PSO's: Reconciling Protection with State Mandatory Reporting

Texas Healthcare Safety Conference

August 18, 2016

WHO WE ARE ----

Center for Patient Safety is a national not-for-profit PSO, dedicated to promoting safe and quality healthcare for all providers

WHO WE SERVE

HOSPITALS

Provide services to **more than 350 hospitals**

LTC

Provide services to **more than 20 long-term care facilities**

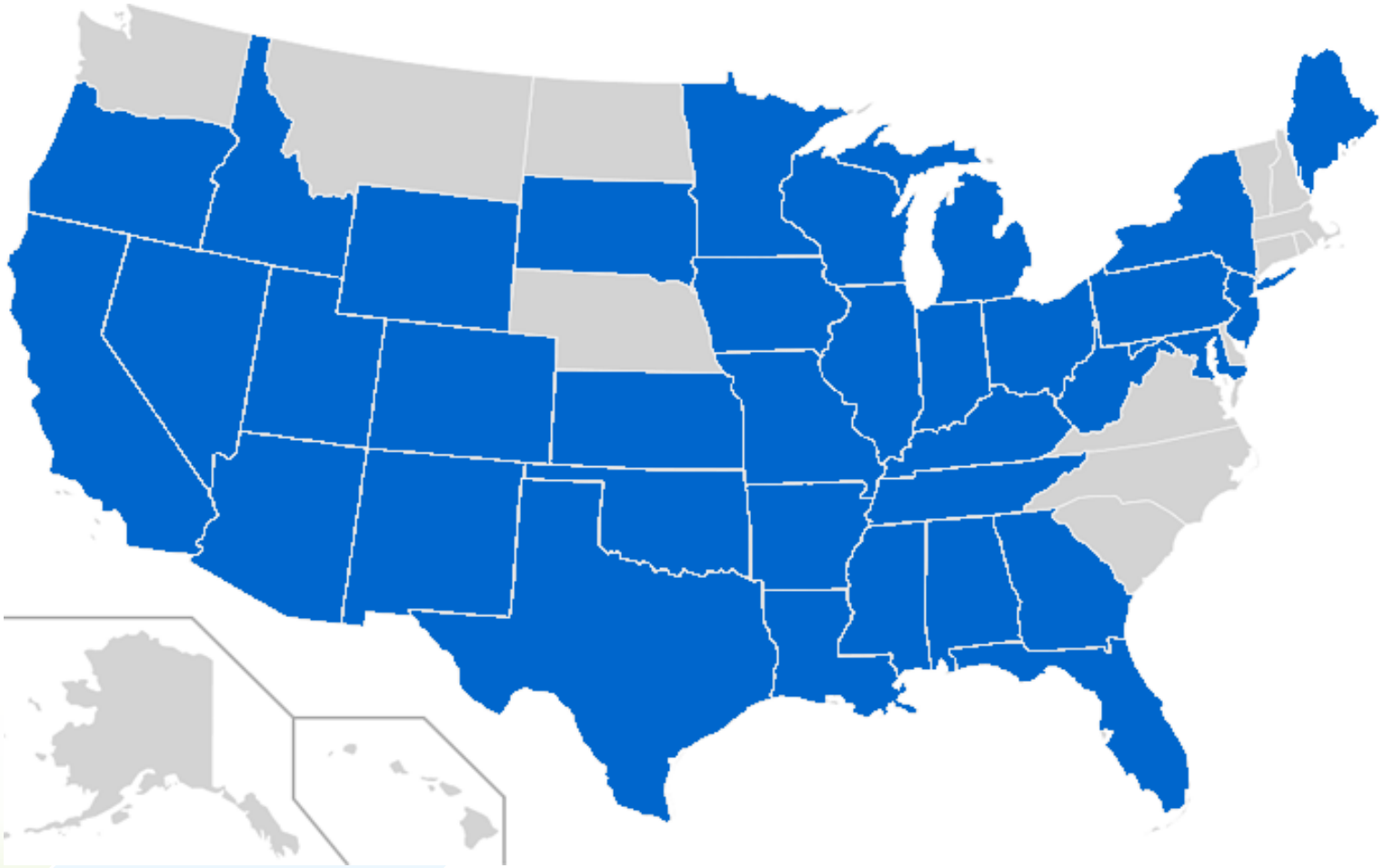
EMS

Provide services to **more than 300 Emergency Medical Services**

Medical Offices

Provide services to more than **1,000 medical offices**

WHERE WE SERVE

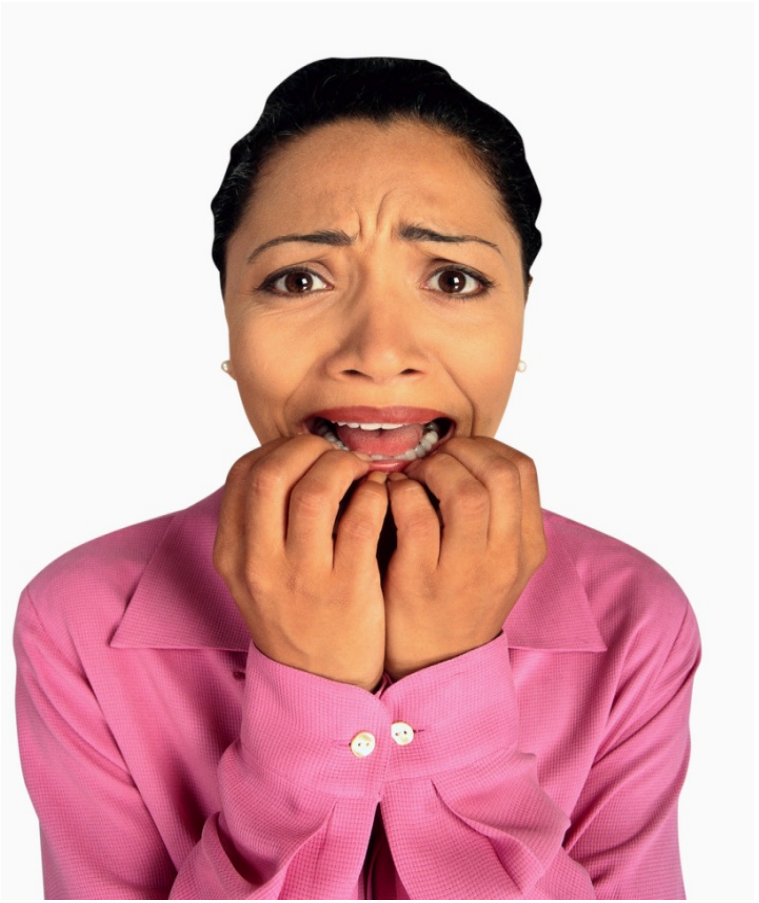


INTENT OF THE PSQIA

- A safe environment supporting reporting, sharing, and learning about safety and quality
- Improve patient safety and reduce patient harm
- Reduction of healthcare costs as a result of safer, better care

WHAT PROBLEMS DID THE ACT ADDRESS?

- Fear of using information against providers
- Inconsistent State protections for safety and quality analyses
- Inability to aggregate data to better and more rapidly identify patterns of care and system failures across providers



Texas: Reporting of Preventable Adverse Events

- Internal reporting
- Facilities are required to track events
- Facilities are required to
  - Monitor effectiveness/safety of services
  - Analyze causes
  - Implement actions to prevent recurrence
- External reporting to CMS, PSO's, States
- Public reporting by time period

Texas Reporting Law

Senate Bill 203 of the 81st Legislature (2009) amended the Health and Safety Code, Chapter 98.102.a.2,4,5, **to require**:

- Healthcare facilities to report certain preventable adverse events to the DSHS
- DSHS to make this data available to the public by facility, by type, and by number.

Texas Preventable Adverse Event Reporting 3 Tier Phase-In Implementation

First Tier PAE Reporting Beginning January 1, 2015

1. Surgeries or invasive procedures involving a surgery on the wrong site, wrong patient, wrong procedure.
2. Foreign object retained after surgery.
3. Post-operative death of an ASA Class 1 Patient.
4. Discharge or release of a patient of any age, who is unable to make decisions, to someone other than an authorized person.
5. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, wrong gas, or are contaminated by toxic substances.
6. Abduction of a patient of any age.
7. Sexual abuse or assault of a patient within or on the grounds of a health care facility.
8. Patient death or severe harm resulting from a physical assault that occurs within or on the grounds of a health care facility.
9. Patient death or severe harm associated with a fall in a healthcare facility resulting in a fracture, dislocation, intracranial injury, crushing injury, burn or other injury.
10. Patient death or severe harm associated with unsafe administration of blood or blood products.
11. Patient death or severe harm resulting from the irretrievable loss of an irreplaceable biological specimen.
12. Patient death or severe harm resulting from failure to follow up or communicate laboratory, pathology or radiology test results.
13. Patient death or severe harm associated with use of physical restraints or bedrails while being cared for in a health care facility.
14. Perinatal death or severe harm (maternal or neonate) associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility.

Second Tier PAE Reporting Beginning January 1, 2016

1. Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) after total knee replacement or after hip replacement.
2. Iatrogenic Pneumothorax with venous catheterization.
3. Stage III, Stage IV or Unstageable pressure ulcer acquired after admission/presentation to a health care facility.
4. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist or other licensed health care provider.
5. Patient suicide, attempted suicide or self-harm that results in severe harm, while being cared for in a health care facility.
6. Patient death or severe harm associated with patient elopement.
7. Patient death or severe harm associated with an electric shock while being cared for in a health care facility.
8. Patient death or severe harm associated with a burn incurred from any source while being cared for in a health care facility.
9. Patient death or severe harm associated with the introduction of a metallic object into the MRI area.

Third Tier PAE Reporting Beginning January 1, 2017

1. Surgical site infections following a spinal procedure, shoulder procedure, elbow procedure, laparoscopic gastric bypass, gastroenterostomy, laparoscopic gastric restrictive surgery or cardiac implantable electronic device.
2. Artificial insemination with the wrong donor sperm or wrong egg.
3. Poor glycemic control: hypoglycemic coma.
4. Poor glycemic control: diabetic ketoacidosis.
5. Poor glycemic control: nonketotic hyperosmolar coma.
6. Poor glycemic control: secondary diabetes with ketoacidosis.
7. Poor glycemic control: secondary diabetes with hyperosmolarity.
8. Patient death or severe harm associated with the use of contaminated drugs/devices or biologics provided by the health care facility.
9. Patient death or severe harm associated with the use or function of a device in patient care, in which the device is used or functions other than as intended.
10. Patient death or severe harm associated with intravascular air embolism that occurs while being cared for in a health care facility.
11. Patient death or severe harm associated with a medication error.

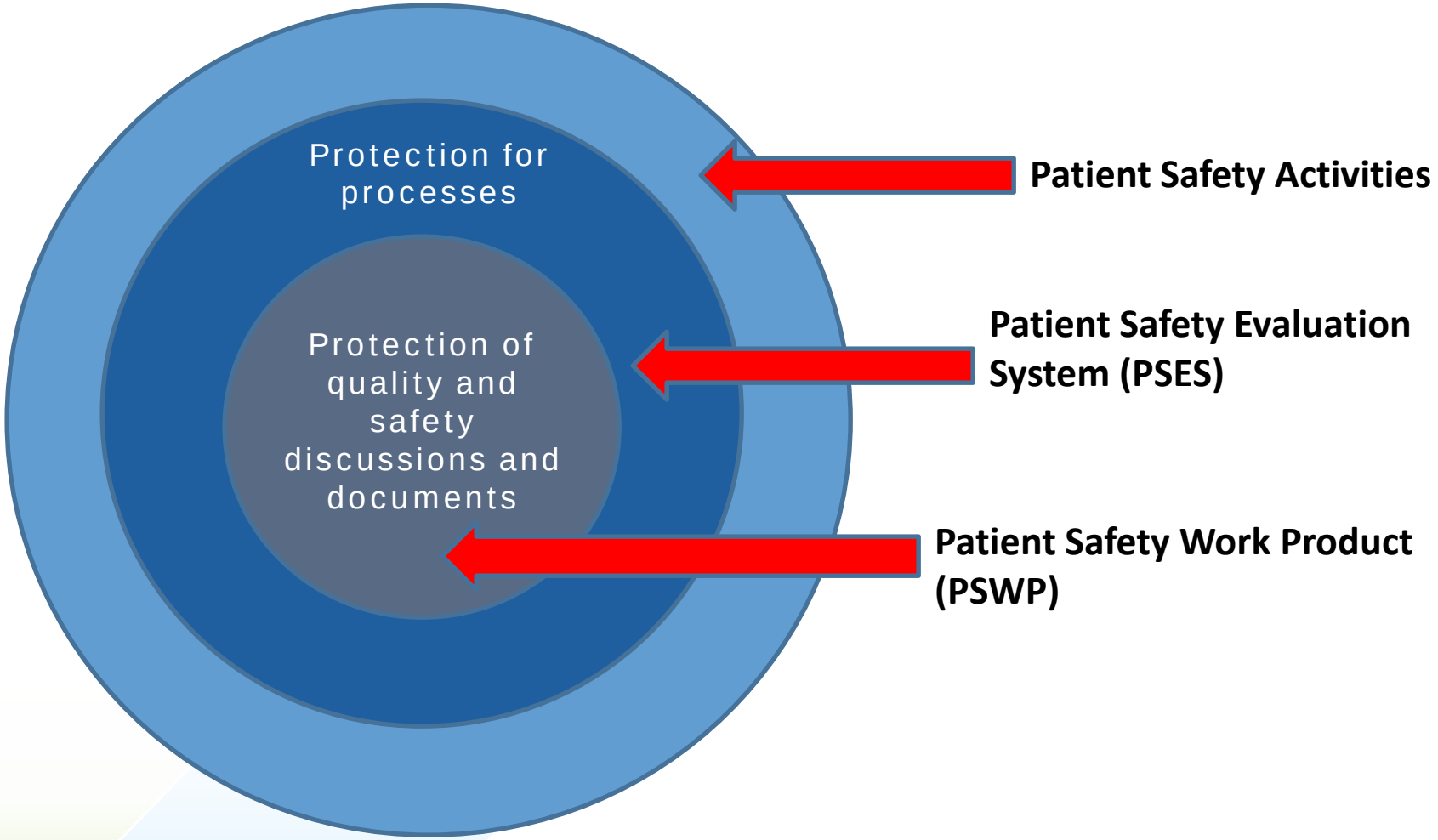
Texas Procedure

- Modified AHRQ Common Formats for the reporting.
- All questions from the Common Formats will be presented but only the following are required:
  - Category of Event
  - Type of Event
  - Date of Event
  - MR/Patient ID#,
  - Degree of Harm
  - Do you want to delete this record?
- Facilities are NOT required to:
  - Report or identify unsafe conditions or near misses—ONLY actual events

HOW DOES PSQIA DEFINE PSES? PSWP?

- PSES: “Collection, management, or analysis of information for reporting to or by a PSO”; exists when:
  - a provider engages in patient safety activities **for the purpose of reporting** to a PSO
- “Data, reports, records, memoranda, analyses or written or oral statements…which…are assembled…and reported” to PSO OR
- “Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES

KEY PROVISIONS - PROCESSES

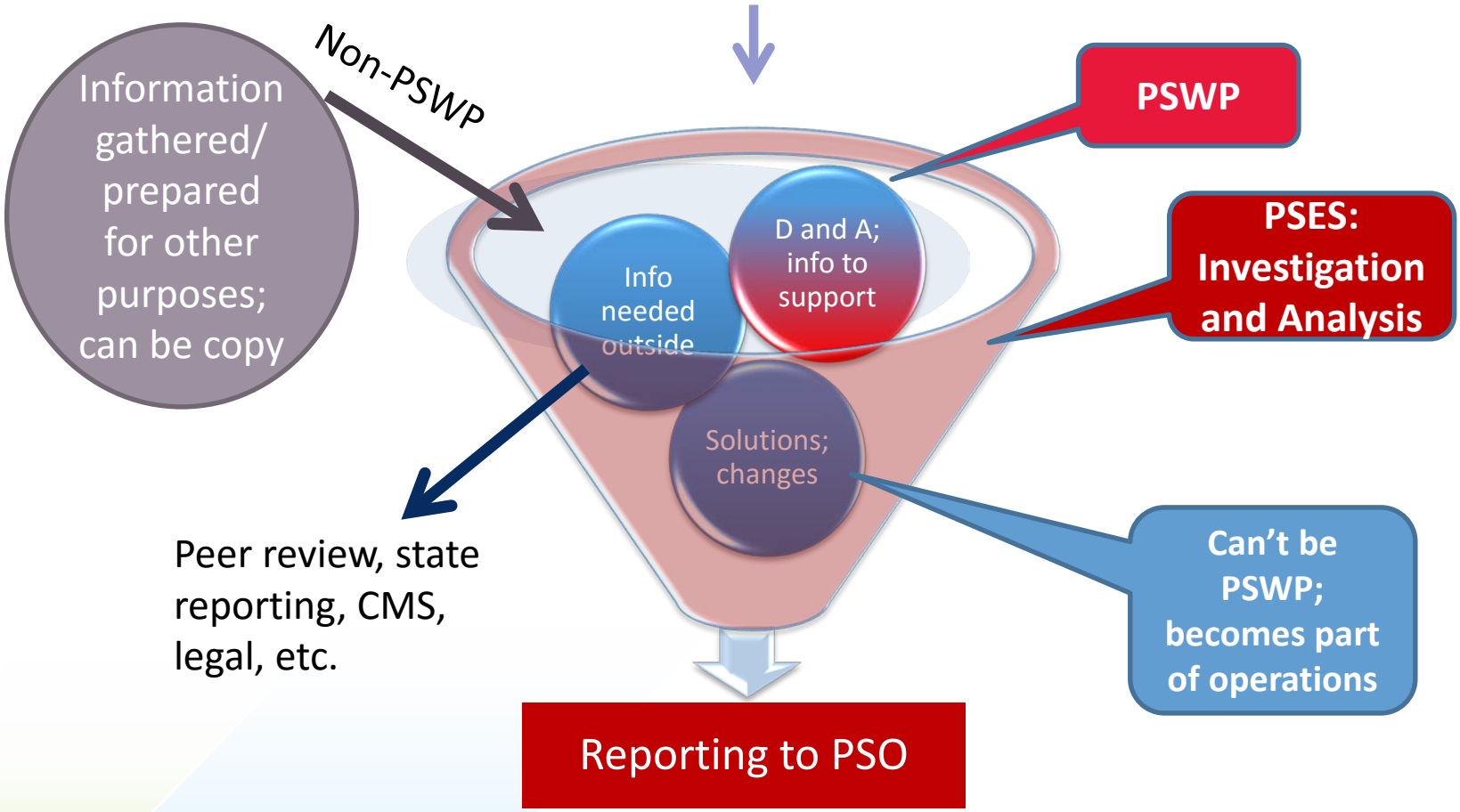


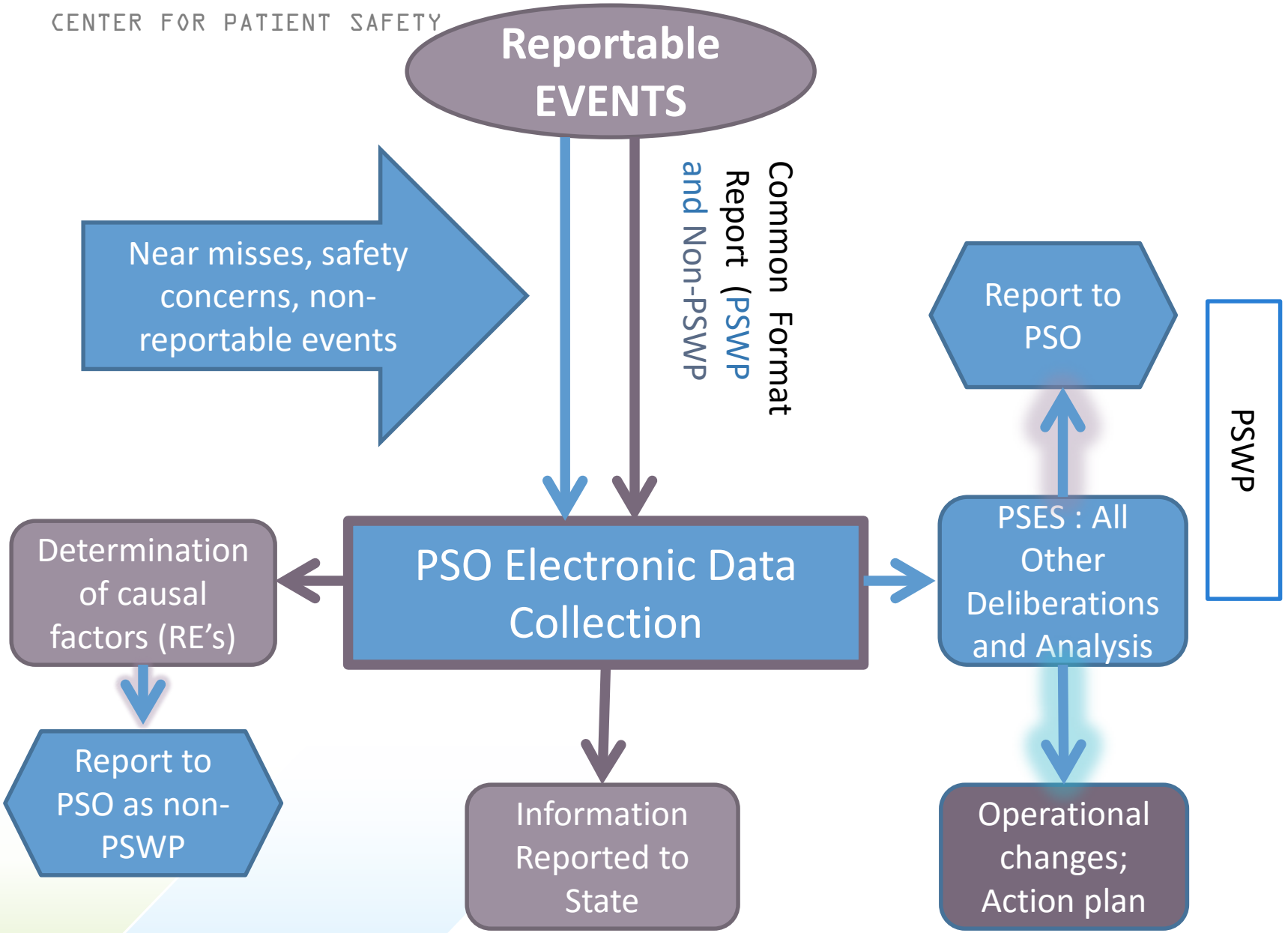
PATIENT SAFETY WORK PRODUCT (PSWP)

- What is **NOT** PSWP?
  - Patient's medical record
  - Billing and discharge information
  - Any other original patient or provider record
  - Information collected, maintained or developed separately, or that exists separately from a PSES

"For the purpose of reporting"

Event happens, preliminary info/investigation, essentials from IR, staff memories




Reportable EVENTS
Common Format Report (PSWP and Non-PSWP
Near misses, safety concerns, non-reportable events
Report to PSO
PSWP
Determination of causal factors (RE's)
PSO Electronic Data Collection
PSES : All Other Deliberations and Analysis
Report to PSO as non-PSWP
Information Reported to State
Operational changes; Action plan

WHAT IS NEW FROM AHRQ AND SG?

- AHRQ "Guidance": https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-12312.pdf
- Solicitor General Brief in Tibbs: http://www.scotusblog.com/wp-content/uploads/2016/05/14-1140-bsac-Tibbs-v-Goff.pdf
- Neither is law, though they may be influential
- Guidance indicates how AHRQ will address issues in PSO certification process

Guidance

"The intent of the …. PSQIA is to protect the additional information created through voluntary patient safety activities, not to protect records created through providers' mandatory information collection activities."

"…in order for information to become PSWP through the reporting pathway, it must … be assembled or developed…for reporting to a PSO and be reported to a PSO."

Guidance

Drop out: "…if the provider is unsure at the time the information is prepared for reporting to the PSO whether that information may be required in the future to fulfill…an obligation."

What were you thinking at the time the information was created?

CMS and surveyors

"HHS has heard reports of providers, PSOs and regulators working together to ensure that the regulator can obtain the information they need without requesting that provider impermissibly disclose PSWP. HHS encourages such communication. Regulatory agencies…are reminded that…PSWP is privileged and confidential ….Therefore, such entities should not demand PSWP from providers or PSOs."

Non-PSWP: Available for CMS/surveyors

- Resident name and other demographic information about the resident and the event (date, place, time, etc.)
- Brief description of event
- Names of witnesses and staff involved (for interviews)
- Medical record, care plans, etc. (Can't be protected)
- Staff for interviews (information about their knowledge of anything outside of PSES can't be protected; all their factual knowledge about the event or routine facility operation is available)
- Simple compilations of information about events (falls in last 90 days, etc.). Possibly basic logs for falls, etc.
- MDS data and quality measure reports (can't be protected)
- Information about changes made/plans of correction developed after an event (can't be protected)
- Records regarding the implementation of changes specified in a submitted plan of correction

PSWP: Protected Information

- Root cause analysis of specific events (vs. staff interviews about the facility's generic root cause analysis process)
- Research regarding solutions/standards of care
- Substance of deliberations and analysis during team meetings regarding safety issues and events (or interviews with team members on those topics)
- Substantive information from QA meetings (can't be disclosed under other federal law) and QAPI team meetings
- Expert consultation reports
- Identifiable information furnished to or received from the PSO
- Records of investigatory interviews
- Statistical compilations prepared specifically as part of the investigation of an event or safety issue
- Statistical compilations prepared to help the participant identify events or safety issues (QAPI surveillance)
- Records of measurements or observations not related to a specific plan of correction

PSQIA ESSENTIALS: Still apply

- Contract with PSO (or more than one)
- Patient Safety Evaluation System (PSES), best defined in policies
- Establish workflow: study and adapt current systems
- Patient Safety Work Product (PSWP): define what is and what isn't
- Define process for protecting PSWP

REPORT!!!!!!!

Takeaways

- Be completely aware of outside reporting obligations and sources of information for those---state and other
- Review COPs/LTC regs about QAPI systems
- Make sure info is available that:
  - Demonstrates identification and review of events
  - Describes QAPI processes
  - Documents that the work is taking place (minutes)
  - The results: changes to procedures, etc.

Takeaways

- Deliberations and analysis inside PSES are always PSWP and cannot be used elsewhere.
- The purpose of the PSES is to report. Courts are paying attention to this. AHRQ is paying attention to this.
- Think about how incidents are reported internally and how you designate the various data points on the reports.
- You can always recreate something that is PSWP.

RECOMMENDATIONS FOR SHARING DATA WITH SURVEYORS/DEPARTMENT OF HEALTH

- Patient/resident name and other demographic information about the individual and the event (date, place, time, etc.)
- Brief description of event
- Names of witnesses and staff involved (for interviews)
- Medical record, care plans, etc. (Cannot be protected)
- Solutions actually developed (Cannot be protected)
- Staff for interviews (information about their knowledge of anything outside of PSES cannot be protected; all their factual knowledge about the event or routine organizational operation is available)
- Protect: Deliberations and analysis inside PSES
- Open for negotiation: causal factors

QUESTIONS?

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