Patient Safety Organizations: Confidentiality and Privilege Challenges
Navigating HIPAA Compliance, Peer Review, and Reporting Requirements

A Live 90-Minute Teleconference/Webinar with Interactive Q&A

Today's panel features:
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Thursday, December 10, 2009
The conference begins at:
1 pm Eastern
12 pm Central
11 am Mountain
10 am Pacific

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Patient Safety – The Problem
Since 1999 IOM Report, “To Err is Human” a spotlight has been turned on the safety of the American health care system
Timeline

Moving the Dial on Safety and Quality

States begin enacting medical error reporting legislation

Physician Quality Reporting Initiative (PQRI) Created

National Quality Forum (NQF) Created

Leapfrog Group Founded

IOM’s “To Err Is Human” report published

IOM’s “Crossing the Quality Chasm” published

Health Grades published first quality study

MMA and DRA tie Medicare payment to quality reporting

CMS launches Hospital Compare

CMS Value based purchasing listening lessons


CMS = Centers for Medicare & Medicaid Services; DRA = Deficit Reduction Act; IOM = Institute of Medicine; MMS = Medicare Prescription Drug, Improvement and Modernization Act; QI = Quality Improvement; UHC = UnitedHealthcare.
But … has there been improvement?
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 a limited study in 2008, the OIG also found a serious adverse event incidence rate of 15% (plus an incidence rate of another 15% for adverse events causing temporary harm).

October 2009 – Health Grades reported some improvement in risk-adjusted mortality.
Using Patient Safety Organizations (PSOs) to Improve Safety
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
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.
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
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
What are PSOs?

- Patient Safety Organizations (PSOs) are entities which devote their primary activity to improving patient safety
- 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?
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.
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
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.”
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).
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
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
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
  - To permit equitable relief for whistleblowers
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
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)
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!**
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
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?*
You Can Remove PSWP From The PSES

Facility may remove PSWP from PSES before submitting; No longer PSWP
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
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?
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
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
Label PSWP

- Helps to prevent inappropriate disclosure
  - “CONFIDENTIAL AND PRIVILEGED 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
Example of PSES Structure: Protecting PSWP Under Federal and State Law

Incident

Dually protected PSES system for investigation

- Report to PSO: Keep in dually protected system
- No Report to PSO: Remove to state protected system
 Reasons to Report to A PSO

- Medical errors often are caused by systemic, rather than individual, breakdowns.
- Payment changes will make medical errors far more costly
  - P4P and VBP
  - Hospital Associated Conditions
  - Readmission rates and bundled payments
  - Accountable Care Organizations
- Enforcement of quality failures on the rise
- If voluntary reporting doesn't work, national mandatory reporting may be imposed.
Questions?
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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Strafford Publications

Presented by: Janice A. Anderson

Thank you

December 10, 2009
PATIENT SAFETY ORGANIZATIONS: CONFIDENTIALITY AND PRIVILEGE CHALLENGES

PRACTICAL IMPLEMENTATION ISSUES

Stafford Publications Webinar
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INTERACTION WITH HIPAA

• Participating Providers must comply with HIPAA Privacy Rule when disclosing PHI in connection with a PSO
• Remember state confidentiality laws
• A PSO is a business associate of Participating Providers (assuming PHI is shared)
• Under HI TECH, Business Associates have expanded liability exposure and must implement HIPAA compliance programs
• Essential that Business Associate Agreements be executed, and that other agreements, policies address HIPAA compliance

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PSO IMPLEMENTATION STRATEGIES: OVERVIEW

• Component PSO or Not?
• Separate entity:
  – FP vs. NFP
  – Tax Exemption
• Role of Providers
  – Who sponsors/funds PSO development?
  – Individual Providers vs. System vs. Association
PSO IMPLEMENTATION STRATEGIES: OVERVIEW

• PSO Scope
  – Single Health System (local, state-wide, national)
  – Geographic Region
  – Specialty PSO
  – Hospital – Only or Vertical Structure
**PSO IMPLEMENTATION STRATEGIES:**

**OVERVIEW**

- **How Does PSO Secure Expertise/Resources?**
  - Clinical/Quality
  - Data Management

- **Key Documents**
  - Corporate documents
  - Certification application
  - Participating Provider Agreements
  - BAA

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PSO IMPLEMENTATION STRATEGIES: OVERVIEW

- PSO Policies and Procedures
- Compliance Programs (including HIPAA)
- Vendor Agreements
- Grant Agreements
- Insurance Policies
PSO IMPLEMENTATION STRATEGIES: STRUCTURING A PSO

•Interested Provider Groups
  – AMCs
  – Health Systems
  – Local and State Provider Associations
  – Geographic Groups of Providers
    • Hospital – Only
    • Vertical Integration
PSO IMPLEMENTATION STRATEGIES: STRUCTURING A PSO

- Overall Interest Accelerated By:
  - ACO Movement / Bundled Payments
  - Payor Application of Quality Measures
  - Mandatory Adverse Events / Report Cards
PSO IMPLEMENTATION STRATEGIES: STRUCTURING A PSO

- Threshold Question: Component PSO?
  - Determinant is measure of control
  - Component PSOs include: division or subsidiary of a provider organization or system; a joint venture in which any or all of the sponsoring organizations have a measure of control
  - If a Component PSO, must meet additional certification criteria
PSO IMPLEMENTATION STRATEGIES: STRUCTURING A PSO

- General Certification Requirements (15)
  - 8 Mandatory Patient Safety Activities
    1. Engage in efforts to improve patient safety and quality
    2. Collection and analyze PSWP
    3. Develop and disseminate information re: improving patient safety
    4. Use PSWP to encourage a culture of safety, provide feedback and assistance
PSO IMPLEMENTATION STRATEGIES: STRUCTURING A PSO

5. Use qualified staff
6. Preserve confidentiality of PSWP
7. Appropriate safety measures for PSWP
8. Pursue activities that enhance PSES
PSO IMPLEMENTATION STRATEGIES: STRUCTURING A PSO

7 Other Mandatory Activities

1. Primary mission and activity is patient safety
2. Appropriately qualified staff
3. Utilizes PSWP for direct feedback and assistance to providers
4. Not a health insurer or component
5. Submits disclosure statements regarding relationships with contracting providers
6. Bona fide contracts with 2+ providers
7. PSWP collected in standardized manner to permit valid comparison
3 Additional Certification Requirements for Component PSOs

1. Maintain PSWP separate from the parent organization(s) and establish appropriate security measures to maintain confidentiality of PSWP

2. Must require that workforce members and contractors not make unauthorized disclosures of PSWP to parent(s)

3. PSO mission implementation must not create conflict with parent organization(s)
PSO IMPLEMENTATION STRATEGIES: STRUCTURING A PSO

• Incorporation likely makes sense
  – Primary purpose and activity requirement
  – Clarity of mission, action, funding
  – Liability mitigation

• Consider nfp corporation
  – 501(c)(3) status
  – Public and private grant fundings

• Articles and Bylaws address key organizational issues, budgets, authority, member controls, conflicts of interest
PSO IMPLEMENTATION STRATEGIES: KEY CONTRACTS

- Participating Provider Agreements
  - Detailed
  - General contractual terms (term, consideration, termination)
  - HIPAA compliance / BAA
  - Scope of PSO/PSWP
  - How PSWP delivered to PSO
  - What PSO will analyze and disseminate
  - PSO quality / patient safety actions and deliverables
PSO IMPLEMENTATION STRATEGIES: KEY CONTRACTS

- Confidentiality obligations on PSO and Provider
- PSO rule compliance
- Permitted vendor agreements
- IRB involvement
- Post-termination obligations, treatment of PSWP
- Insurance and indemnification issues
- Ownership and control of PSWP
PSO IMPLEMENTATION STRATEGIES: KEY CONTRACTS

• Vendor Agreements
  – Scope of technical, clinical support
  – Compliance with Participating Provider Agreement, PSO laws, PSO Policies and Procedures
  – BAA / HIPAA Compliance
  – Insurance and Indemnification
PSO IMPLEMENTATION: KEY CONTRACTS

- Grant Agreements
  - PSO requirements
  - Other contracts
PSO IMPLEMENTATION STRATEGIES: POLICIES AND PROCEDURES

- Mandated by PSO rules; a condition to certification
- Experienced consultants have templates to be customized
- Must cover:
  - Patient Safety and Quality Improvement Activities
  - Collection and Analysis of PSWP
  - Development and Dissemination of Information
  - Preservation, Confidentiality and Security of PSWP
PSO IMPLEMENTATION STRATEGIES: POLICIES AND PROCEDURES

- Qualified Staff
- Operation of PSES and Provision of Feedback
- Conflicts of Interest
- Separation and Nondisclosure of PSWP to Parent Organization(s)
PSO IMPLEMENTATION STRATEGIES: CONCLUSION

• PSO certification is relatively streamlined
• Affords significant liability protection, especially for inter-institutional data exchange
• Template organizational documents, agreements and policies and procedures now exist
• In an era of heightened interest in quality measurement and patient safety, PSOs are an important new tool
• Should determine how best to use this tool for any given provider or system

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PSO IMPLEMENTATION STRATEGIES: CONCLUSIONS

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