

**Katten**

**Nebraska Coalition for Patient Safety**

**June 2, 2021**

**Patient Safety Organizations 101:  
PSWP Privilege in the Context of PSOs**

**Michael R. Callahan, Senior Counsel  
Katten Muchin Rosenman LLP  
312.902.5634  
michael.callahan@katten.com**

# 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 attendees 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 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 and will continue the program.
- If we are unsuccessful with reconnecting, the date of the rescheduled program will be communicated to you via email as soon as it is made available.

# Continuing Medical Education Credit



- This program has been approved to award 1.0 hours 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.
- 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 Wednesday, June 9 in order to receive continuing education credit.

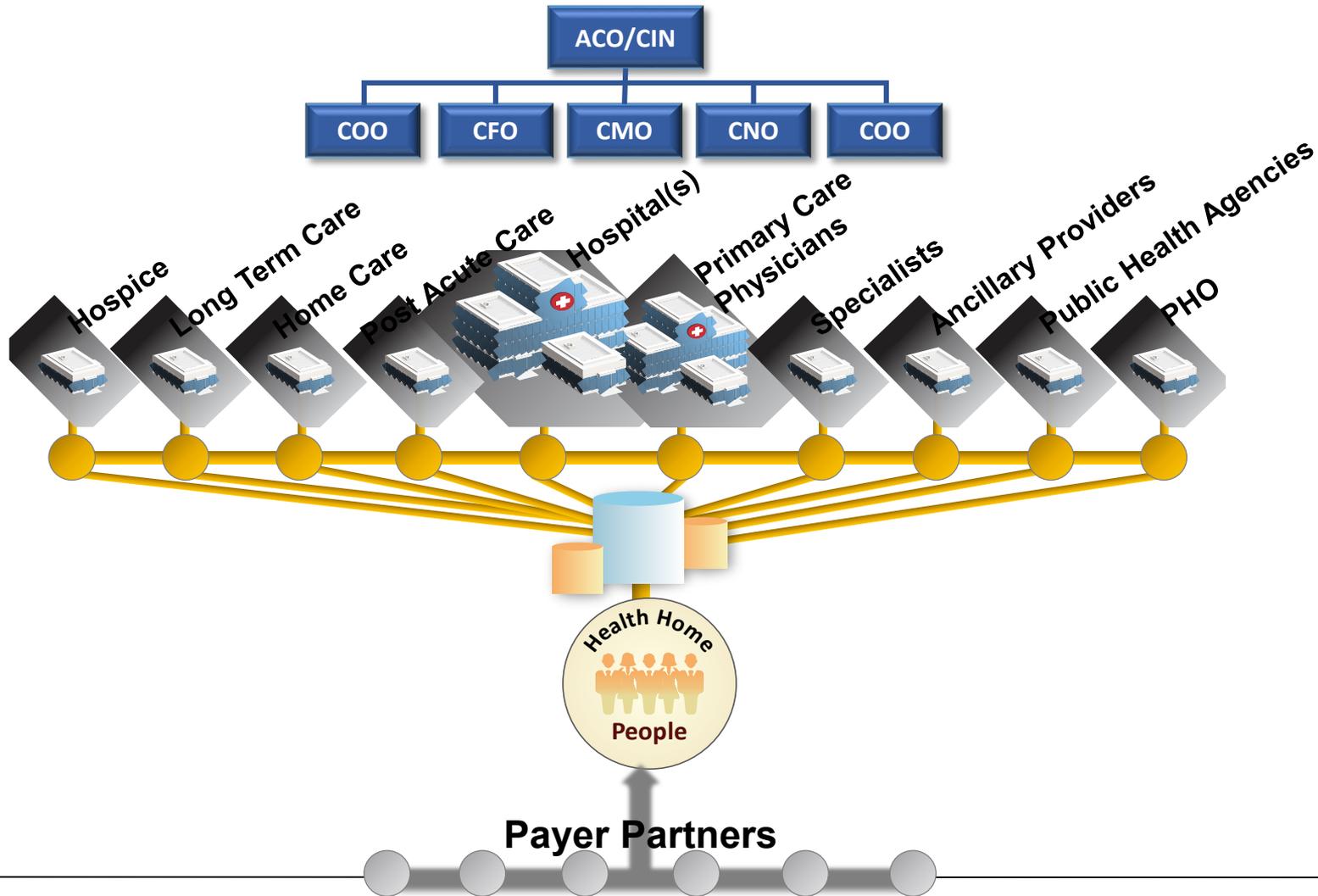
# Continuing Nursing Education Credit

- This program has been approved to award 1.0 hour of continuing education for nurse attendees who are NCPS members.
  - *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.
- Attendees will be emailed a link to an online program evaluation that we ask you to complete by Wednesday, June 9 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.
  - The email that is sent with a link to the program evaluation will contain a pdf attachment with instructions. Please read these.
  - Completed profile and CE registration need to be submitted by Wednesday, June 9 in order to receive continuing education credit.

# Disclosure

The speaker(s) and planning committee have no relevant financial relationships to disclose.

# Complete View of an Operational ACO/CIN



# Factors/Questions to be Assessed

- Are you seeking state and/or federal privilege protections?
- What is the scope of protected activities? -- peer review, quality improvement, RCAs, adverse events?
- What corporate entities, licensed facilities, licensed health care practitioners or others are protected under state/federal laws?
- What committees or organizational construct is required in order to assert the protections?
- Are your existing bylaws, rules, regs and policies properly structured to maximize available privilege protections?
- Can privileged information be shared across the CIN without waiving the privilege?

# Factors/Questions to be Assessed *cont'd*

- How does applicable case law affect statutory interpretation?
- What impact, if any, of mandated adverse event reporting obligations, i.e., never, events, hospital acquired infections
- Do state privilege protections apply to federal claims filed in federal court, i.e., antitrust, discrimination?
- Can CMS, IDPH and The Joint Commission access the privileged information?

# Hypothetical

- You get a call from the CIN's Chief Medical Officer, Dr. Susan Carealot, who also Chairs the Health System's CIN Quality and Credentials Committee. She informed the risk manager and general counsel that the CIN's administrative offices have received a subpoena from a medical malpractice attorney requesting all CIN and Health System medical and other records and documents pertaining to the CIN's review of care provided to a Ms. Hada Bad-Outcome.

# Hypothetical *cont'd*

- Ms. Hada Bad-Outcome's family is suing the providers involved in her care for malpractice and negligent credentialing. All of her providers are CIN participants, including a PCP employed by Health System Physician Group, a cardiac surgeon who is a member of a participating independent physician group and member of the medical staff along with the CIN's hospital and an affiliated skilled nursing facility where she allegedly received negligent services.

# Hypothetical *cont'd*

- Dr. Carealot tells you that Ms. Hada Bad-Outcome is a 40 year old CEO of a large, closely-held family company, who has 4 minor children and a stay-at-home husband, who experienced severe complications after her hypertension went undiagnosed by a Health System PCP. Ms. Bad-Outcome had seen the PCP because she was experiencing severe headaches, anxiety and nosebleeds. He believed she was stressed and dehydrated from travel, and prescribed Zolofl and regular exercise.

# Hypothetical *cont'd*

- Two weeks later she experienced a heart attack, and after a CABG procedure performed by the independent surgeon, developed post-surgical complications, and had a stroke. During her subsequent rehabilitation at a SNF, a medication error caused her to have another stroke, and she is now in a permanent vegetative state.

# Hypothetical *cont'd*

- Dr. Carealot asks you the general counsel, for copies of the applicable peer review policies for the Health System, and the credentialing and quality review procedures of the CIN, the hospital, the SNF, and the physician group and to pull all of the responsive documents from the physician credentials and quality files and any other relevant information. In addition, she wants copies of any root cause analysis (“RCA”) or other reviews that were generated by any of the provider entities involved in the patient’s care. She then plans to have the general counsel analyze whether the medical records and peer review materials reviewed and created within the CIN are privileged from discovery.

# Hypothetical *cont'd*

- After reviewing the requested information, the CMO does not want to release the records because the CIN's Quality and Credentials Committee determined that the PCP, who had a history of noncompliance with care protocols and poor quality scores, had not followed standard procedures for assessing the patient for hypertension. She also tells the general counsel that the cardiac surgeon had a history of similar post-surgical complications, and that based on this data, they decided he should be terminated from participation in the ACO that was established by the CIN.

# Summary and Analysis of Nebraska Healthcare Quality Improvement Act

## Healthcare Quality Improvement Act

- Section 71-7907 – Healthcare provider defined
  - A facility licensed under the healthcare facility licensure act
  - A healthcare professional licensed under the Uniform Credentialing Act
  - A professional healthcare service entity
  - An organization or association of healthcare professionals licensed under the Uniform Credentialing Act

# Summary and Analysis of Nebraska Healthcare Quality Improvement Act *cont'd*

- Section 71-7909 – Peer review defined
  - Peer review means the procedure by which the providers evaluate the quality and efficiency of services ordered or performed by other healthcare providers, including practice analysis, inpatient hospital and extended care facility, utilization review, medical audit and inventory care review, cause analysis, claims review, underwriting assistance and the compliance of a hospital, nursing home, or other healthcare facility operated by a healthcare provider with the standards set by an association of healthcare providers and with applicable laws, rules and regulations.

# Summary and Analysis of Nebraska Healthcare Quality Improvement Act *cont'd*

- Section 71-7910 – Peer Review Committee
  - Peer review committee means a utilization review committee, quality assessment committee, performance improvement committee, issue committee, credentialing committee, or other committee established by a professional healthcare service entity or by the governing board of the facility, which is a healthcare provider that does either of the following:
    - Conducts professional credentialing or quality review activities involving the competence of, professional conduct of, or quality of care provided by a healthcare provider, including both an individual who provides healthcare and an entity that provides healthcare, or
    - Conducts any other attendant hearing process initiated as a result of a peer review committee's recommendations or actions

# Summary and Analysis of Nebraska Healthcare Quality Improvement Act *cont'd*

- To conduct peer review pursuant to the Healthcare Quality Improvement Act, a professional healthcare service entity shall adopt and adhere to written policies and procedures governing the peer review committee of the professional healthcare service entity.
- Section 71-7912 – Confidentiality; Discovery; Availability of Medical Records, Documents or Information
  - The proceedings, records, minutes and reports of the peer review committee shall be held in confidence and shall not be subject to discovery or introduction into evidence in any civil action.

# Summary and Analysis of Nebraska Healthcare Quality Improvement Act *cont'd*

- No person who attends a meeting, peer review committee, works for or on behalf of a peer review committee provides information to a peer review committee, or participates in a peer review activity shall be permitted or required to testify in any such civil action as to any evidence of other matters produced, presented during the proceedings or activities of the peer review committee, or asked to any findings, recommendations, evaluations, opinions, or other actions of the peer review committee or any members thereof.

# Summary and Analysis of Nebraska Healthcare Quality Improvement Act *cont'd*

- Medical records, documents of information otherwise available from which sources are kept with respect to any patient in the organic course of business is not privileged, but cannot be made available or obtained from the peer review committee's proceedings or records.
- A healthcare provider or individual claiming the privileges under the Section has the burden of proving that the communications and documents are protected.

# Summary and Analysis of Nebraska Healthcare Quality Improvement Act *cont'd*

- Section 71-7913 – Incident report or risk management report
  - Incidents in risk management reports are not discoverable. They are not admissible in evidence on any civil action for damages, for injury, death or loss of a patient of a healthcare provider.
  - A person who prepares or has knowledge of the contents of an incident report or risk management report shall not testify and shall not be required to testify in any civil action as to the contents of the report.
  - The individual claiming the privilege has the burden of proving that the communications and documents are protected.

# Summary and Analysis of Nebraska Healthcare Quality Improvement Act *cont'd*

- Section 25-12,123 – Peer review committee proceedings
  - Proceedings and records of the peer review committee shall not be subject to discovery or introduction into evidence in any civil action against the person licensed pursuant to the act or arising out of matters which are the subject of the evaluation review by such committee.
  - This includes findings, recommendations, evaluations, opinion and other actions of such committee already members, except that information from original source materials are not privileged.
  - Any person who testifies before such committee or is a member of such committee shall not be prevented from testifying as to matters within his or her knowledge, but they cannot be asked about his or her testimony before such a committee or opinions formed as a result of such committee hearings.
  - Nothing in this Section shall prohibit a court of record, after a hearing and for good cause arising from extraordinary circumstances.

# Summary and Analysis of Nebraska Healthcare Quality Improvement Act *cont'd*

- Section 44-32, 174 – Healthcare review committee information and records
  - The information considered by a healthcare review committee in the records of their actions and proceedings shall be confidential and not subject to subpoena or order to produce, except in proceedings before the appropriate state licensing or certifying agency or in an appeal from the committee's findings or recommendation.
  - No person involved in such proceedings may be subpoenaed to testify in any judicial or quasi-judicial proceeding if such subpoena is based solely on such activities.
  - Any information that is disclosed to a state licensing or certifying agency or in an appeal shall not otherwise be discoverable in any legal actions set forth under this Act.

# Summary and Analysis of Nebraska Healthcare Quality Improvement Act *cont'd*

## Analysis

- Does the statute arguably protect requested records?
  - Medical records – No, never privileged.
  - Bylaws, policies and procedures – No.
    - Questions whether documents support privileged argument.
  - Peer review records and provider entities – Depends.
- Does CIN quality and credentials committee qualify as a peer review committee?
  - Only if the CIN is a professional healthcare service entity or is a healthcare provider. If not, then the information is arguably discoverable.

# Summary and Analysis of Nebraska Healthcare Quality Improvement Act *cont'd*

—What about the hospital's physician group?

- Although the physician group would be considered a healthcare provider, any peer review information which it is creating, must be conducted through an appropriate committee. If not, the information is discoverable.

—What about the SNF?

- As with the physician group, the SNF is a healthcare provider, but must conduct information through a qualified peer review committee.

—What about the PHO?

- PHOs typically are a contracting entity and not a healthcare provider, so probably not.

# Summary and Analysis of Nebraska Healthcare Quality Improvement Act *cont'd*

- What about risk management documents?
  - Incident and risk management reports are privileged and not subject to discovery.
- It is important to keep in mind that the privileged protections are limited to committee activities.

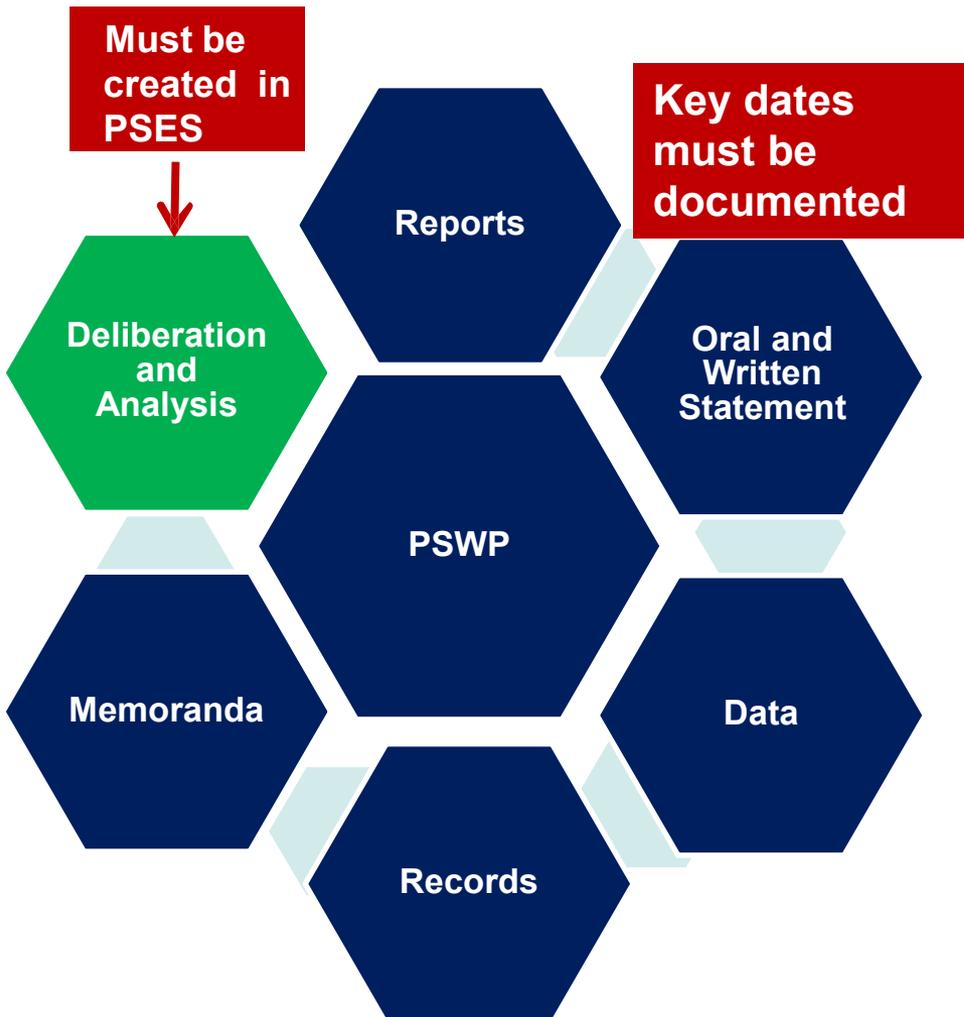
# Patient Safety and Quality Improvement Act of 2005

- Privileged Patient Safety Work Product
  - Any data, reports, records, memoranda, analyses (such as Root Cause Analyses (RCA), or written or oral statements (or copies of any of this material) which could improve patient safety, healthcare quality, or healthcare outcomes;
- And that:
  - Are assembled or developed by a provider for reporting to a PSO and are reported to a Patient Safety Organization (PSO), which includes information that is documented as within a patient safety evaluation system (PSES) for reporting to a PSO, and such documentation includes the date the information entered the PSES; or
  - Are developed by a PSO for the conduct of patient safety activities; or
  - Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES.

# Patient Safety Act

- What types of information can be considered for inclusion in the PSES for collection and reporting to the PSO if used to promote patient safety and quality?
  - Medical error or proactive risk assessments, root cause analysis
  - Risk Management — Not all activities will qualify such as claims management, but incident reports, investigation notes, interview notes, RCA notes, etc., tied to activities within the PSES can be protected
  - Outcome/Quality—may be practitioner specific
  - Peer review
  - Relevant portions of Committee minutes for activities included in the PSES relating to improving patient quality and reducing risks
  - Deliberations or analysis

# What is Patient Safety Work Product (PSWP)?



## Requirements

**Data which could improve patient safety, healthcare quality, or healthcare outcomes**

- Data assembled or developed by a provider for reporting to a PSO and are reported to a PSO

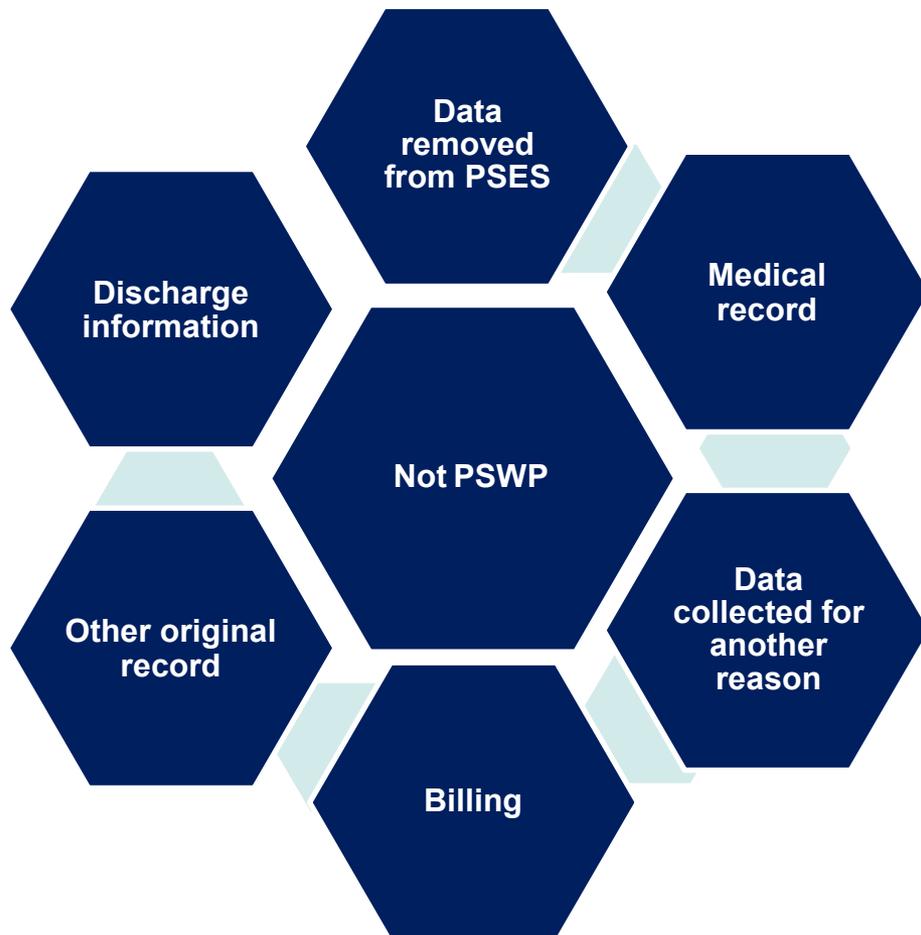
**Analysis and deliberations conducted within a PSES**

- Data developed by a PSO to conduct of patient safety activities

# Patient Safety Act

- What is not PSWP?
  - Patient's medical record, billing and discharge information, or any other original patient or provider information
  - Information that is collected, maintained, or developed separately, or exists separately, from a PSES. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered PSWP
  - PSWP assembled or developed by a provider for reporting to a PSO but removed from a PSES is no longer considered PSWP if:
    - Information has not yet been reported to a PSO; and
    - Provider documents the act and date of removal of such information from the PSES

# What Is Not PSWP?



## Requirements

**Information collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system.**

- Data removed from a patient safety evaluation system**

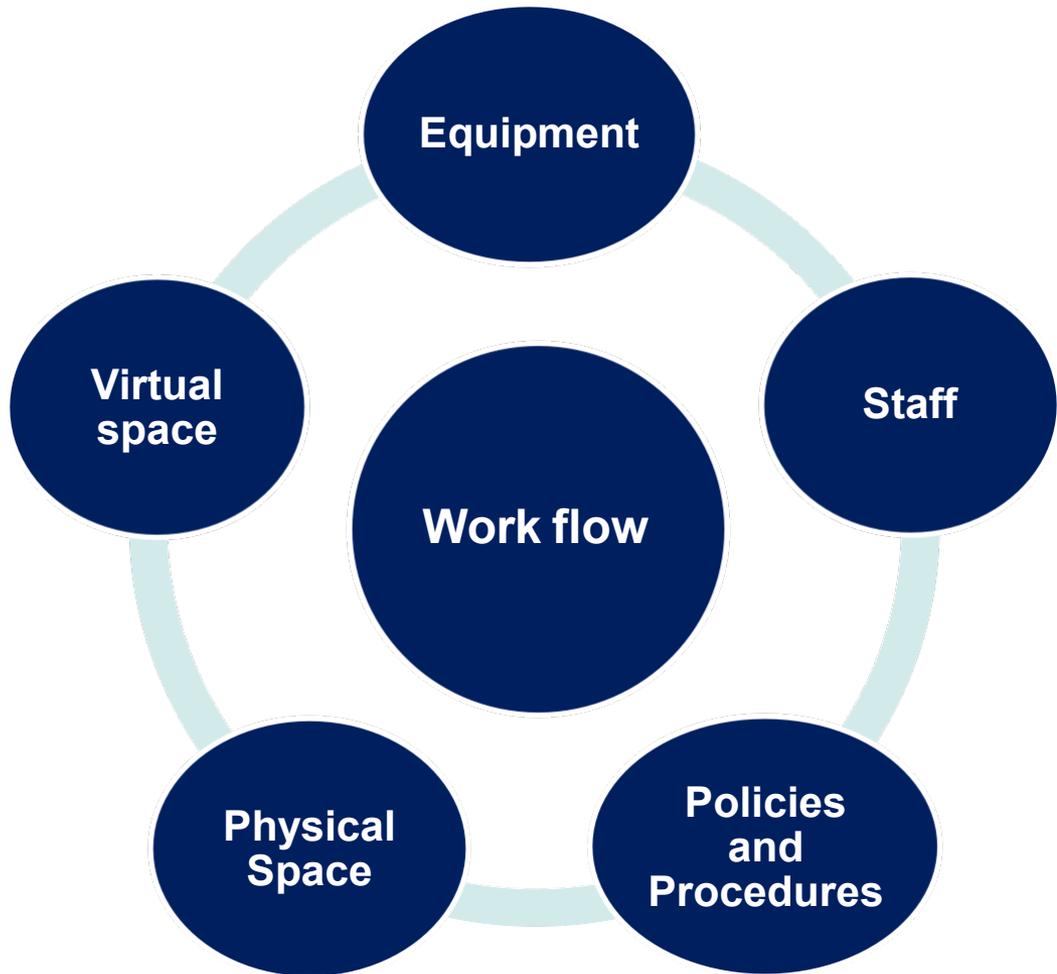
**Data collected for another reason**

# Patient Safety Act

- Reports that are the subject of mandatory state or federal reporting or which may be collected and maintained pursuant to state or federal laws be treated as PSWP.
- What entities are covered under the Act?
  - All entities or individuals licensed under state law to provide healthcare services or which the state otherwise permits to provide such services, i.e., hospitals, SNFs, physicians, physician groups, labs, pharmacies, home health agencies, etc.
  - A non-licensed corporate entity that owns, controls, manages or has veto authority over a licensed provider is considered a provider.

# Patient Safety Evaluation System (PSES)

The collection, 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 patient safety work product.



# PSES Operations

## **Establish and Implement a PSES to:**

- Collect data to improve patient safety, healthcare quality and healthcare outcomes
- Review data and takes 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 Proactive Risk Assessments, in-depth reviews, and aggregate medication errors
- Determine which data will/will not be reported to the PSO
- Report to PSO
- Conduct auditing procedures

# Patient Safety Act Privilege and Confidentiality Prevail Over State Law Protections

*The privileged and confidentiality protections and restriction of disciplinary activity supports development of a Just Learning Culture*

## State Peer Review

- Limited in scope of covered activities and in scope of covered entities
- State law protections do not apply in federal claims
- State laws usually do not protect information when shared outside the institution – considered waived

## Patient Safety Act

- Consistent national standard
- Applies in all state and federal proceedings
- Scope of covered activities and providers is broader
- Protections can never be waived
- PSWP can be more freely shared throughout a healthcare system
- PSES can include non-provider corporate parent



*Working with a PSO must be implemented in a way that facilitates a Just Learning Environment while taking advantage of privilege and confidentiality protections.*

# Patient Safety Act

- Analysis

- Do the protections apply to the requested documents?

- Medical records – No
- PSES policies and procedures – No
- Records that must be reported (or collected and maintained) by a state or federal law – No
- Committee reports, provider analyses, RCA

- Yes, if collected and identified in a system-wide PSES or in the PSES of a provider which has collected the PSWP for reporting to a PSO and is reported or if it constitutes deliberation or analysis

# Patient Safety Act *cont'd*

—Are all CIN entities covered?

- All licensed providers, facilities and the physicians are covered if participating in a PSO
- CIN is not covered unless it is a licensed provider and/or it owns, controls or manages licensed providers or has veto authority over decision making
- If not, patient safety and peer review activities must be conducted in a licensed facility.

—What about the PHO? – No, it is not a licensed provider

# Comparison of Nebraska Act to Patient Safety Act

- Scope of Covered Entities
  - Although the scope of covered entities in Nebraska is very broad, the Patient Safety Act applies to all licensed entities and individuals, or healthcare providers under the state's law, as well as non-provider corporate entities which own, control or manage affiliated licensed providers.
- Scope of Covered Activities
  - Again, the activities under Nebraska which are considered privileged are very broad, but are remitted to activities conducted through peer review committees. The scope of privileged patient safety activities under the Patient Safety Act are broader and are not limited to activities which take place through a committee.

# Comparison of Nebraska Act to Patient Safety Act *cont'd*

- Protections in state and/or federal proceedings
  - The privileged protections under Nebraska law only apply in state proceedings, whereas the privileged protections under the Patient Safety Act apply in all state and federal proceedings.
- Waiver
  - Privileged information which is improperly disclosed by a hospital or other covered healthcare entity can lead to a waiver of the privilege. The privileged protections under the Patient Safety Act can never be waived. Instead, improper disclosures, if identified, can result in a civil fine.

# Comparison of Nebraska Act to Patient Safety Act *cont'd*

- Disclosure among affiliated providers
  - It is not clear whether privileged information can be shared among affiliated providers under Nebraska law without risking a waiver. Under the Patient Safety Act, PSWP can be shared among all affiliated providers who are participating in the PSO, including the non-provider corporate parent.
  - Moreover, Nebraska law provides that a court could “under extraordinary circumstances” order the disclosure of privileged information.
  - Keep in mind that the privileged protections under the Nebraska Act and the Patient Safety Act are not mutually exclusive. You can insert both depending on the documents you are seeking to protect.

# Impact and Lessons Learned

- **Develop Both a Specific and Broadly Worded PSES policy**
  - One of the fundamental documents for internal educational purposes as well as to be introduced to a court in demonstrating that the materials in dispute are indeed PSWP is a provider's PSES policy.
  - The courts are not going to simply accept the word of the hospital or other provider that information qualifies as PSWP.
  - The provider should conduct an inventory of all of its performance improvement, quality assurance, peer review and other related patient activities as well as the various committees, reports and other analyses being conducted within the organization.
  - This is the starting point when determining the scope of activities you wish to include within the PSES and therefore claim as privileged PSWP.

# Impact and Lessons Learned *cont'd*

- The details of these activities and the information to be protected should be reflected within the PSES.
- When seeking to claim privilege protections over an incident report, committee minutes or other internal analysis, a provider can then cite to the specific reference within the PSES as evidence of the hospital's intent to treat this information as privileged.
- The provider should also include a “catch all” to account for other privileged patient safety activities that are not included in the PSES policy.
- **Carefully Describe Your PSWP Pathway**
  - As reflected in the Appellate Court's decision in Daley, a provider can create PSWP via actual reporting, function reporting or through deliberations or analysis.

# Impact and Lessons Learned *cont'd*

- It is critical that your PSES policy distinguish which forms of information, incident reports, etc., are being actually reported to the PSO or scanned and downloaded and reported and what forms of information are being treated as deliberations or analysis.
- As a practical matter, most patient safety activities can be characterized as deliberations or analysis.
- Information that is deliberations or analysis automatically becomes PSWP when collected within the PSES and does not need to be reported to the PSO although reporting is certainly an option.
- Most of the PSO appellate court decisions, including the Daley decision, involved actual reporting and not deliberations or analysis.
- Ramsey v. Guthrie Clinic is the first “deliberations or analysis” decision.

# Impact and Lessons Learned *cont'd*

- Keep in mind too, that information which is being treated as deliberations or analysis cannot be “dropped out” and used for other purposes but can be shared if you meet one or more of the disclosure exceptions. These include disclosing to consultants, your attorney, independent contractors that are assisting the hospital in patient safety activities and other disclosures permitted under the PSA.
- It is unlikely the hospital actually reports every single incident report to the PSO. Your PSES policy, therefore, should treat these unreported incident reports as deliberations or analysis.

# Impact and Lessons Learned *cont'd*

- **Use Detailed Affidavits to Support Argument**

- The role of the provider and its legal counsel is to effectively educate the courts about the PSA so the judges have a better understanding as to the context as to why the disputed materials are PSWP.
- As is true in most cases, courts rely heavily on the affidavits that were submitted to demonstrate compliance with the PSA requirements in order to determine whether the information qualified as PSWP.
- All representations in an affidavit are accepted as true unless they are otherwise rebutted.
- Sometimes multiple affidavits may be required.

# Impact and Lessons Learned *cont'd*

- The type of representations and documents to include within an affidavit include the following:
  - The PSO AHRQ certification and recertification letters.
  - The provider's PSO membership agreement.
  - The PSES policy.
  - Citations to the policy where disputed documents are referenced and whether the information was reported to a PSO or treated as deliberations or analysis.
  - Screenshots of the redacted forms, reports, etc., for which the privilege is being asserted.
  - Documentation as to when the information was reported, either electronically or functionally, or when the information qualified as “deliberations or analysis” under this separate pathway.

# Impact and Lessons Learned *cont'd*

- A description of how information is collected within the PSES, how it qualifies as PSWP, if not otherwise set forth in the PSES.
- Representation as to how the PSWP was or is used for internal patient safety activities and used by the PSO.
- Representation that the information has not been collected for unrelated purposes, such as satisfying a state or federal mandated reporting requirement but is being collected for reporting to a PSO.
- If possible, a representation that the provider is not required by state or federal law to make the information available to a government agency or other third party.

# Impact and Lessons Learned *cont'd*

- An affidavit from the PSO acknowledging the provider's membership and that the information, if reported, was received and is being used to further the provider's and the PSO's privileged patient safety activities.
- Make sure that use of outside experts used to conduct patient safety activities to benefit the hospital or PSO are correctly documented and use references in PSES. Considering including the engagement letter with PSES.
- Remember, risk management information and activities relating to claims and litigation support will not be considered PSWP.
- Assert other privilege protections if applicable.
- Policies are not privileged references.

# Additional Litigation Lessons Learned and Questions Raised

- Types of Legal Challenges:
  - Timing of when provider connected with a PSO versus dates of the claimed privileged documents.
  - Did the provider and PSO establish a PSES? When?
  - Was the information sought identified by the provider/PSO as being collected within a PSES?
  - Was it actually collected and either actually or functionally reported to the PSO? What evidence/documentation?
  - If not yet reported, what is the justification for not doing so? How long has information been held? Does your PSES policy reflect a practice or standard for retention?
  - Is the information being treated as deliberations or analysis?

# Additional Litigation Lessons Learned and Questions Raised *cont'd*

- Has information been dropped out? Did you document this action?
- Is it eligible for protection?
- May be protected under state law.
- Is provider/PSO asserting multiple protections?
  - If collected for another purpose, even if for attorney-client, or in anticipation of litigation or protected under state statute, plaintiff can argue information was collected for another purpose and therefore the PSQIA protections do not apply – cannot be PSWP and privileged under attorney-client.

# Additional Litigation Lessons Learned and Questions Raised *cont'd*

- Is provider/PSO attempting to use information that was reported or which cannot be dropped out, i.e., an analysis, for another purpose, such as to defend itself in a lawsuit or government investigation?
  - Once it becomes PSWP, a provider may not disclose to a third party or introduce as evidence to establish a defense.
- Is the provider required to collect and maintain the disputed documents pursuant to a state or federal statute, regulation or other law or pursuant to an accreditation standard?
- Was the information being used for HR, claims management or litigation management purposes?

# Additional Litigation Lessons Learned and Questions Raised *cont'd*

- Document, document, document
  - PSO member agreement
  - PSES policies
  - Forms
  - Documentation of how and when PSWP is collected, reported or dropped out
  - Detailed affidavits
  - Separate Attorney-client privilege protections
  - Independent contractor agreements
  - Utilization of disclosure exceptions

# Katten Locations

## **CHARLOTTE**

550 South Tryon Street  
Suite 2900  
Charlotte, NC 28202-4213  
+1.704.444.2000 tel  
+1.704.444.2050 fax

## **CHICAGO**

525 West Monroe Street  
Chicago, IL 60661-3693  
+1.312.902.5200 tel  
+1.312.902.1061 fax

## **DALLAS**

2121 North Pearl Street  
Suite 1100  
Dallas, TX 75201-2591  
+1.214.765.3600 tel  
+1.214.765.3602 fax

## **LONDON**

Paternoster House  
65 St Paul's Churchyard  
London EC4M 8AB  
United Kingdom  
+44 (0) 20 7776 7620 tel  
+44 (0) 20 7776 7621 fax

## **LOS ANGELES – CENTURY CITY**

2029 Century Park East  
Suite 2600  
Los Angeles, CA 90067-3012  
+1.310.788.4400 tel  
+1.310.788.4471 fax

## **LOS ANGELES – DOWNTOWN**

515 South Flower Street  
Suite 4150  
Los Angeles, CA 90071-2212  
+1.213.443.9000 tel  
+1.213.443.9001 fax

## **NEW YORK**

575 Madison Avenue  
New York, NY 10022-2585  
+1.212.940.8800 tel  
+1.212.940.8776 fax

## **ORANGE COUNTY**

100 Spectrum Center Drive  
Suite 1050  
Irvine, CA 92618-4960  
+1.714.966.6819 tel  
+1.714.966.6821 fax

## **SHANGHAI**

Suite 4906 Wheelock Square  
1717 Nanjing Road West  
Shanghai 200040  
P.R. China  
+86.21.6039.3222 tel  
+86.21.6039.3223 fax

## **WASHINGTON, DC**

2900 K Street NW  
North Tower - Suite 200  
Washington, DC 20007-5118  
+1.202.625.3500 tel  
+1.202.298.7570 fax

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