Work Product Confidentiality

Exceptions (cont’d):

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

Exceptions (cont’d):

- Voluntary disclosure to accrediting body by a provider of PSWP but if about a provider who is not making the disclosure provider agrees identifiers are removed
  - Accrediting body may not further disclose
  - May not take any accrediting action against provider 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
Hypothetical: Post Op Infections

- Ortho group identified as having several post op infections as per screening criteria.
- Department of Surgery and Committee on Infection Control and Prevention decide to conduct review of all ortho groups in order to compare practices and results
  - Data and review collected as part of PSES
- Review identifies a number of questionable practices generally, which are not consistent with established infection control protocols
  - Data and analysis and recommendations eventually reported to PSO
- Review also discloses member of targeted ortho group as having other identified issues including:
  - Total shoulder procedures in elderly patients
  - Questionable total ankle procedures
Hypothetical: Post Op Infections

- Untimely response to post op infections

  • Issues identified are significant enough to trigger 3rd party review

  • Third party review identifies and confirms issues that may lead to remedial/corrective action

  • Decision is made by Department Chair that physician’s cases need to be monitored for six month period
    - Monitoring reveals repeat problems relating to questionable judgment and surgical technique which have resulted in adverse outcomes
    - Department Chair recommends formal corrective action
Hypothetical: Ortho Post Op Infections

PSES

Physician-Specific Issues

Outside Review

Department Imposes Monitoring

Monitoring Identifies New Cases

Formal Corrective Action

General Issues

Medical Staff Quality Management Committee

MEC

Administrative Quality Management Committee

Professional Standards Committee

PSO
Hypothetical: Wrong Breast Milk

- 3 month old premie in NICU received 15ccs of breast milk in an IV line
- Infant weighed 5lbs, 3 oz.
- Infant in isolette through which all lines (feeding tube, IVs, EKG cord, arterial line, etc.) were fed through
- Within 20 minutes the baby exhibited signs of respiratory distress and was placed back on the ventilator
Hypothetical: Wrong Breast Milk

- Risk management rec’d call at 6:15AM – notes taken to capture details of event
- Medical record reviewed by RM – notes taken
- Staff interviewed – RM notes taken
- IV line equipment changed out and sequestered - sent to forensics lab with expected report in 2 weeks
- Chair of QI committee requested RCA - Group pulled together and started within 24 hours of event
- Graphics of room design/layout as well as position of isolette and lines submitted as part of RCA
Hypothetical: Wrong Breast Milk

• Risk management communicated with national databank for neonatal events and obtained date and time in which to expect a call from another organization that experienced same event

• Risk management and several staff participated in that subsequent phone call – notes taken

• After phone call course of treatment significantly modified to match experience of other organization and that reflected the lessons learned

• Infant survived
Hypothetical: Wrong Breast Milk

**PSES**

- Collection of facts – Medical record review
- Collection of facts from nrsg staff and MDs
- Reported to TJC and state as reportable event
- Facts as reported – discoverable
- Subsequently lawsuit filed

**Risk Management Dept.**

- Notified and requested permission to investigate pursuant to PSRM plan

**Initiated investigation**

- RM notes collected

**QI committee**

**RCA/action plan**

**Event information entered into web-based event reporting program**

**Committee determined event Should be reported to PSO**

**PSO**
PSO: Advancing Patient Safety

Positive Trajectory of Change

- Heightened Awareness through Reporting
- Best Practices Identified through the Amplified Power of Aggregated Data
- Enhanced Patient Safety and Improved Patient Outcomes through Implementation
Questions?

• Monica Berry
  – mberry@mchc.com

• Michael Callahan
  – michael.callahan@kattenlaw.com