

**Katten**

**Nebraska Coalition for Patient Safety**

October 13, 2021  
12:00 – 1:00 PM Central Time

Patient Safety Organizations (PSOs): What Every Physician Group and Ambulatory Services Provider Needs to Know

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**Welcome!**

- This webinar will be recorded and available on the members-only page of the NCPS website ([www.nepatientsafety.org](http://www.nepatientsafety.org)).
- Continuing Education Credit will only be available for participants who attend the live webinar. CE credit is not available for viewing the webinar recording.
- Participants are in listen-only mode.
  - If you have questions, please type them in the question or chat box.
  - If we are unable to answer your question during the webinar, we will do our best to provide answers via email after the webinar.
- If we experience technical difficulties and our connection to attendees is lost, we will make one attempt to reconnect to continue the program.
- If we are unable to reconnect, we will reschedule the program.

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- This program has been approved to award 1.0 hour of continuing medical education.
- The Nebraska Medical Education Trust designates this webinar for 1.0 AMA PRA Category 1 Credit(s).™ Physicians should claim only the credit commensurate with the extent of their participation in the activity.
- This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of Nebraska Medical Education Trust and the Nebraska Coalition for Patient Safety. The Nebraska Medical Education Trust is accredited by the Nebraska Medical Association to provide continuing medical education for physicians.
- Participants must attend the entire event to obtain CE credit.
- All attendees will be emailed a link to an attestation of attendance, and a link to an online program evaluation that we ask you to complete by **October 20** in order to receive continuing education credit.
- *The speaker(s) and planning committee have no relevant financial relationships to disclose.*

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**Nursing Continuing Education Credit**

- This program has been approved to award 1.0 hour of continuing education for nurses.
- Continuing Education Contact Hours awarded by Iowa Western Community College, Iowa Board of Nursing Provider #6.
- Participants must attend the entire event to get CE credit.
- All attendees will be emailed a link to an online program evaluation that we ask you to complete by **October 20** in order to receive continuing education credit.
- Nurse attendees who desire continuing education credit are required to register and create a personal profile on Iowa Western Community College's web site.
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  - Completed profile and CE registration need to be submitted by **October 20** in order to receive continuing education credit.

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### Patient Safety Organization Key Takeaways

- PSOs offer privilege and confidentiality protections that are national in scope
- PSOs aggregate data to identify patterns, trends, and the underlying causes of infrequent, but often tragic, adverse events faster than individual organizations
- PSOs can convene its reporting providers in a protected environment to leverage learning and improvement
- PSOs collect data in a standard format to allow for meaningful comparisons amongst similar providers

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### 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 and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices
- The utilization of PSWP to encourage a culture of safety and provide feedback and assistance to effectively minimize patient risk
- The maintenance of procedures to preserve confidentiality with respect to PSWP
- The provision of appropriate security measures with respect to PSWP
- The utilization of qualified staff
- Activities related to the operation of a PSES and to the provision of feedback to participants in a patient safety evaluation system.

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### What is Patient Safety Work Product?

The diagram illustrates the components of Patient Safety Work Product (PSWP) and the requirements for Patient Safety Activities (PSA). It features a central 'PSWP' hexagon surrounded by other hexagons: 'Reports', 'Deliberation and Analysis', 'Memoranda', 'Records', 'Data', and 'Oral and Written Statement'. A box labeled 'Must be created in PSES' points to 'Deliberation and Analysis'. A box labeled 'Key dates must be documented' points to 'Oral and Written Statement'. To the right, a green box titled 'PSA Requirements' lists four bullet points: 'Data which could improve patient safety, health care quality, or health care outcomes', 'Data assembled or developed by a provider for reporting to a PSO and are reported to a PSO and/or which constitute', 'Analysis and deliberations conducted within a PSES', and 'Data developed by a PSO to conduct patient safety activities'.

**PSA Requirements**

- Data which could improve patient safety, health care quality, or health care outcomes
- Data assembled or developed by a provider for reporting to a PSO and are reported to a PSO and/or which constitute
- Analysis and deliberations conducted within a PSES
- Data developed by a PSO to conduct patient safety activities

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### What is Not PSWP?

- Information collected, maintained, or developed separately, or exists separately, from a PSES.
- Data removed from a patient safety evaluation system
- Data collected for another reason
- Mandatory adverse event report

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### Patient Safety Evaluation System (PSES)

PSES is the collection, development, management, or analysis of information for reporting to or by a PSO. A provider's PSES is an important determinant of what can, and cannot, become PSWP.

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### PSA Privilege and Confidentiality Standards Prevail Over State Law Protections

The privileged and confidentiality protections and certain restrictions on disciplinary activity supports development of a Just Learning Culture

State Peer Review	Patient Safety Act
<ul style="list-style-type: none"><li>• Limited in scope of covered activities and in scope of covered entities</li><li>• State law protections do not apply in federal claims</li><li>• State laws usually do not protect information when shared outside the institution – considered waived</li></ul>	<ul style="list-style-type: none"><li>• Consistent national standard</li><li>• Applies in all state and federal proceedings</li><li>• Scope of covered activities and providers is broader</li><li>• Protections can never be waived</li><li>• PSWP can be more freely shared among affiliated providers throughout a health care system</li><li>• PSES can include non-provider corporate parent</li></ul>

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**PSWP is Privileged**

**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

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**PSWP is Confidential and Not Subject to Disclosure with Limited Exceptions**

**Please see Patient Safety Final Rule for a complete description**

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**Peer Review Protections For Physician Groups and Ancillary Providers**

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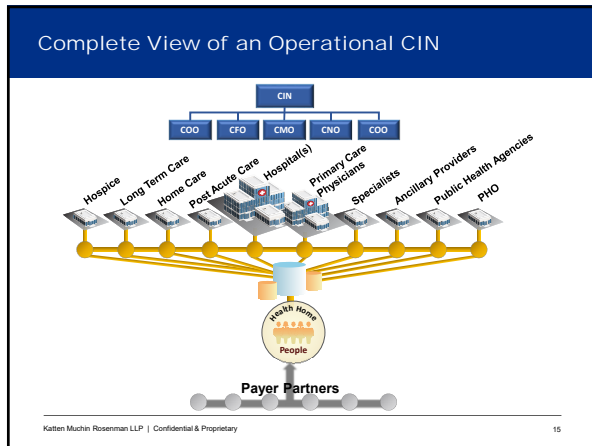
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### What is "Peer Review"

- The term "peer review" is a catch-all reference used by hospitals and other providers to cover and describe a broad range of activities, discussions, analyses and work product involving:
  - Quality assurance and improvement
  - Performance improvement
  - Ongoing monitoring under OPPE/FPPE and other quality standards
  - Tracking outcomes and compliance with quality metrics
  - Monitoring, proctoring, investigating, analyzing and correcting substandard practices and disruptive behavior
  - Similar remedial measures and efforts to evaluate the current competency of physicians, advanced practitioners, nurses and other healthcare practitioners

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### What is "Peer Review"

- Consequently, if these peer review activities, which is a subset of patient safety activities, are identified, collected, developed, analyzed and utilized for the purpose of improving patient care by the provider as subscribed within the provider's PSES policy, all of the work product and discussions can be treated as PSWP
- The Final Rule states that PSWP can be used for peer review, credentialing and other peer review and quality purposes within a single legal entity, i.e., hospital, physician group, without limitation if used for patient safety activities

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**Asserting PSA and/or State Peer Review Protections**

- Keep in mind that physician groups and other providers may also be able to assert the privileged protections under state law
  - You need to review Nebraska statutes and the case law in order to determine the scope of covered entities and covered activities
  - Nebraska Healthcare Quality Improvement Act applies to physician groups, physicians and other licensed healthcare facilities but privileged peer review activities need to be conducted by a "Peer Review Committee".
  - Depending on the document in question, both the state and the PSA privilege protections could apply although PSA protections usually are broader
  - You cannot also assert attorney-client work product privilege for these materials

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**Sharing PSWP**

- Physician/ancillary provider PSWP can be shared by and between affiliated providers
  - Identifiable PSWP may be freely "used" within the physician group or other ancillary entity – a disclosure exception is not required
  - Physician identifiable PSWP may be "disclosed" to other affiliated entities but you must some how obtain the prior written authorization of the provider. Options include:
    - Specific written authorization language in the physician appointment/re-appointment application
    - Specific written authorization language in the employment agreement
    - Use of a specific form each time physician/provider PSWP is disclosed

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**Need to Choose a PSWP Pathway**

- Your PSES policy should identify in some detail all of the patient safety activities, reports, analyses, peer review activities, etc., which the provider wants to treat as PSWP.
- Reporting Pathway
  - PSWP is either electronically or physically reported to APSO.
  - PSWP is "functionally reported" to the PSO.
- Deliberations or Analysis Pathway
  - The definition of PSWP also includes any data, reports, records, memorandum, analyses or written or oral statements which... identify or constitute the deliberations or analysis of, or identify the fact of reporting to a ["PSO"] (Emphasis added).
- Any PSWP which is not physically or functionally reported to a PSO should be categorized as deliberation or analysis within the PSES policy.

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### Need to Choose a PSWP Pathway

- PSWP which is deliberation or analyses automatically becomes PSWP when collected within the PSES and cannot be "dropped out" and used for other purposes.
- PSWP which is deliberation or analyses does not need to be reported to a PSO in order to be treated as privileged and confidential.

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### Working with a PSO in Physician Practices

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### Increased Ambulatory Safety Events Reported to One AHRO-Listed PSO

• Ambulatory patient safety events reported to PSO

Year	Patient	Unsafe conditions	Total
2017	~9500	~1000	~10500
2018	~11500	~1500	~13000
2019 (9 months)	~13500	~1500	~15000

PSO database Year: 2017 - 2019  
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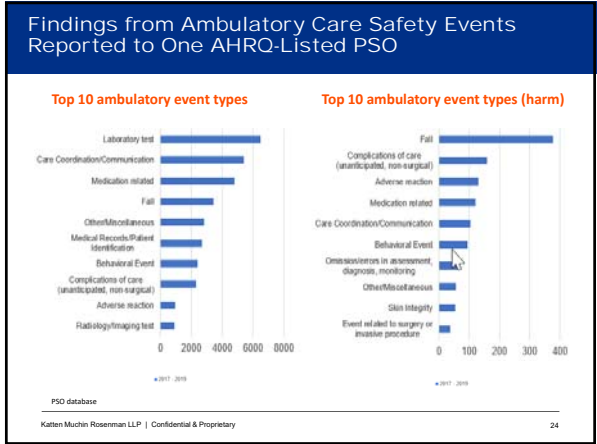
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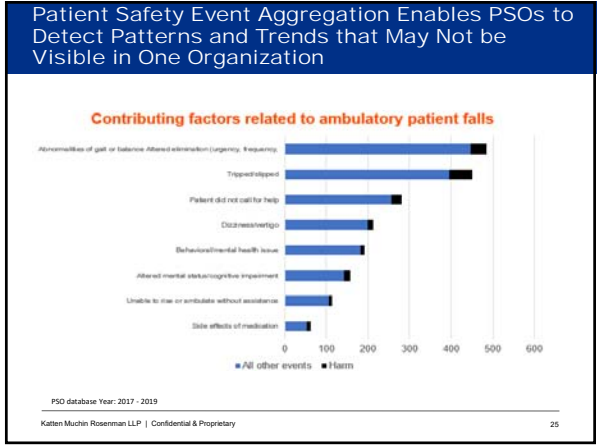
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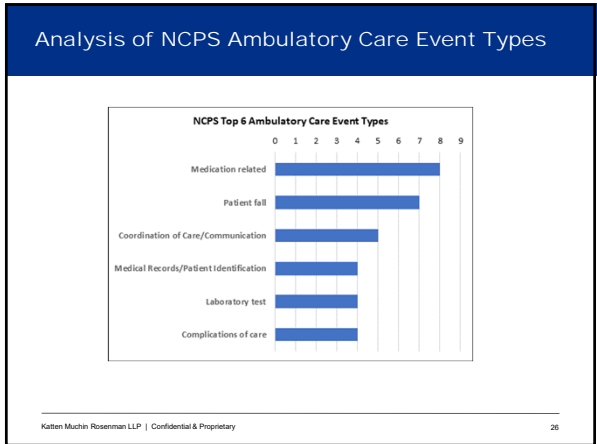
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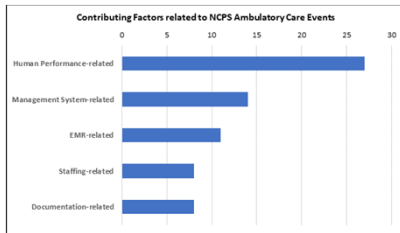
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### Analysis of NCPS Ambulatory Care Event Types



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### PA Employment Profiles



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Questions?

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## Additional Resources

- NCPS Webinar presented by Michael Callahan June 2, 2021: Patient Safety Organizations: What Every Ambulatory Care Provider Needs to Know.
  - This webinar provides an overview of patient safety organizations (PSOs) and the federal laws and privilege protections afforded to providers who report patient safety information to federally listed PSOs, such as NCPS.
  - Using a hypothetical scenario, the presenter compares and contrasts the Nebraska state laws with the privilege and confidentiality protections afforded by participation in a PSO under federal law.
  - Available to NCPS members: <https://www.nepatientsafety.org/members/member-login.html>
- Davey, S., et al. (2002). A preliminary taxonomy of medical errors in family practice. *Quality & Safety in Health Care*; 11: 233-238. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1743626/pdf/v011p00233.pdf>
- ECRI: DEEP DIVE - Safe Ambulatory Care. Strategies for Patient Safety & Risk Reduction. Available at: <https://www.ecri.org/landing-ambulatory-care-deep-dive>
- Kravet, S., et al. (2019). Prioritizing patient safety efforts in office practice settings. *Journal of Patient Safety*; 15(4): e98 – e101.

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## Michael R. Callahan

A nationally recognized advisor to health care providers across the country, Michael Callahan provides deeply informed business and legal counseling in all areas of hospital-physician relations and health care regulatory compliance and governmental investigations, including the Emergency Medical Treatment and Active Labor Act (EMTALA), the Health Insurance Portability and Accountability Act (HIPAA), Medicare Conditions of Participation (CoPs), hospital licensure and accreditation standards. He is widely respected for his leading work on the Patient Safety Act from a regulatory compliance, policy and litigation standpoint, including the development of patient safety organizations (PSOs).

### Practice focus

- Federal and state licensure and accreditation for hospitals and health systems
- Hospital-physician relations including contracts, bylaws, peer review investigation and hearings and related health care litigation
- PSOs and participating provider policies, compliance and litigation support
- Centers for Medicare and Medicaid Services (CMS) and state departments of health surveys and investigations
- Assisting health systems with medical staff integration and hospital/medical staff disputes

### The knowledge to identify efficient and practical solutions

- Health systems, hospitals and physician groups large and small across the country come to Michael for practical, real-world guidance and answers to challenging legal and operational issues, which he can provide quickly because of his many years of experience. He understands the reality of hospital quality, peer review, risk management and related operational, legal and regulatory complexities and can rely on a large client base in order to provide better and comparative solutions.
- He also is sought out by many of the largest health systems around the country for his understanding and interpretation of the Patient Safety Act. In a case of first impression he advised a national pharmacy that became the first provider to successfully assert an evidentiary privilege under the Patient Safety Act. Since that case, he has represented or advised many hospitals, physician groups and other licensed providers in creating or contracting with federally certified PSOs and has been directly involved in most of the major state appellate and federal court decisions interpreting the Patient Safety Act.

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