

# Patient Safety and Quality Improvement Act of 2005

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# Protecting Patient Safety – Current Practice

- Report incidents
- Identify and analyze problems
- Create and implement corrective actions
- Collect and analyze data
- Identify and address trends

... and is all this information discoverable?

# “To Err is Human: Building a Safer Health System”

A 1999 Institute of Medicine Report:

- At least 44,000 people die in hospitals each year due to preventable medical errors
- Most errors result from faulty systems and processes
- Barriers to hospitals solving own problems:
  - Fear of disclosure - weak peer review laws
  - Isolated data - greater aggregation would teach us more

# Congress Responds with an Option

## Patient Safety and Quality Improvement Act of 2005

- Amends the Public Health Service Act provisions which establish the Agency for Healthcare Quality and Research within HHS
- Creates “patient safety organizations” (PSOs) to receive, aggregate and analyze safety data
- Makes “patient safety work product” privileged and confidential
- Prohibits accrediting bodies from requiring “patient safety work product” or from taking action against providers for participating in PSO activities

# Making your State's Decision

- Proposed Rules published Feb. 12, 2008 at 73 FR 8112-8183. Expected to be final by end of 2008.
- AHRQ published Interim Guidance, which is in effect as of publication on October 14, 2008.
- Interim Guidance effective until Rule final.
- Information created now that is Patient Safety Work Product will retain its privilege and confidentiality after Rules become final.
- Secretary of HHS is now accepting certifications from Patient Safety Organizations (PSOs).

# Patient Safety and Quality Improvement Act of 2005 - Definitions

“Patient Safety Work Product” (PSWP) means:

Any data, reports, records, memoranda, analyses (such as root cause analyses) or written or oral statements which:

- Are assembled by a provider for reporting to a Patient Safety Organization (PSO) and are so reported
- Are developed by a PSO for “patient safety activities” OR
- Identify or constitute deliberations or analysis of, or identify the fact of reporting to a “patient safety evaluation system.”

Does not include patient medical records, billing records, or information that exists separately from a “patient safety evaluation system.” Information does not become “patient safety work product” just because it is reported to a PSO.

# Patient Safety and Quality Improvement Act of 2005 - Definitions

“Patient safety work product” (PSWP),  
con’t.

Identifiable PSWP is that which allows  
identification of:

- Healthcare provider
- Consumer (individually identifiable information under HIPAA)
- An individual who reported information to the provider or directly to the PSO.

# Patient Safety and Quality Improvement Act of 2005 - Definitions

“Patient safety work product” (PSWP),  
con’t.

Nonidentifiable PSWP is that which is not identifiable as defined above.

Different rules apply to identifiable and nonidentifiable PSWP.

# Patient Safety and Quality Improvement Act of 2005 - Definitions

“Patient safety evaluation system” means:

The collection, management or analysis of information for reporting to or by a patient safety organization.

# Patient Safety and Quality Improvement Act of 2005 - Definitions

“Patient safety organization” (PSO)  
means:

A private or public entity or a component thereof that is listed by the Secretary of HHS, including

- Certification and
- Compliance with statutory criteria.

## Patient Safety and Quality Improvement Act of 2005 - Definitions

“Patient safety organization” (PSO),  
con’t.

- States may establish PSOs, (but state agency probably cannot be a PSO – check final Rule).
- Health insurers or components thereof may not be PSOs.

# Patient Safety and Quality Improvement Act of 2005 - Definitions

“Patient safety activities” includes:

- Efforts to improve patient safety and quality of care
- Development and dissemination of information re: improving patient safety
- Collection and analysis of patient safety work product (PSWP)
- Maintenance of procedures to preserve confidentiality of PSWP
- Utilization of PSWP to create culture of safety, including feedback to minimize patient risk
- Provision of PSWP security measures
- Utilization of qualified staff and activities re: patient safety evaluation systems.

# Patient Safety and Quality Improvement Act of 2005 - Definitions

“Provider” means:

An individual or entity licensed under state law to provide health services, including

- a hospital, nursing home, long term care facility, behavioral health residential facility, or
- Physician, CNS, psychologist, etc. or
- Any other individual or entity specified in HHS regulations.

# Patient Safety and Quality Improvement Act of 2005 - Privilege Sec. 922

Notwithstanding other laws, PSWP is privileged and shall not be:

- Subject to subpoena or order, including in disciplinary actions against providers
- Subject to discovery, including disciplinary actions
- Subject to FOIA or similar state laws,
- Admitted as evidence, or
- Admitted in disciplinary proceedings of a professional disciplinary body under state law

Privilege does not apply to voluntary disclosure of nonidentifiable PSWP.

# Patient Safety and Quality Improvement Act of 2005 - Confidentiality

Notwithstanding other laws, PSWP shall be confidential and shall not be disclosed, except for disclosure:

- To carry out patient safety activities
- Of nonidentifiable PSWP
- For research that is sanctioned by HHS
- Voluntarily to an accrediting body
- To law enforcement re: criminal investigation
- Other than to PSO, IF the information does not assess quality of care or pertain to actions or failure to act of a identifiable provider.

# Patient Safety and Quality Improvement Act of 2005 - Confidentiality and HIPAA

Patient Safety Organizations (PSOs) are treated as business associates under HIPAA.

Patient safety activities of PSOs are deemed to be “health care operations” of the provider.

Therefore no consumer authorization is required for disclosures of PHI to a PSO.

Civil monetary penalties for wrongful disclosures can't be imposed under both the Act and under HIPAA simultaneously for a single violation.

# Patient Safety and Quality Improvement Act of 2005 - Privilege and Confidentiality

Exceptions re: privilege and confidentiality

- In criminal proceedings, in camera review for evidence of a criminal act, materiality, and unavailability otherwise.
- Enforcement proceedings to protect reporters of information
- If disclosure is authorized by *each* Provider identified in the PSWP.

# Patient Safety and Quality Improvement Act of 2005 - Privilege and Confidentiality

## The “Lock Box”:

- Privilege and confidentiality are continuing
- Disclosure does not operate to waive privilege or confidentiality
- Privilege and confidentiality apply to PSWP in the possession of person to whom the PSWP was disclosed.
- BUT confidentiality is lost for disclosures in criminal proceedings (and privilege is retained).
- Nonidentifiable PSWP, if disclosed, loses privilege and confidentiality.

# Patient Safety and Quality Improvement Act of 2005 - Privilege and Confidentiality

A PSO cannot be compelled to disclose information collected or developed, whether it is PSWP or not, unless:

- it is not PSWP
- it is identified as such, and
- It is not reasonably available from another source.

# Patient Safety and Quality Improvement Act of 2005 - Privilege and Confidentiality

Stronger privilege or confidentiality laws at Federal, State or local levels still apply.

Providers or PSO's may contract for greater confidentiality.

State laws requiring reporting of information that is not PSWP are not preempted by this Act.

# Patient Safety and Quality Improvement Act of 2005 - Privilege and Confidentiality

Check the final Rule for more on how:

- HHS – Office of Civil Rights enforces the confidentiality provisions.
- Privilege belongs to the holder and the holder would raise the issue for enforcement through existing applicable laws.

## Patient Safety and Quality Improvement Act of 2005 – National Database

HHS will create a Network of Patient Safety Databases which will aggregate and analyze nonidentifiable PSWP voluntarily reported by PSOs, providers or other entities.

AHRQ has established Privacy Protection Center to advise PSOs on common format for reporting and on deidentification. See [www.pso.ppc.org](http://www.pso.ppc.org)

## Patient Safety and Quality Improvement Act of 2005 - Accrediting Bodies

A provider can't be required by an accrediting body to reveal its communications with a PSO.

A provider is protected from accrediting actions based on good faith participation involving PSWP.

# Patient Safety and Quality Improvement Act of 2005 - Reporter Protection

A provider cannot take adverse employment action against a person for his/her good faith reporting of information

- To the provider for reporting to PSO or
- To the PSO directly.

# Patient Safety and Quality Improvement Act of 2005 - Enforcement

Civil monetary penalties for disclosing identifiable PSWP knowingly or recklessly.

Follow same procedures as in Section 1128 A of Social Security Act.

# Patient Safety and Quality Improvement Act of 2005 - Enforcement

Equitable relief to enjoin any violation of reporter protections.

BUT, a State agency must consent to be subject to such equitable action if it wishes to assert the privilege protecting PSWP.

## Interim Guidance by AHRQ

### PSO criteria for certification:

- Mission and primary activity is patient safety
- Ability to maintain PSWP separately from the rest of the organization
- Appropriate security measures (cf. HIPAA Security Rule)
- Ability to prevent unauthorized disclosures of PSWP
- Mission of the PSO does not create a conflict of interest with the rest of the organization
- Expertise, capacity and purpose to do patient safety activities as defined

## Interim Guidance by AHRQ

Provider's PSWP is protected only if sent to a certified and listed PSO.

- Therefore AHRQ has an e-mail list for automatic notice to providers re: PSOs, including revocation of certification and de-listing.
- See [www.pso.ahrq.gov](http://www.pso.ahrq.gov).

PSOs must collect PSWP in a “standardized manner.”

PSOs are required to have at least 2 contracts with providers, initially and each 2 years thereafter.

## Interim Guidance by AHRQ

- HHS Office of Civil Rights is the enforcement body for the Act.
- Information that becomes PSWP during the interim period will remain PSWP afterward.
- Final Rules will give further guidance on anything that is not from the Act.

## Proposed Regulations: 42 CFR Part 3

In addition to privilege and confidentiality rules:

- Process and requirements for initial and continued listing of PSOs
- Secretarial actions
- Security requirements
- Correction of deficiencies, revocation
- Assessment of PSO compliance
- Submissions and forms
- Enforcement program

# Patient Safety and Quality Improvement Act of 2005 - Some Considerations

- “Patient safety evaluation system” for reporting to PSOs must be a separate system from existing performance improvement, quality improvement, risk management, root cause analysis, peer review, etc. because PSWP goes into the “lockbox.”
- Analyze state laws on privilege, confidentiality, quality assurance, peer review, employment action. What information do you need to have out of a “lockbox”? How would the reporting system to the PSO be designed?

# Patient Safety and Quality Improvement Act of 2005 - Some Considerations

- Fine-tuning with HIPAA.
- Narrow the field? Report only certain types of data to PSO if you like.
- There is no federal funding for the Act.
- Analyze issues relating to availability of data in CRIPA cases, tort litigation, JCAHO and other accreditation, CMS surveys.
- Protection and Advocacy access? Check the Act's rule of construction.
- NASMHPD as a PSO - conflict?

# Patient Safety and Quality Improvement Act of 2005 – Implementation Issues

Inform and educate:

- *Consumer associations, councils\*\*\**
- Attorney General
- Commissioner/Director
- FOIA staff
- HIPAA Privacy Officer
- JCAHO staff
- Risk Management, Quality Improvement, Performance Improvement, Root Cause Analysis Team, Peer Review Teams

# Patient Safety and Quality Improvement Act of 2005 – Implementation Issues

- Identify and create Patient Safety Evaluation Systems for reporting to PSO
- Policies and Procedures
- Create a culture of safety, quality improvement and candid self-scrutiny
- Contracted Providers:
  - Include PSES in deliverables
  - Require policies and procedures
  - Design PSES to include them - who contracts with the PSO, the State MH agency or the Contractor?
  - Flow of information and reporting
  - Monitor performance

# Patient Safety and Quality Improvement Act of 2005 – Implementation Issues

- Analyze state laws on privilege, confidentiality, quality assurance, peer review, employment action for possible changes needed.
- Contract with a PSO
  - Do you need or want greater privilege or confidentiality than the Act provides?
  - Check with state Hospital Association, other state agencies having hospitals, to identify PSO possibilities
  - Understand PSO compliance requirements
  - Monitor PSO performance

# Patient Safety and Quality Improvement Act of 2005 – Implementation Issues

- Results - Improvements

- Benchmarking - document it proactively, follow up on issues and trends identified.
- Consider whether and how you can make public any nonidentifiable data that is helpful.
- Keep in touch with NASMHPD on issues.

# PSOs Listed to Date

- California Hospital Patient Safety Organization
- ECRI Institute PSO
- Florida Patient Safety Corporation
- Health Watch, Inc. (Quality Health Strategies, Inc.)
- Human Performance Technology Group
- Institute for Safe Medication Practices
- Missouri Center for Patient Safety
- Peminic, Inc.
- Sprixx (Harbor Medical, Inc.)
- University Healthsystem Consortium

# Patient Safety and Quality Improvement Act of 2005 - References

- Patient Safety and Quality Improvement Act of 2005 (Pub.L. 109-41, S.544 of the 109<sup>th</sup> Congress)  
42 USC § 299b-21 through 299b-26.
- Notice of Proposed Rulemaking: 73 Federal Register 8112-8183 (February 12, 2008)
- **Interim Guidance from HHS - AHRQ:**  
<http://www.pso.ahrq.gov/regulations/intguid.htm>
- AHRQ's PSO website: [www.pso.ahrq.gov](http://www.pso.ahrq.gov)
- Privacy Protection Center: [www.pso.ppc.org](http://www.pso.ppc.org)