California Hospital Patient Safety Organization

Rory Jaffe, MD MBA
Executive Director

- Dedicated to eliminating preventable harm and improving the quality of health care delivery in California hospitals.
Outline

- High level run through of the rules
- The nitty-gritty
  - Definitions, exceptions, etc.
- Rules that PSOs must comply with are not addressed today
  - Security and privacy
  - Mission and patient safety activities
  - Related organizations
  - Excluded entities—e.g., health plans

WHY PSOS?
People are not the only problem

- By themselves, individual practitioners are no longer able to reliably provide good care
  - Health care is too complex and dangerous
  - Many people, machines, and resources involved in the care
- Recognition that there can be errors without negligence
- Traditional peer review protection is oriented towards deliberations about skills and knowledge of individuals
- Safety is more about systems
  - Many human errors are just that—normal human error
  - The health care system has been designed with the assumption that well-trained people don’t make mistakes

Patient Safety and Quality Improvement Act of 2005

- Encourage reporting of medical errors without fear that the reports will be used against the provider
- Encourage the development of a safer health care system — culture of safety
- Break down the legal barriers that impede patient safety improvement
  - Encourage open discussion in a protected environment
- Senate: unanimous vote, House: 428–3
- Goals 1 and 3 required changing the legal rules
- Goals 1 and 2 are the same goals that a compliance program has—success in either program helps the other
Encourage Reporting of Medical Errors

**PRIVILEGE**

- Focused on professional reviews, not system reviews
- Sharing information tends to break privilege, yet information sharing is vital to building safer health care systems
Patient safety work product privilege

- Patient safety work product is privileged and is not
  - Subject to a Federal, State, or local civil, criminal, or administrative subpoena or order
  - Subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding
  - Subject to disclosure pursuant to the Freedom of Information Act or any other similar Federal, State, or local law
  - Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law
- Patient safety work product disclosed, even if impermissibly, will continue to be privileged

Exceptions to privilege

- Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an in camera determination that such patient safety work product contains evidence of a criminal act and that such patient safety work product is material to the proceeding and not reasonably available from any other source.
- Disclosure of patient safety work product to the extent required to protect from retaliation a person who reports patient safety information.
- Disclosure of identifiable patient safety work product if authorized by each provider identified in such work product.
What about reporting requirements?

- “The fact that information is collected, developed, or analyzed under the protections of the Patient Safety Act does not shield a provider from needing to undertake similar activities, if applicable, outside the ambit of the statute, so that the provider can meet its obligations with nonpatient safety work product. The Patient Safety Act, while precluding other organizations and entities from requiring providers to provide them with patient safety work product, recognizes that the original records underlying patient safety work product remain available in most instances for the providers to meet these other reporting requirements.” — Final Rule p. 70732
Disclosures for patient safety activities

- Provider ↔ Affiliated Provider
- Provider ↔ PSO
- Provider ↔ Contractor
- PSO ↔ Contractor
  - Contractor may not disclose to others unless permitted in the contract

Limited data set disclosures for patient safety activities

- PSO ↔ PSO
- Provider ↔ Different Provider
- PSO ↔ Different Provider
- If:
  - Use limited data set (per HIPAA), and
  - Use “limited data set” for provider identifiers, unless
    - All identified providers sign authorizations
NEW DEFINITIONS

**Patient Safety Evaluation System (PSES)**

- “The collection, management, or analysis of information for reporting to or by a PSO.”
- Documentation of the system is optional but extremely strongly encouraged
- This system probably won’t have anything that doesn’t already exist
  - Except for the reporting activity
Why document?

- “Documentation may provide substantial proof to support claims of privilege and confidentiality and will give notice to, will limit access to, and will create awareness among employees of, the privileged and confidential nature of the information within a patient safety evaluation system which may prevent unintended or impermissible disclosures.”

What to document?

- How information enters the patient safety evaluation system
- What processes, activities, physical space(s) and equipment comprise or are used by the patient safety evaluation system
- Which personnel or categories of personnel need access to patient safety work product to carry out their duties involving operation of, or interaction with the patient safety evaluation system
- What procedures or mechanisms the patient safety evaluation system uses to report information to a PSO or disseminate information outside of the patient safety evaluation system
Patient Safety Work Product (PSWP)

- Any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material)
  - In short, anything (with some exceptions—see next slide)
- That is either ‘born’ in a PSES or is imported into a PSES
- Once something becomes PSWP it is permanently PSWP (with one exception—see slide after next)

What cannot become PSWP

- Patient safety work product does not include
  - A patient’s medical record,
  - Billing and discharge information, or
  - Any other original patient or provider information
- Nor does it include
  - Information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system.
  - Example: collected to comply with external reporting requirements
What can be un-PSWP’d

- Information assembled or developed for reporting to a PSO if:
  - It hasn’t yet been reported to a PSO, AND
  - The provider documents the act and date of removal from the PSES

Patient Safety Activities (1)

- 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 (2)

- 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.

Patient Safety Activities

- This definition important when discussing allowable disclosures outside your organization
HOW DOES SOMETHING BECOME PATIENT SAFETY WORK PRODUCT?

Deliberations and Analysis

- Information that identifies or constitutes the deliberations or analysis of, or identifies the fact of reporting pursuant to, a patient safety evaluation system.
- In short, this can cover anything that originates in the PSES
  - data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material)
Assembled or Developed for Potential Reporting

- Information that is assembled or developed by a provider for reporting to a PSO, and meets the following two specifications:
  - Specification 1
    - is reported to a PSO or
    - documented as within a patient safety evaluation system for reporting to a PSO
      - Including the date the information entered the patient safety evaluation system
  - Specification 2
    - It could improve patient safety, health care quality, or health care outcomes
- Typically, includes incident report, RCA, mitigation plan

PERMISSIBLE USES AND DISCLOSURES
Uses

- Unrestricted
- PSWP protection persists even when used for non-patient safety purposes

Disclosures

- Disclosures are to another legally separate entity or natural person, other than a workforce member of, or a health care provider holding privileges with, the entity holding the patient safety work product
- PSWP is confidential and cannot be disclosed, except…
Criminal Proceedings

- Court needs to make *in camera* determination that
  - The PSWP contains evidence of a criminal act;
  - The PSWP is material to the proceeding; and
  - The PSWP is not reasonably available from any other source

Equitable relief for reporters

- To the extent required to permit equitable relief for a person claiming retaliation for reporting in good faith
  - To the provider with the intent of having the information reported to a PSO or
  - Directly to the PSO
- Provided that there has been issued a protective order to protect confidentiality of the work product
**Authorized**

- By each provider identified in the PSWP
  - In writing and signed
  - Sufficient detail to fairly inform of nature and scope of the disclosures
- Authorization must be retained for six years from date of last disclosure

**Patient safety activities**

- See earlier slides (“Patient Safety Disclosures”) for list of parties to whom it may be disclosed
Nonidentifiable PSWP

- No restrictions
- “Nonidentification” requires HIPAA deidentification plus a similar process for provider identities

Research

- Project must be authorized, funded, certified or otherwise sanctioned by rule or other means by the Secretary
- Other rules still apply (e.g., HIPAA, research common rule)
FDA and entities reporting to FDA

- For quality, safety or effectiveness of an FDA-regulated product or activity
- “Downstream” disclosures only allowed for the purpose of evaluating the quality, safety or effectiveness of that product or activity

Voluntary disclosure to an accrediting body

- With direct provider identifiers removed, or
- The provider agrees to the disclosure
- “Downstream” disclosures prohibited
- Accrediting body may not take accrediting action against a provider merely because the provider works in good faith with a PSO and has information unavailable to the body
**Business operations**

- Attorneys, accountants and other professionals
- “Downstream” disclosures prohibited

**Law enforcement**

- PSWP relating to an event that constitutes the commission of a crime (reasonable belief needed), and
- The PSWP is necessary for criminal law enforcement purposes (reasonable belief)
- Law enforcement personnel may only disclose to other law enforcement authorities as needed related to the event that gave rise to the disclosure
To the Secretary HHS

- To determine compliance with the Patient Safety and Quality Improvement Act or HIPAA

CONTINUED PROTECTION AFTER DISCLOSURE
Protected even when disclosed

- PSWP disclosed, even if disclosed impermissibly, continues to be privileged and confidential, except:
  - If disclosed for a criminal proceeding remains privileged but not confidential
  - If non-identifiable it is no longer regulated by the PSO rule
  - Note that the exceptions only apply to the specific information disclosed

Penalties for impermissible disclosures

- Disclosure of PSWP in knowing or reckless violation of the confidentiality provisions
- Maximum penalty $10,000
WE’RE AT THE END!

Useful resources

- [http://www.chpso.org/providerpol/confid.doc](http://www.chpso.org/providerpol/confid.doc) sample confidentiality training form
- [http://www.chpso.org/providerpol/chpsohsa.pdf](http://www.chpso.org/providerpol/chpsohsa.pdf) confidentiality agreement on pages 23 and 24 – useful for disclosures to consultants or for business operations
QUESTIONS?