Patient Safety Organizations

Improving Patient Safety, Healthcare and Outcomes

Janice Suchyta, Shareholder
Baker, Donelson, Bearman,
Caldwell & Berkowitz, PC
1301 McKinney Street
Suite 3700
Houston, TX 77010
jsuchyta@bakerdonelson.com

BAKER DONELSON

Patient Safety Organization Fundamentals

The purpose of this presentation is to provide an overview of Patient Safety Organizations and the Patient Safety Act including the principles and requirements under the Act. Topics discussed include the following:

- Overview of the Patient Safety Act
- What is a Patient Safety Evaluation System (PSES) and how is it formed?
- What information is privileged and confidential as Patient Safety Work Product (PSWP) which is not subject to discovery or admissibility into evidence?
- The benefits of a Patient Safety Organization

The Patient Safety and Quality Improvement Act of 2005

- The goal of the Act was to improve patient safety by encouraging voluntary and confidential reporting of health care events that adversely affect patients. To implement the Patient Safety Act, the Department of Health and Human Services issued the Patient Safety and Quality Improvement Rule (Patient Safety Rule).
- The Patient Safety Act and the Patient Safety Rule authorize the creation of PSOs to improve quality and safety through the collection and analysis of aggregated, confidential data on patient safety events. This process enables PSOs to more quickly identify patterns of failures and develop strategies to eliminate patient safety risks and hazards.

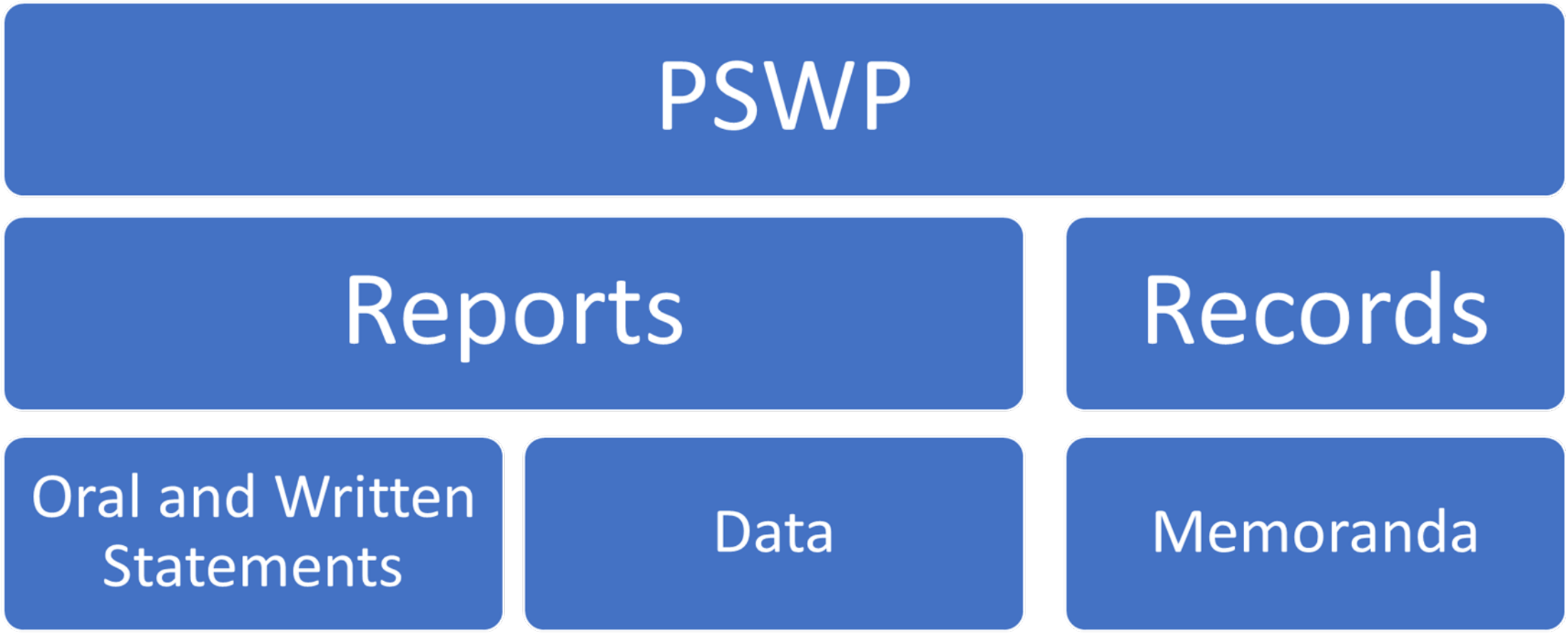
The Patient Safety and Quality Improvement Act of 2005, (cont.)

- Provides privilege & confidentiality protections for information when providers work with Federally listed PSOs to improve quality, safety and healthcare outcomes
- Authorizes establishment of “Common Formats” for reporting patient safety events
- Establishes “Network of Patient Safety Databases” (NPSD)
- Requires reporting of findings annually in AHRQ’s
- National Health Quality / Disparities Reports

Patient Safety Activities

- Efforts to improve patient safety and the quality of health care delivery
- The collection and analysis of patient safety work product
- The development of information for 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 providing feedback and assistance to effectively minimize patient risk
- Procedures to preserve confidentiality for patient safety work product

What is Patient Safety Work Product (PSWP)?



Patient Safety Work Product Requirements

Deliberation and Analysis

- Must be created in PSES

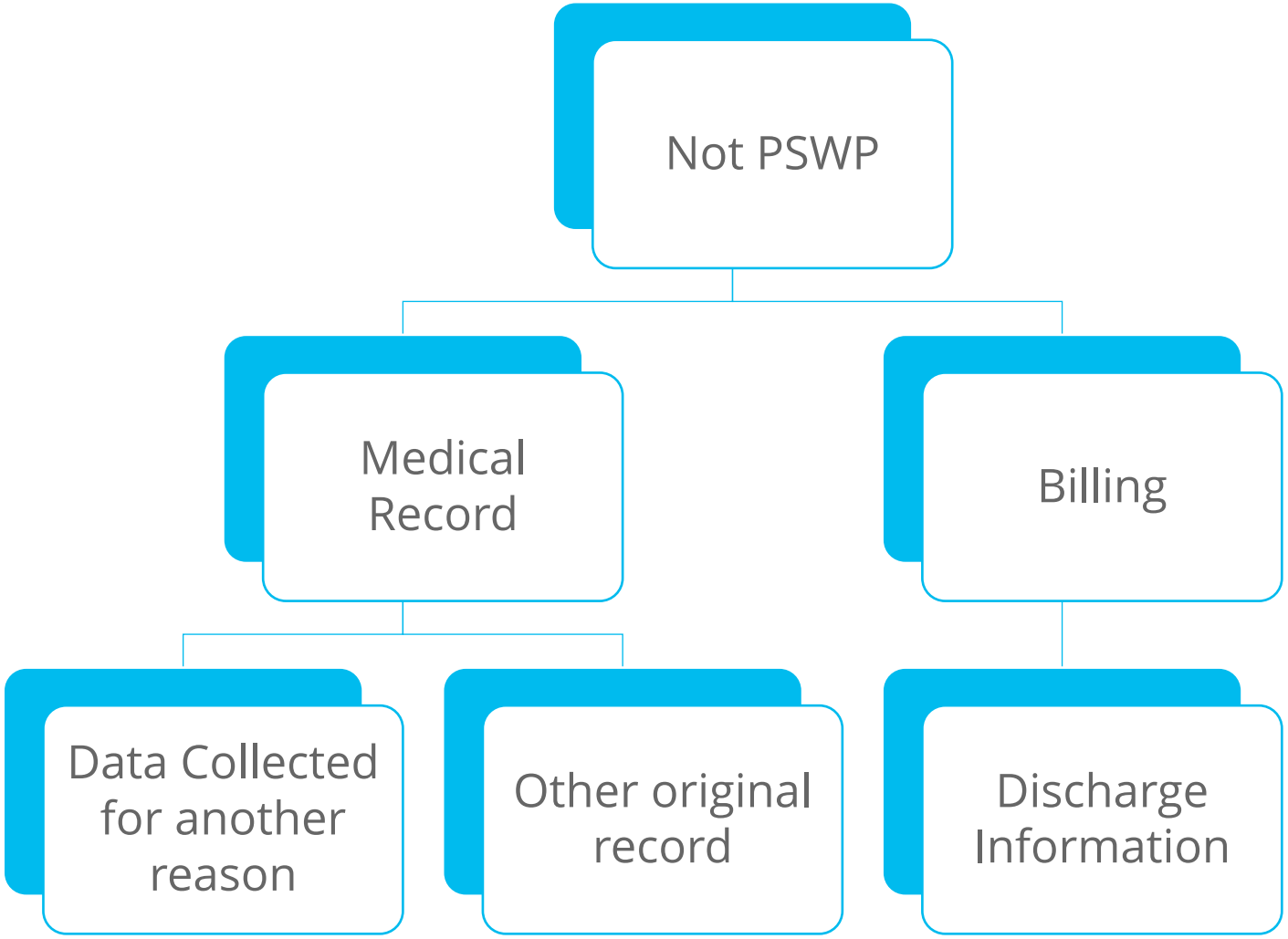
Data

- Improve patient safety, health care quality or outcomes
- Assembled by provider for reporting to PSO and are reported to PSO

PSO

- Develops data to conduct patient safety activities

What Is Not Patient Safety Work Product (PSWP)?



PSES Operations

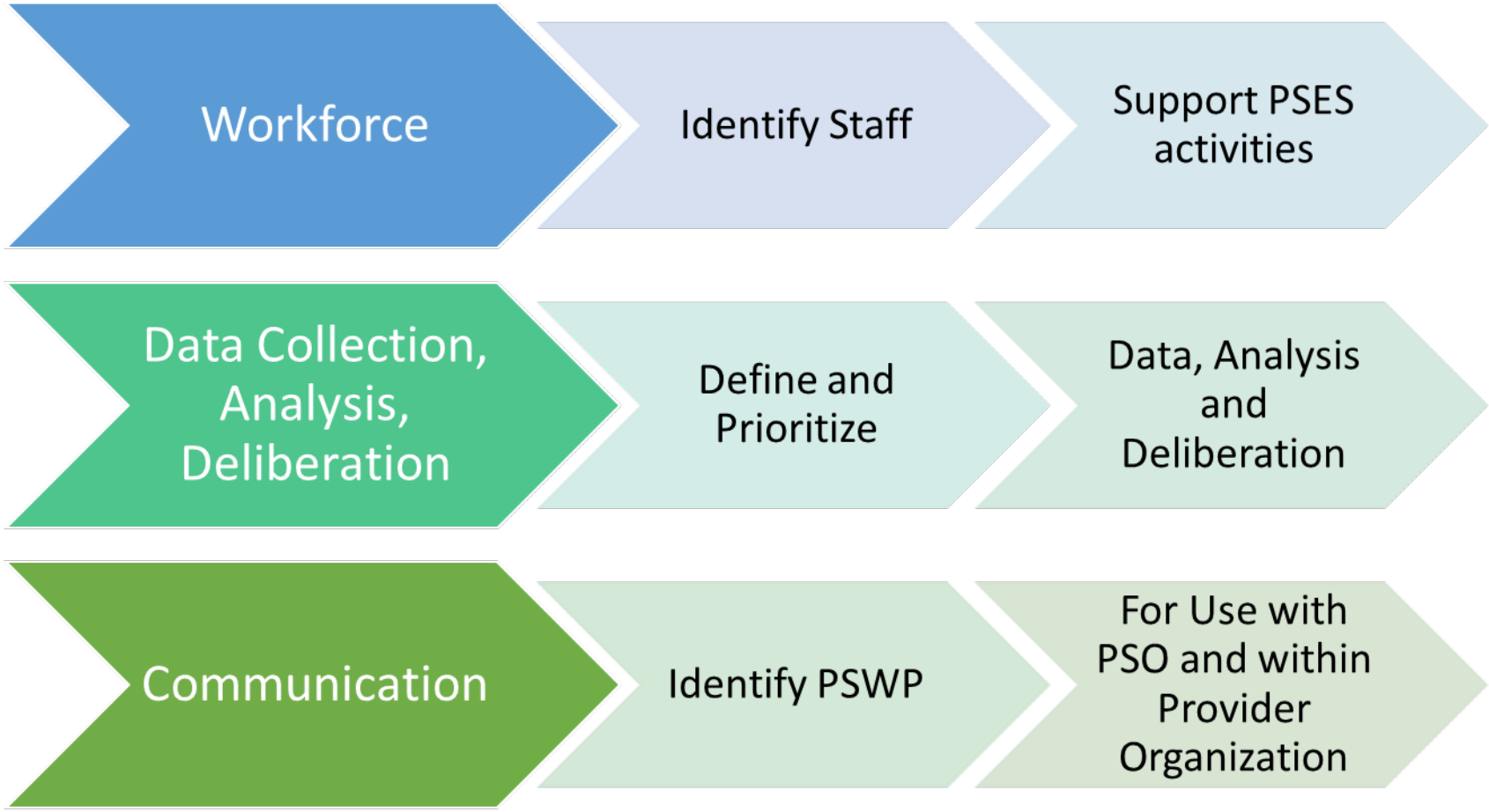
Implement Your PSES To:

- **Collect** data to improve patient safety, healthcare quality and healthcare outcomes
- **Review** data and take action when needed to mitigate harm or improve care
- **Analyze** data and makes recommendations to continuously improve patient safety, healthcare quality and healthcare outcomes
- Conduct RCAs, Proactive Risk Assessments, in-depth reviews, and aggregate RCAs
- Determine which data will/will not be reported to the PSO
- Report to PSO
- Conduct auditing procedures

PSES Operations (cont.)

- Examples of Collecting and Reporting To a PSO:
- Medical Error investigations, FMEA or Proactive Risk Assessments, Root Cause Analysis
- Risk Management - incident reports, investigation notes, interview notes, RCA notes, notes from risk recommendations via phone calls or conversations, notes from PS rounds which relate to identified patient safety activities
- Outcome/Quality - may be practitioner specific, sedation, complications, blood utilization etc.
- Peer Review
- Committee minutes – Those portions of Safety, Quality, Quality and Safety Committee of the Board, Medication, Blood, Physician Peer Review relating to identified patient safety activities

Documentation Steps For The PSES



PSO Reporting Operations

PSES Operations

Review Data

Conduct Patient safety activities

Report Data to PSO (document and date)

Receive PSWP from PSO with recommendations

PSO Operations

Conduct deliberations

Conduct analysis

Collect additional data

Provide PSWP feedback

Offer evidence based recommendations

PSWP and Privilege

Not Subject to:

- subpoenas or court order
- discovery
- FOIA or other similar law
- requests from accrediting bodies or CMS

Not Admissible in:

- any state, federal or other legal proceeding
- state licensure proceedings
- hospital peer review disciplinary proceedings

Federal Privilege Vs. State Law Protections

State Peer Review

- Limited in scope of covered activities
- State law protections do not apply in federal claims
- State laws usually do not apply when information shared outside the institution

Patient Safety Act

- Consistent national standard
- Applies in all state and federal proceedings
- Broader scope of covered activities and providers
- Protections can never be waived
- PSWP can be freely shared throughout organization

Primary PSO Activities

Collection and analysis of “Patient Safety Work Products”

Development and dissemination of best practices recommendations, protocols, etc.

Provide case specific feedback and assistance to help minimize risk

Encourage a culture of safety!

PSO Advantages

- Independent, external experts
- Aggregate data locally, regionally, and nationally to better understand safety events
- Learn from other's mistakes
- Trends can be developed across similar type services
- Develop best practices, benchmarks, and compliance standards

Additional Benefits

Protecting the reputation of the agency or provider

Interagency collaboration

Data sharing