How Should Providers and PSOs Work Together?: Issues from a Variety of Perspectives

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Introduction: 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; and
  - Offer feedback and assistance to each provider about minimizing patient risk

Introduction: What are PSOs? (cont'd)

- PSOs were authorized by the Patient Safety and Quality Improvement Act in 2005 (PSQIA), but the United States Department of Health and Human Services' (HHS) regulations implementing the law did not take effect until Jan. 19, 2009
- Entities that successfully apply to be PSOs are listed by HHS

Introduction: What are PSOs? (cont'd)

- PSOs were created to improve patient safety by allowing the aggregation of sufficient data to identify and address underlying causal problems related to patient safety
  - Data is collected by PSOs in a standardized manner (such as the Common Formats being published by HHS) to allow valid comparisons
  - The Patient Safety Act made documents which qualify as Patient Safety Work Product (PSWP) confidential and privileged

Introduction: What are PSOs? (cont'd)

- Reasons for Patient Safety and Quality Improvement Act of 2005 (PSQIA)
  - Currently, fear of discovery of peer deliberations
  - Underreporting of events
  - Inability to aggregate data for analysis
  - Not enough encouragement for patient safety efforts

Introduction: What are PSOs? (cont'd)

- The Patient Safety Act also authorizes HHS to create a Network of Patient Safety Databases (NPSD), which will accept and aggregate data submitted by PSOs or providers
  - The submitted data must be *non-identifiable* PSWP
  - Goal: create an interactive evidence-based management resource for providers, PSOs, and other entities
  - Findings from the analysis of the aggregate data will be published in the Agency for Health Research and Quality's (AHRQ) annual *National Healthcare Quality Report*

Introduction: What are PSOs? (cont'd)

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

Selecting a PSO

- The AHRQ, a division of HHS, maintains a web site which lists all recognized PSOs: http://www.pso.ahrq.gov/listing/psolist.htm
- Currently 52 PSOs are listed, in 23 states plus the District of Columbia
- Some PSOs are components of larger organizations
  - *e.g.*, The California Hospital Association, The Institute of Medicine in Chicago, Walgreen Co., etc.

Selecting a PSO (cont'd)

- HHS does not intend to limit the number or variety of PSOs
- The final rule contemplates that the "market" will regulate the quality of PSO services (?)
- AHRQ oversees the certification and listing

Selecting a PSO (cont'd)

- Office of Civil Rights (OCR) oversees investigation and enforcement; cooperative and educational approach to providers
  - Authority to issue civil monetary penalties of up to $10,000 per violation
  - Expedited revocation:
    - PSO excluded
    - Components fail to keep PSWP separate
    - Adverse consequences could occur if PSO remains listed
  - Delisting: notice and opportunity to be heard

Selecting a PSO (cont'd)

NOTICE

- AHRQ's website contains 2 important warnings for providers considering contracting with a PSO
  - Before submitting information to an entity that claims to be a PSO, health care providers should always verify that the entity is currently listed by the Secretary. Information submitted to entities that are not listed will not receive confidentiality or privilege

Selecting a PSO (cont'd)

  - Never submit information to a PSO before its effective listing date. Information provided to a PSO before its effective listing date will not receive confidentiality or privilege
    - AHRQ's list may be updated a day or two before the PSO's status as a PSO becomes effective. However, the list will prominently display the date the PSO's listing becomes effective

http://www.pso.ahrq.gov/listing/psolist.htm

Selecting a PSO (cont'd)

- To be listed as a PSO by HHS, applicants must make 15 certifications:
  - Entity has policies and procedures to improve patient safety and the quality of health care delivery
  - Entity has policies and procedures for the collection and analysis of PSWP

Selecting a PSO (cont'd)

- Entity has policies and procedures to develop and disseminate information to improve patient safety, such as recommendations, protocols, or information regarding best practices
- Entity has policies and procedures to utilize PSWP to encourage a culture of safety and to provide feedback and assistance to effectively minimize patient risk

Selecting a PSO (cont'd)

- Entity has policies and procedures to preserve PSWP's confidentiality
- Entity has policies and procedures to protect PSWP
- Entity has policies and procedures to assure the utilization of qualified staff

Selecting a PSO (cont'd)

- Entity has policies and procedures in place to perform activities related to the operation of a patient safety evaluation system (PSES) and the provision of feedback to its participants
- The mission and primary activity of the PSO must be to conduct patient safety activities
- Have a qualified workforce, including licensed or certified medical professionals

Selecting a PSO (cont'd)

- Have 2 bona fide contracts with different providers for each 24 month sequential period after listing
- Not be a health insurer or component thereof
- Make the required disclosures to HHS
- Collect PSWP in a standardized manner to permit valid comparisons of similar cases among similar providers to the extent practical and appropriate (such as by using the published Common Formats); and
- Utilize PSWP to provide direct feedback and assistance to providers to effectively minimize patient risk

Selecting a PSO (cont'd)

- Documentation is *not required* to support the certifications, and *no investigation* is done at the time of application
  - Unannounced spot-checks can be conducted randomly or in response to complaints
- Providers should investigate new PSOs carefully!
  - Sophistication and security are likely to vary

"Component" PSOs

- Caution!
- Applicant entities which are components of a larger organization must also certify they will:
  - Keep PSWP separately from the rest of the parent organization and establish appropriate security measures to maintain confidentiality
  - Require members of its workforce and any other contractor staff not make any unauthorized disclosures to the parent organization
  - Ensure that the pursuit of its mission will not create a conflict of interest with the parent organization

"Component" PSOs (cont'd)

- Proposed rule
  - Required component PSOs to keep separate information systems from their parent organizations
  - Prohibited use of shared staff
- Final rule
  - May use shared information systems so long as unauthorized access to PSWP is not allowed
  - Shared staff permitted
  - Exercise care!

PSO Contracts

- Contracts between providers and PSOs are not regulated, and subject to negotiation:
  - Price
  - Security offered by the PSO
  - Services/types of analysis offered by the PSO
- Factors to evaluate:
  - Likely value of resulting patient safety assistance
  - Risk of breach
  - Cost to provider of collecting, storing, and transmitting reports to the PSO
  - Others?

What Should be Submitted to a PSO?

- Information not developed *for the purpose* of submission to a PSO does not qualify as PSWP, and should not be submitted
  - Only PSWP receives confidentiality and privilege
  - Ex: Medical records, billing and discharge information, *peer review findings*, information collected to comply with external reporting obligations

What Should be Submitted to a PSO? (cont'd)

- "The Patient Safety Act establishes 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." -- From the Final Rule implementing the PSO regulations (73 FR 70732, 70742)

What Should be Submitted to a PSO? (cont'd)

- PSOs should provide guidance on the information that may be submitted, and dictate the format for submission
  - PSOs must (to the extent practical and appropriate) collect PSWP in a standardized manner to permit valid comparisons of similar cases among similar providers
  - To qualify as PSWP, the preparation of these documents should be separate from existing quality assurance programs

What Should be Submitted to a PSO? (cont'd)

- AHRQ recommends PSOs use "Common Formats" it is currently developing
  - The Common Formats include standard forms for reporting patient safety events and common definitions of key terms
  - They are designed to be filled out at the point of care
  - Use of the Common Formats is voluntary for PSOs

What Should be Submitted to a PSO? (cont'd)

- The Common Formats can be found here: https://www.psoppc.org/web/patientsafety/commonformats
  - Currently in Version 0.1 Beta, but updates are expected
  - Forms are currently designed to be printed out, but electronic versions are being developed by private entities
  - Forms are currently available only for inpatient hospitals, but forms applicable to other providers are in development

What Should be Submitted to a PSO? (cont'd)

- The Common Formats include forms for reporting all patient safety concerns, including:
  - Incidents in which a patient safety event reached the patient, even if the patient was not harmed
  - Near misses, in which a patient safety event did not or could not reach the patient
  - Unsafe conditions, which are any condition that raises the probability of a patient safety event
- A Patient Safety Concern is "any circumstance involving patient safety"

What Should be Submitted to a PSO? (cont'd)

- Specific forms currently exist for patient safety events related to:
  - Anesthesia
  - Blood, Tissue, Organ Transplantation, or Gene Therapy
  - Device and Medical or Surgical Supply
  - Falls
  - Healthcare-Associated Infections
  - Medication & Other Substances
  - Perinatal
  - Pressure Ulcer
  - Surgical & Other Invasive Procedure

Setting up a Patient Safety Evaluation System

- For a provider's work product to qualify as PSWP (and receive privilege and confidentiality), it must be developed for reporting to a PSO
  - Under the proposed rules, information was not PSWP until transmitted to the PSO
  - Under the final rules, information may be PSWP if it is documented as *within a PSES* for reporting to a PSO
  - Need not actually be transferred; provider could authorize PSO access
  - Must be accessible by the PSO to be PSWP

Setting up a Patient Safety Evaluation System (cont'd)

- HHS recommends providers document how information enters the PSES, who has access to the PSES, and what physical space or equipment is used by the PSES
- Documented entry in a clearly identified PSES creates substantial proof to support a claim the document was developed for transmittal to a PSO (and thus qualifies for confidentiality and privilege)

Setting up a Patient Safety Evaluation System (cont'd)

- If the provider removes work product from the PSES, the work product loses its status as PSWP if:
  - The information has not yet been reported; and
  - The provider documents the act and date of removal

Setting up a Patient Safety Evaluation System (cont'd)

- Other issues
  - Are there events which should not be reported?
  - If so, should reports be screened before entering them into to the PSES, or removed before reporting to the PSO?
  - Others?

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* a PSO

How Secure is PSWP? (cont'd)

- PSO security requirements
  - PSWP and non-PSWP may be in the same location, but PSWP must be separate
  - Security requirements include training of workforce and contractors on policies and procedures
  - PSO must have control and robust monitoring programs to ensure security of PSWP

How Secure is PSWP? (cont'd)

- 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)
  - Be developed by a PSO for the conduct of patient safety activities; or
  - Identify or constitute the deliberations of a PSES
- Other documents receive no protection, *even if reported* to a PSO

How Secure is PSWP? (cont'd)

- Exceptions to confidentiality and privilege:
  - Providers may authorize disclosure in writing
  - PSWP may be disclosed if it meets specified standards to ensure it does not identify any providers
  - Disclosure permitted if a court makes an in-camera determination that the PSWP
    1) contains evidence of a criminal act,
    2) is material to the case, and
    3) is not reasonably available by other means

How Secure is PSWP? (cont'd)

- Disclosure permitted to the extent required to permit equitable relief under 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

How Secure is PSWP? (cont'd)

- 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
  - 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? (cont'd)

- To professionals (*e.g.* attorneys or accountants) in the course of business operations
- To the FDA or entities which are required to report to the FDA
- To an accrediting body that accredits the provider if the information is stripped of identifying information
- To persons carrying out research, evaluation, or demonstration projects which are funded or otherwise sanctioned by the Secretary

How Secure is PSWP? (cont'd)

- Information disclosed under these exceptions remains confidential and privileged
- Providers may enter into contracts requiring greater confidentiality

How Secure is PSWP? (cont'd)

- 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

Relation to State Law

- UNCERTAIN
  - The Patient Safety Act preempts State or other laws that require or permit disclosure of information contained in PSWP
  - The Patient Safety Act does not limit the application of other Federal, State, or local laws that provide greater privilege or confidentiality
- Disclosure to a PSO might cause loss of state peer review protection or constitute a waiver of a state law peer review privilege

Relation to State Law (cont'd)

- Are peer review findings protected under PSQIA?
  - They may be protected as PSWP
    - **If** they are assembled or developed to report to a PSO
    - **If** they are part of a PSES
    - **CAUTION:** OCR will expect to see a significant percentage of peer review findings reported to a PSO to consider the findings to be PSWP
  - Ordinarily, probably not

Relation to State Law (cont'd)

- There is a patchwork of state-by-state medical staff peer review "protections" (California) and "privileges" (Michigan)
- State law may offer more protection than PSQIA: preemption analysis required
- Problem: the decision to characterize peer review findings as PSWP or part of a PSES may well jeopardize state law protections or privileges

How Secure is PSWP? (cont'd)

- Florida's Amendment 7 granted Florida patients a "right to know about adverse medical incidents"
  - "Patients have a right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident." Fl. Const. Art. X § 25(a)
  - In providing such access, the identity of patients involved in the incidents shall not be disclosed, and any privacy restrictions imposed by federal law shall be maintained. Fl. Const. Art. X § 25(b)

Amendment 7

- "Patient's Right to Know About Adverse Medical Incidents" passed in November 2004 by over 81% of voters
- FL Constitution, Article X, Section 25
- In June, 2005, the Legislature attempted to limit amendment by statute (SB 938; FL Stats. §381.028)
- The enacting statute included provisions to preserve peer review confidentiality, despite the language in Amendment 7
- Dozens of suits followed, with conflicting DCA opinions

Supreme Court Ruling

- On March 6, 2008, the Florida Supreme Court (4-3) found the 2005 statute unconstitutional and severed those portions seeking to preserve peer review confidentiality. *Florida Hospital Waterman, Inc. v. Buster; Notami Hospital of Florida, Inc. v. Bowen*
- Resolved conflicting DCA opinions
- Amendment 7 preempts all Florida statutory peer review privileges

Supreme Court Ruling (cont'd)

- *Florida Hospital Waterman, Inc. v. Buster:* plaintiff sought production of documents relating to the investigation of her husband's death
- *Notami Hospital of Florida, Inc. v. Bowen*: plaintiffs sought documents relating to the selection, retention and termination of a physician

Supreme Court Ruling (cont'd)

- "We believe that Amendment 7 heralds a change in the public policy of this state to lift the shroud of privilege and confidentiality in order to foster disclosure of information that will allow patients to better determine from whom they should seek health care."

  - *Waterman, p. 31*, quoting Judge Thomas D. Sawaya (5th DCA) in *Buster*, 932 So.2d at 355-56.

Supreme Court Ruling (cont'd)

- "While [a medical provider's] history was not previously accessible [due to peer review statutes], it became accessible when the electorate approved a constitutional override of the prior statutory restrictions."
  - *Waterman*, p. 18.

Adverse Medical Incident

- The definition of "adverse medical incident" in Amendment 7 is broader than the definition used for purposes of State adverse incident reporting
- What is an "adverse medical incident"?

Any Ideas?

Adverse Medical Incident (cont'd)

- The phrase "adverse medical incident" means medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient, including, but not limited to, those incidents that are required by state or federal law to be reported to any governmental agency or body, and incidents that are reported to or reviewed by any health care facility peer review, risk management, quality assurance, credentials, or similar committee, or any representative of any such committees. FL Constitution, Art X, Sec 25(c)(3)

Adverse Medical Incident (cont'd)

Who determines what constitutes an "adverse medical incident"?

Adverse Medical Incident (cont'd)

- "… [§ 381.028(3)-(4), 7(b)] provides definitions of important terms, dictates that patient privacy restrictions be upheld, and identifies pursuant to other statutes the party responsible for identifying records of adverse medical incidents." -*Waterman*, p. 30 (upholding portions of the statute)
- 7(b) 1. Using the process provided in s. 395.0197, the health care facility shall be responsible for identifying records as records of an adverse medical incident, as defined in s. 25, Art. X of the State Constitution
- 2. Using the process provided in s. 458.351, the health care provider shall be responsible for identifying records as records of an adverse medical incident, as defined in s. 25, Art. X of the State Constitution, occurring in an office setting

Who can Access Records?

- Patients seeking their own medical chart?
- Patients seeking documents outside their own chart, but concerning their care?
- Patients seeking medical records of other patients, treated by the same physician for the same condition?
- Patients seeking documents concerning peer review, credentialing, etc. of their treating physician?
- Patients seeking documents concerning peer review, credentialing, etc. of other physicians?

Who can Access Records? (cont'd)

- "Here, the plain language of the amendment permits patients to access <u>any</u> record relating to <u>any adverse medical incident</u>, and defines "patient" to include individuals who <u>had previously undergone treatment</u>. The use of the word "any" to define the scope of discoverable records relating to adverse medical incidents, and the broad definition of "patient" to include those who "previously" received treatment expresses a clear intent that the records subject to disclosure include those created prior to the effective date of the amendment"

  - *Waterman* at p. 16 (quoting *Notami Hosp.*, 927 So.2d at 145) (emphasis in original)

Who can Access Records? (cont'd)

- "[W]e also note that [§ 381.028(7)(a)] provides that patients can only access the records of the facility or provider of which they themselves are a patient, a restriction not contained within the amendment."
  - Waterman, p. 28 (striking down that requirement)

What Medical Records can a Patient Access?

- To what extent are patients entitled to records of other patients or records pertaining to other physicians?
- Amendment 7 states all HIPAA restrictions must be upheld and patient identifying information redacted

What Peer Review Records can a Patient Access?

- So long as the credentialing file or peer review minutes contain "adverse medical incidents" information, they are arguably discoverable
- To the extent such records do not relate to "adverse medical incidents," they are arguably not discoverable

What Else?

- Only applies to written documents. Cannot compel physicians to testify
- Identity of peer review committee members remains confidential
- Does not eliminate immunity for participation in peer review activities
- Applies retroactively to records created prior to enactment
- "Immediate right to access existing medical records…" - *Waterman* at p. 16-17
- "[F]ees for the production of records cannot exceed the reasonable cost of complying with the request and that requests for production must be processed in a timely manner" - *Waterman*, p. 30

What's New: California?

- California's Proposed Senate Bill 58 (Aanestad)
- Name: Patient Safety Act of 2009
- Intent: Improve patient safety in California by reforming medical peer review

What's New: California? (cont'd)

- Aanestad believes the current system does not fully identify doctors who have delivered sub-standard medical care in California
  - Believes peer review can be reformed to a point where fears of professional ties, personal relationships and malpractice lawsuits can be avoided
  - Desires honest, open and forthright examination
  - Safety of patients should outweigh all other factors

What's New: California? Lumetra Study

- "The 2008 Lumetra Comprehensive Study of Peer Review in California"
  - Lumetra used to be California's Quality Improvement Organization
  - Their study concluded that the present peer review system is broken for various reasons and is in need of a major fix
  - Would set up a pilot project
  - Medical Board control of peer review
  - Question authority of hospitals and their medical staffs in the new regime

What's New: California? SB 58 Provisions

- Variations among healthcare entities in conducting, selecting, and applying criteria for peer review of physicians and surgeons
- Peer review process fails in its purpose to ensure the quality and safety of medical care in California

What's New: California? SB 58 Provisions (cont'd)

- In light of these serious patient safety concerns, an overview of the peer review process applicable to physicians and surgeons is necessary
- The Medical Board of California shall conduct a pilot program to redesign the peer review process

Questions and Answers

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