
# 5th Annual Meeting of PSOs

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## Creating and Operating a Patient Safety Evaluation System

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# Disclaimer

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# Patient Safety Evaluation System (PSES)

- Definition:
  - "Patient safety evaluation system means the collection, management, or analysis of information for reporting to or by a PSO."
    - Patient Safety and Quality Improvement Act, Final Rule, Section 3.20.
- It is the mechanism through which information can be collected, maintained, analyzed, and communicated.
  - "Protected Space"

# Patient Safety Evaluation System (PSES)…Benefits of Documenting

- *Documentation* of a PSES could designate secure physical and electronic space for the conduct of PSAs and better delineate various functions of a PSES, such as:
  - When and how information would be reported by a provider to a PSO,
  - How feedback concerning PSEs would be communicated between PSOs and providers,
  - Within what space deliberations and analysis of information are conducted, and
  - How protected information would be identified and separated from information collected, maintained, or developed for purposes other than reporting to a PSO.
    - See PSQIA Final Regulations from AHRQ

# PSES Documentation

- The Department also recommends the PSES be documented for the following reasons:
  - To support identification protection of PSWP
  - To provide substantial proof to support claims of privilege & confidentiality
  - Will give notice to, will limit access to, & will create awareness among employees of, the privileged & confidential nature of the information within a PSES which may prevent unintended or impermissible disclosures

# AHRQ's Recommendations Regarding Documentation of PSES

- AHRQ Recommends Documenting the Following:
  - How information enters the PSES
  - What processes, activities, physical space(s) and equipment comprise or are used by the PSES
  - Which personnel or categories of personnel need access to PSWP to carry out their duties involving operation of, or interaction with, the PSES
  - The category of PSWP to which access is needed, and any conditions appropriate to such access
  - What procedures the PSES uses to report information to a PSO or disseminate information outside the PSES

# Documentation of the PSES

TIP:

Documenting a PSES is critical in my judgment

# Where Does the PSES Exist?

- Typically at the single provider level, but can exist within a parent organization as well as with individual providers.

- A provider may ***not*** maintain a PSES ***within*** a PSO

# Option to Remove ("Dropout")

- Allows providers to voluntarily remove, & document the removal of, information from the PSES that has not yet been reported to a PSO, in which case, the information is no longer PSWP, e.g., when information is needed for state/federal regulatory reporting issues

*An Important Concept!*

# Constructing a PSES

1. Decide on a platform
   a. Can you piggy-back on an existing IT system?
   b. What are the system capabilities & how does that match the level of anticipated activity?
   c. Can patient safety activities be appropriately segregated from other operations functions?
   d. Research vendor options as well

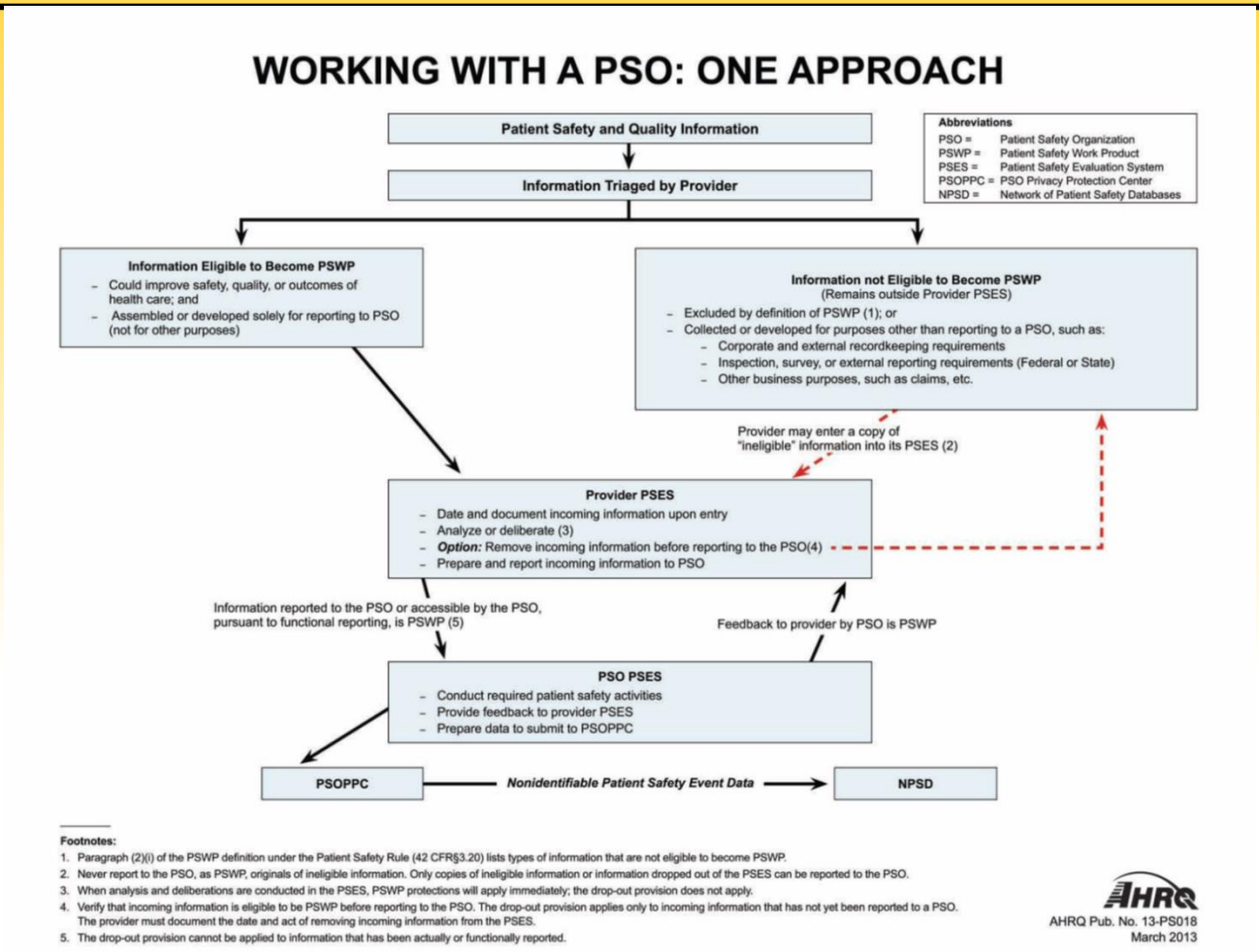
# Constructing a PSES

2. Design the protected space
   a. What sort of physical space suits the need?
   b. How can it be secured?
   c. How do we account for "shared staff" activities? How do we manage this?
3. Map the Process (start with "the old")
   a. Who will work directly with the PSES?
   b. How will the PSES interface with the PSO(s)?
   c. What are the Intake procedures?

# Constructing a PSES

4. Train & Audit
   a. Who will train the PSES staff and reporters?
   b. How will internal auditing occur?

# Working with a PSO: One Approach



# Operating a PSES

- Interfacing with a PSO
  - Define the "rules of engagement"
  - Develop a comprehensive agreement outlining the rights & responsibilities of each party including what you should expect in terms of support. (The market will evolve in this area.)
- Be careful with the use of templates

# How Others Will Try to Get to Your PSES Information

- Good focus for audit activities!
  - Had the provider established a PSES for PSO participation?
  - Does it meet the definition of PSWP? Or was it original patient records or separately maintained materials?
  - Was the subpoenaed information appropriately identified by the provider/PSO as part of its PSES?
  - Was the information reported to the PSO? Evidence of the report?

# Virginia Board of Pharmacy Requirement – Continuous Quality Improvement in Pharmacies

- New incentive for pharmacies to join a PSO or create a PSO.
- 18VAC110-20-418. Continuous quality improvement programs.
  - Emergency Regulation effective October 1, 2012 to September 30, 2013
- Requires pharmacies to implement a continuous quality improvement program to provide for a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response & to develop or improve pharmacy systems & workflow processes designed to prevent or reduce future errors.
- 2 options for complying:
  - Report errors to a PSO
  - Implement a CQI program (numerous elements to the CQI program listed in the regulation)

# 18VAC110-20-418 (*Emergency Regulation*) Continuous Quality Improvement Programs

- Notwithstanding practices constituting unprofessional practice indicated in 18VAC110-20-25, any pharmacy that actively reports dispensing errors and the analysis of such errors to a patient safety organization consistent with §54.1-3434.03 and 18VAC110-20-10 shall be deemed in compliance with this section. A record indicating the date a report was submitted to a patient safety organization shall be maintained for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record.

- Pharmacies not actively reporting to patient safety organizations, consistent with §54.1-3434.03 and 18VAC110-20-10, shall implement a program for continuous quality improvement in compliance with this section. . .

# Questions