

Patient Safety Organizations: Improving Safety Through Reporting

HCCA Quality of Care Conference

**Polsinelli
Shughart.**

*Presented by:
Janice A. Anderson*

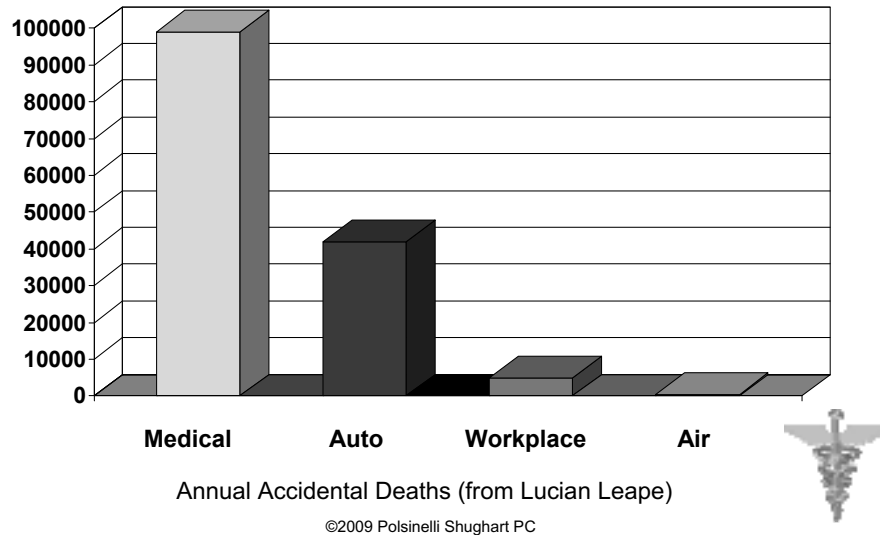


October 11-13, 2009

Patient Safety – The Problem



The Problem: 1999 – To Err is Human



- Since 1999 IOM Report, a spotlight has been turned on the safety of the American health care system




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But ... has there been improvement?

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- In 1999, IOM estimated 44,000 - 98,000 Americans die from medical errors annually. In 2004, Health Grades estimated 195,000 deaths!
 - In 2006, a consortium of National Academies found medication-related errors caused 1.5 million injuries and cost \$3.5 billion annually
 - In 2008, OIG found that the lag between the discovery of more effective forms of treatment and their incorporation into routine patient care averages 17 years
 - In 1999, IOM pegged the incidence rate for SAEs averaged 2-20%. In 2008, OIG estimated 15% (with an overall error rate of 30%!) 
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The Leapfrog 2008 Hospital Survey Report:

April, 2009

- Only 7% of hospitals met medication error prevention (CPOE) standards and few hospitals are meeting mortality standards
- Efficiency of care (high quality and low resource use) – only 24% for heart bypass surgery, 21% for heart angioplasty, 14% for heart attack care and 14% for pneumonia care
- 65% of hospitals do NOT have all recommended policies in place to prevent common hospital-acquired infections (HAIs)



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The Leapfrog Hospital Survey Report: *(continued)*

- Only 32% meet 90% of 13 evidence-based safety practices, ranging from hand washing to nursing staff competency
- 26% and 34% are meeting for treating two common acute conditions, hearts attacks (AMI) and pneumonia, respectively
- 30% and 25% are meeting the standards for reductions in hospital-acquired pressure ulcers or hospital-acquired injuries, respectively



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Secretary Sebelius, May 9, 2009

Some comments from the AHRQ National Quality Report

- One in seven hospitalized Medicare patients experience one or more adverse events
- Patient safety measures have worsened by nearly 1 percent each year for the past 6 years
- Central line associated blood stream infections strike hundreds of thousands of patients each year



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So what do you think? Are we safer?

Enter

Patient Safety Organizations (PSO)



Federal Patient Safety Act of 2005

Purposes:

- To improve healthcare quality and patient safety
- To share data within a protected legal environment
- To identify and reduce the potential risks associated with patient care
- The Act is voluntary and does not provide federal funding of PSOs



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Why Federal Protection is Needed

- Providers fear that patient safety reports could be used against them
- State protections vary – may offer no or inadequate protections (e.g., no protection if data is shared outside the hospital)
- For improvement, we need *robust reporting and aggregation of data*; by analyzing more events, patterns of failures could be more rapidly identified



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Patient Safety Organizations (PSO)

- November 21, 2008 HHS rule created a system of voluntary reporting to PSOs, effective January 19, 2009
- Designed to implement the 2005 PSQIA (Pub. L. No. 109-41; S. 544)
- AHRQ has responsibilities for credentialing and oversight of PSO operations
 - Maintains a list of approved PSOs
- OCR has responsibility to enforce PSO requirements



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New Terms and Acronyms – What Do They Mean?

- Patient Safety Organizations (PSOs)
 - Entities that meet the requirements of the Patient Safety Act and Rule
- Patient Safety Work Product (PSWP)
 - Information that is privileged and confidential
- Patient Safety Evaluation System (PSES)
 - The protected space in which PSWP is assembled or developed for reporting to or from a PSO
 - A provider's deliberations and analyses within a PSES are confidential and privileged



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What are PSOs?

- Patient Safety Organizations (PSOs) are entities which devote their primary activity to improving patient safety
- At a minimum, PSOs must
 - Contract with multiple providers to receive data regarding patient safety, known as Patient Safety Work Product (PSWP)
 - Aggregate and analyze PSWP from the multiple providers
 - Offer feedback and assistance to each provider about minimizing patient risk



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What are PSOs?

(continued)

- Provider use of a PSO is *voluntary*
- Many details about PSOs will remain uncertain until the market becomes established
 - What activities/analyses will PSOs perform?
 - What will the value of the services offered by PSOs be in terms of improved patient safety and provider finances?
 - Is there any risk to providers of increased liability for disclosures to PSOs?



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What is Patient Safety Work Product (PSWP)?

- Information is classified as PSWP only if it could result in improved patient safety, health care quality or health care outcomes
- PSWP includes any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements which
 - Is gather for purposes of reporting to a PSO
 - Is developed by a PSO in the conduct of defined patient safety activities
 - Reveals the internal deliberations or analysis regarding reporting pursuant to a patient safety evaluation system



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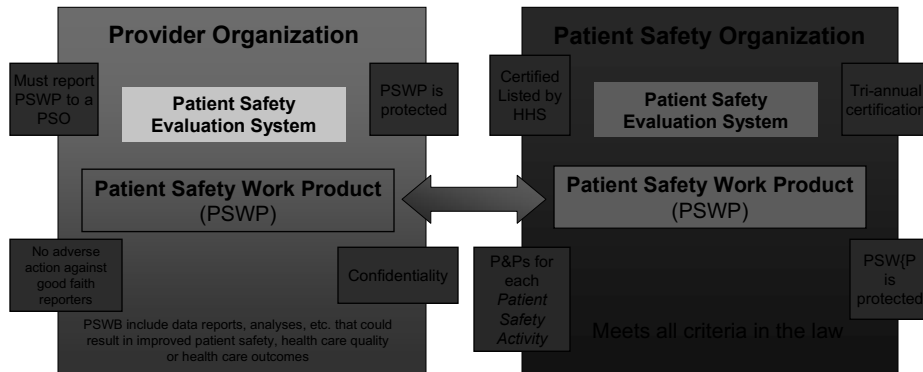
What Is Not PSWP?

- Patient's medical record, billing and discharge information, or any other original patient or provider record
- Information collected, maintained, or developed separately, or that exists separately from a patient safety evaluation system
- Information gathered in another context such as risk management or peer review is not protected, *even if it subsequently is reported to a PSO*



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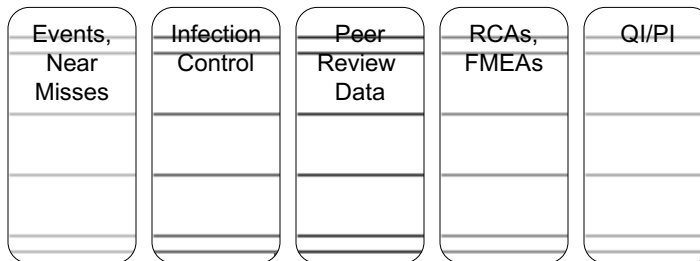
Collaborative Model



No written contract is required. Should there be one?

Patient Safety Evaluation System (PSES)

- Defined as: the collection, management or analysis of information for reporting to or by a PSO
- Meant to be flexible and scalable to individual operations
- Best practice is to document the PSES



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PSES . . . The Regulations Say

“A protected space or system that is separate, distinct, and resides alongside but does not replace other information collection activities mandated by laws, regulations and accrediting and licensing requirements as well as voluntary reporting activities that occur for the purpose of maintaining accountability in the health care system.”



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So, What is a Patient Safety Evaluation System (PSES)?

- PSES is mechanism by which provider collects, manages and analyzes information
- HHS does not mandate requirements for PSES, but recommends careful documentation!!
- Documented entry into and removal from a clearly identified PSES creates substantial proof to support that the document was developed for transmittal to a PSO (thus qualifying for federal confidentiality and privilege)



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How Secure is PSWP?

- The Patient Safety Act of 2005 granted privilege and confidentiality to all PSWP
 - Privilege protects against subpoena, discovery, or admission into evidence in connection with a legal proceeding or professional disciplinary proceeding
 - Confidentiality protects against any form of disclosure of PSWP to a third party
 - There are no limits on how information may be used *within* the entity making the report or within a PSO



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How Secure is PSWP?

- To qualify as PSWP
 - Must be developed for reporting to a PSO and actually reported to a PSO (or documented as entered into a PSES for purposes of reporting)
 - Be developed by a PSO for the conduct of patient safety activities
 - Identify or constitute the deliberations of a PSES
- Other documents receive no protection, *even if reported* to a PSO



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How Secure is PSWP?

- Exceptions to both *confidentiality* and *privilege*
 - Providers may authorize disclosure in writing
 - PSWP may be disclosed if de-identified according to specified standards
 - Disclosure permitted if a court makes an in-camera determination that the PSWP:
 - Contains evidence of a criminal act;
 - Is material to the case; and
 - Is not reasonably available by other means



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How Secure is PSWP?

- Exceptions to both *confidentiality* and *privilege*
 - Disclosures permitted to the extent required to permit equitable relief under whistleblower protections of the Public Service Health Act, provided a protective order has been obtained from the court or administrative tribunal to protect the confidentiality of the PSWP in the course of proceedings



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How Secure is PSWP?

- Disclosure is *permitted* (though privilege remains) in the following scenarios
 - To law enforcement personnel, if the PSWP is related to an event the discloser reasonably believes constitutes a crime and the discloser reasonably believes the PSWP is necessary for law enforcement purposes (may be further disclosed for law enforcement purposes)
 - Providers and PSOs may disclose PSWP to each other, or to contractors who undertake patient safety activities on their behalf. Disclosure to a second provider is permitted if the PSWP is stripped of identifying information



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How Secure is PSWP?

- To professionals (*e.g.* attorneys or accountants) in the course of business operations (no further disclosure permitted)
- To the FDA or entities which are required to report to the FDA (limits on further disclosure)
- To an accrediting body that accredits the provider if the information is stripped of identifying information (no further disclosure permitted)



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How Secure is PSWP?

- To persons carrying out research, evaluation or demonstration projects which are funded or otherwise sanctioned by the Secretary, subject to HIPAA privacy rule
- Providers may enter into contracts requiring greater confidentiality – Important to consider!



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How Secure is PSWP?

- The Secretary of HHS has immunity from both confidentiality and privilege, and can require providers and PSOs to disclose information. The Secretary can assert this power in order to:
 - Investigate or ascertain compliance with the Patient Safety Act (including decisions related to listing PSOs)
 - Investigate or ascertain compliance with the HIPAA Privacy Rule
 - Seek or impose civil monetary penalties



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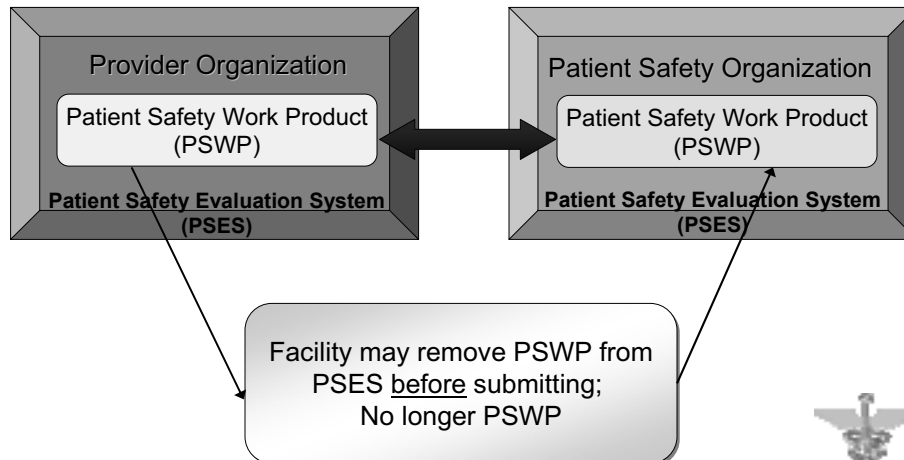
When is PSWP Protected?

- Upon collection within a PSES
- Provider documents that the information was collected for reporting to a PSO and the date of collection
- *Query: How long is too long before submission to the PSO?*



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You Can Remove PSWP From The PSES



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Internal Use of PSWP

- Is not regulated
- “Affiliated providers” may share identifiable PSWP
- May share with practitioners having privileges
- May share de-identified data with non-affiliated providers



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PSOs and HIPAA Privacy

- Providers bound by HIPAA privacy law
 - “minimum necessary” and other HIPAA requirements apply
- PSOs are business associates
 - BA agreements mandatory
- PSOs bound by security provisions of the PSO regulations



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Establishing the PSES

- Take inventory – Where are PSES activities conducted?
 - Committees, departments
- Research state peer review laws and structure accordingly (ex: does report to PSO waive state peer review protections?)
- Determine when to place in PSES (ex: occurrence of incident? Just prior to PSO reporting?)
- Will the PSES be centralized? Multi-facility?



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Document the PSES

- Some ideas . . .
 - Diagram PSES and its relationship to other systems
 - Identify processes, activities, the physical space, computer systems, and equipment that compose the PSES
 - Develop procedures for entering data and information into the PSES
 - Identify personnel who have access to the PSES and how they carry out their duties and the system's operations
 - Define conditions for accessing PSWP that is part of the PSES



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Document the PSES

(continued)

- Some ideas . . .
 - Clearly mark information as it moves in and out of PSES and date it
 - Develop procedures for reporting the information to the PSO and receiving feedback from the PSO
 - Develop procedures for removing information from the PSES and reporting it elsewhere
 - Carefully consider state peer review protection at each step



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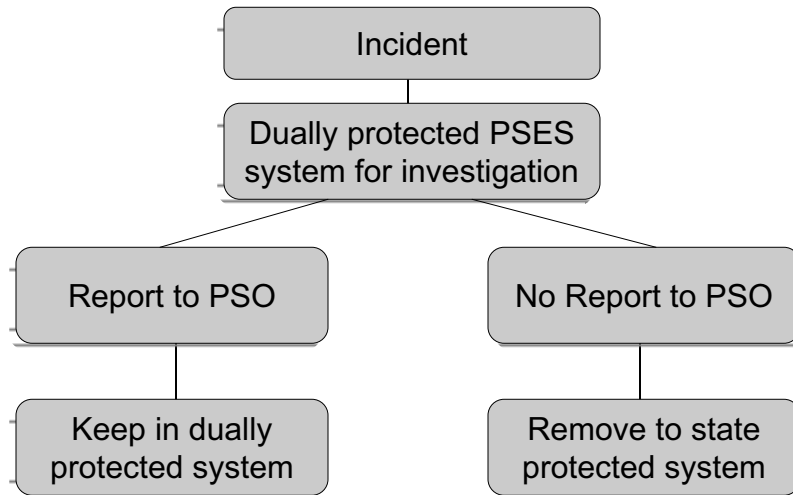
Document PSWP

- Label PSWP
 - Helps to prevent inappropriate disclosure
 - *CONFIDENTIAL PATIENT SAFETY WORK PRODUCT. Protected under the Patient Safety and Quality Improvement Act. Do not disclose unless authorized by [name of governing document, office or body].*
 - Label placement of information in and removal from PSES
 - Label for state peer review privilege as well



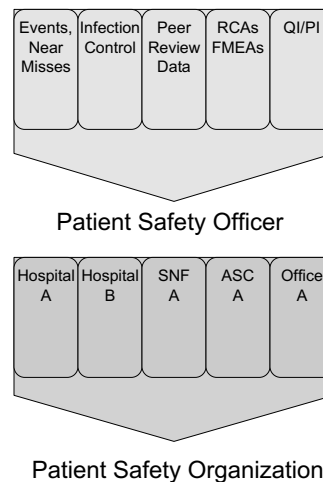
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Example of PSES Structure: Protecting PSWP Under Federal and State Law



When Should Reporting Occur? Questions to Consider

- Where to start . . .
What types of data?
- How to use existing structures, processes?
- How long data can stay in the PSES before reporting to a PSO?



Prioritize Reportable Data

- Prioritize based on criteria:
 - Promotes a culture of safety/improves care
 - Impressions/subjective data that is not available in the medical record
 - Not required to be reported elsewhere (although there are permissible disclosures)
 - Report will not be used for other purposes; *i.e.* to make adverse employment decisions



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Questions?



About the Presenter

Janice Anderson is a Shareholder at Polsinelli Shughart PC and has 25 years' experience focusing on health regulatory and compliance issues as well as over 30 years' experience working in the health care industry.



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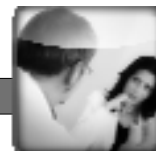
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Thank you



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