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Illinois Health and Hospital Association Presents Privilege Protections for Healthcare Organizations under the Patient Safety Act and the Illinois Medical Studies Act

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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. 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

- 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 zoloft and regular exercise. 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

- 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") on 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.
- 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.

Health Care Providers/Systems Participating in a PSO

Ascension

HCA

Universal Health Services

AMITA

Advocate Aurora

AdventHealth

Trinity Health

Northwestern Medicine

OSF

Lurie Children's

MAPS contracts with 81 hospitals/health systems

Walgreens

CVS

Walmart

DuPage Medical Group

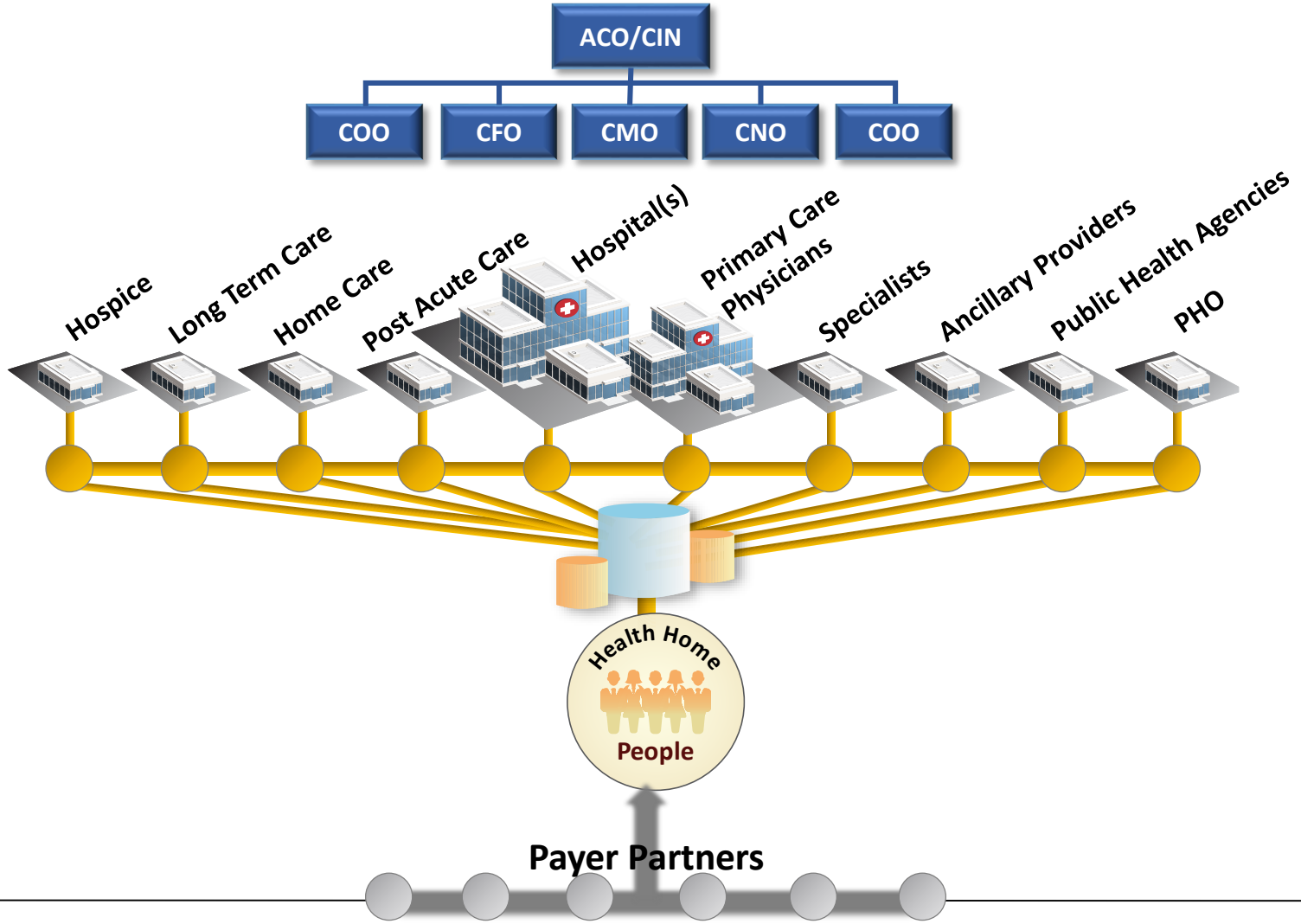
Factors/Questions to be Assessed

- 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

- 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?

Complete view of an operational ACO/CIN



Summary and Analysis of Illinois Medical Studies Act

- Medical Studies Act
  - 735 ILCS 5/8-2101
    - All information, interviews, reports, statements, memoranda, recommendations, letters of reference or other third party confidential assessments of a health care practitioner's professional competence, or other data.
    - Allied medical societies, health maintenance organizations, medical organizations under contract with health maintenance organizations or with insurance or other health care delivery entities or facilities.
    - Their agents, committees of ambulatory surgical treatment centers or post-surgical recovery centers or their medical staffs, or committees of licensed or accredited hospitals or their medical staffs.

Summary and Analysis of Illinois Medical Studies Act

- Including Patient Care Audit Committees, Medical Care Evaluation Committees, Utilization Review committees, Credential Committees and Executive Committees, or their designees (but not the medical records pertaining to the patient), used in the course of internal quality control or of medical study for the purpose of reducing morbidity or mortality, or for improving patient care or increasing organ and tissue donations.
- Shall be privileged, strictly confidential and shall be used only for medical research, the evaluation and improvement of quality care, or granting, limiting or revoking staff privileges or agreements for services.
- Information can be used in disciplinary hearings and subsequent judicial review.
- Protections have been interpreted fairly broadly but information produced for a different purpose, i.e., risk management, is not protected even if used by a peer review committee.

Summary and Analysis of Illinois Medical Studies Act

- Although the Medical Studies Act references “medical organizations” under contract with HMOs or other healthcare delivery entities or facilities, surgicenters and hospitals, Appellate Courts have not extended protections to nursing homes or pharmacies.
- Recent 2nd District Appellate Court decisions have limited the application of the privilege protections to materials and discussions generated after an event or investigation has been initiated by an identified peer review committee and only if used exclusively for peer review/ quality activities.
- Protections cannot be waived if used for statutory purposes.
- Information arguably can be shared throughout the system among controlled affiliates as well as specific physician information if authorized.
- Protections do not apply to federal claims brought in federal court.

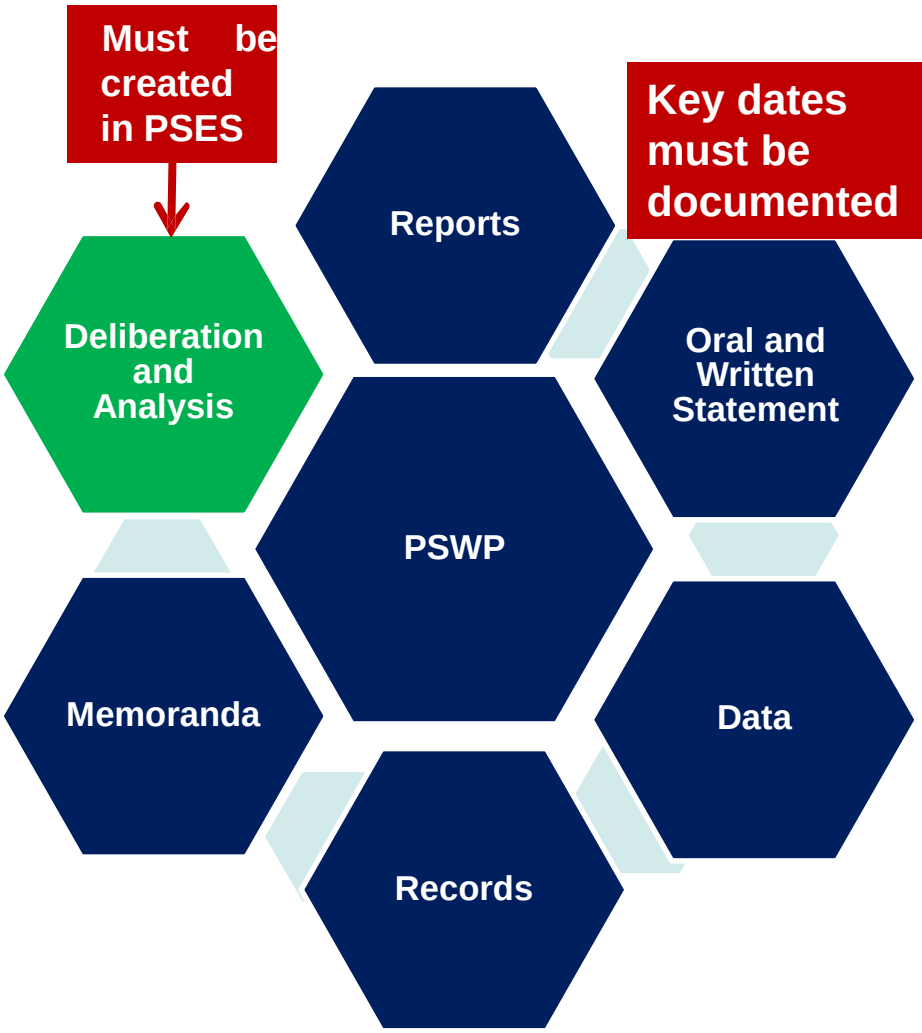
Patient Safety and Quality Improvement Act of 2005

- 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, health care quality, or health care 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, 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

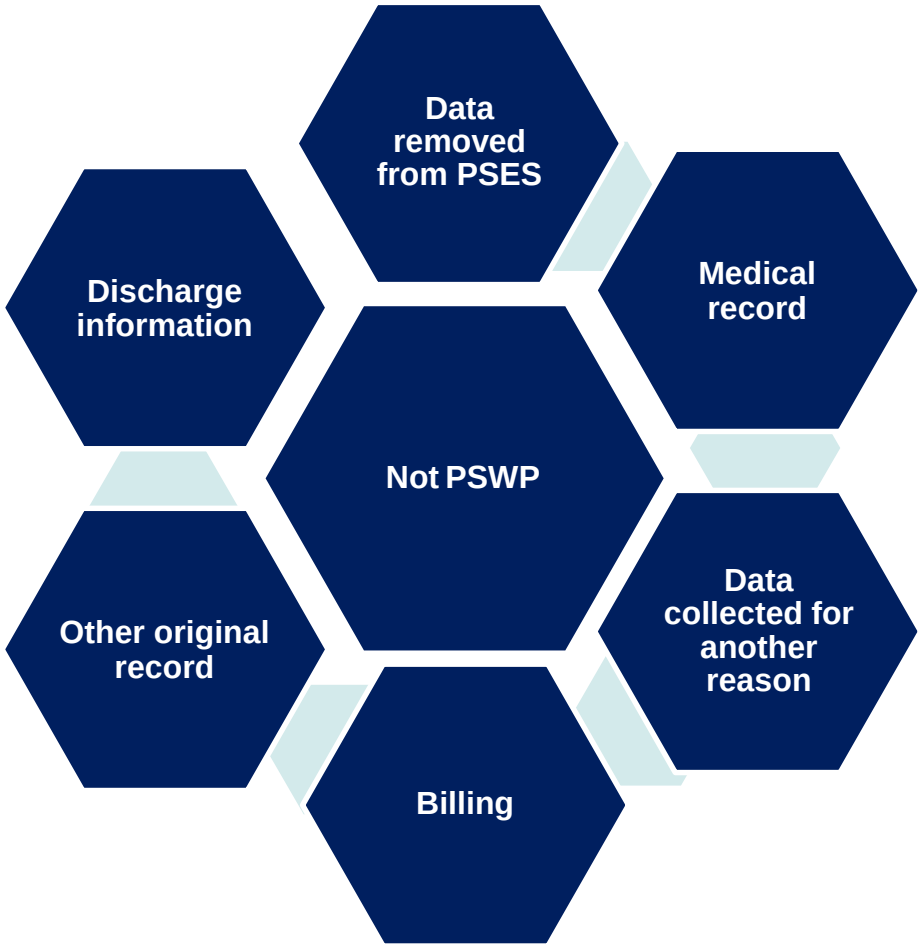
Analysis and deliberations conducted within a PSES

- 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

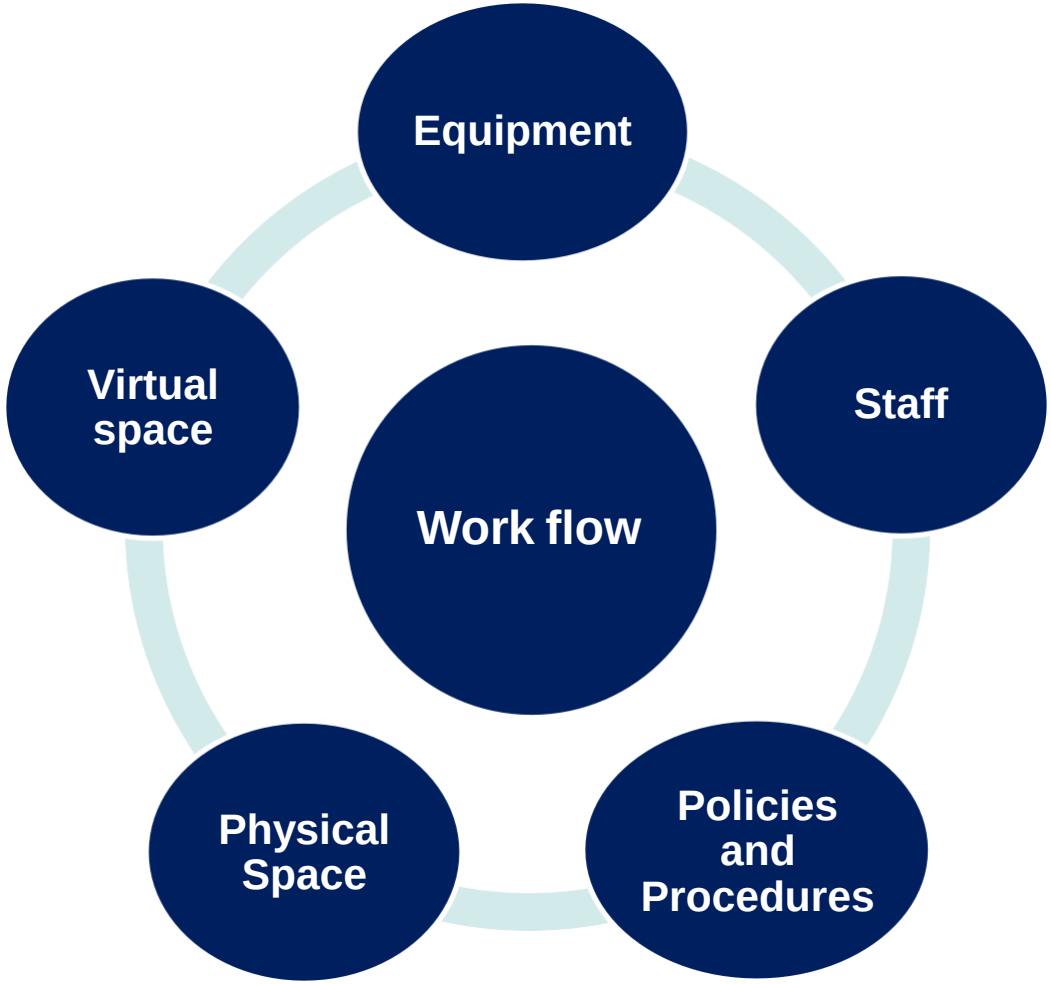
Patient Safety Act

- 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 health care 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

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

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 health care 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 (cont'd)

- 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

Patient Safety Act (cont'd)

- Can PSWP be shared?
  - Identifiable PSWP can be shared by and between affiliated providers
  - Physicians and other licensed professionals need to authorize, in writing, the sharing of identifiable PSWP
- Can protections be waived?
  - There are disclosure exceptions but privilege protections are never waivable
- Do protections apply in all state and federal proceedings?
  - Yes

Comparison of Medical Studies Act to the Patient Safety Act

- Patient Safety Act
  - The confidentiality and privilege protections afforded under the PSA generally apply to reports, minutes, analyses, data, discussions, recommendations, etc., that relate to patient safety and quality if generated or managed, or analyzed within the PSES and collected for reporting to a PSO.
  - The scope of what patient safety activities can be protected, generally speaking, is broader than the activities and documents privileged under the MSA – not limited to committees.
  - The scope of what entities can seek protection is much broader.

Comparison of Medical Studies Act to the Patient Safety Act

- The protections apply in both state and, for the first time, federal proceedings.
- The protections can never be waived under any circumstances.
- PSA pre-empts state law – Daley v. Ingalls Memorial Hospital.
- Non-provider corporate parent organization involved in patient safety activities as well as owned, controlled or managed provider affiliates can be included in a system-wide PSES and be protected.
- PSWP can be shared among affiliated providers.
- PSWP is not admissible into evidence nor is it subject to discovery.
- Key to these protections is the design of the provider's and PSO's patient safety evaluation system ("PSES").
- The MSA and PSA are not mutually exclusive. You can assert both depending on the documents you are seeking to protect

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- **Background**
  - Case involves a lawsuit brought by the estate of a patient alleging that Ingalls Memorial Hospital and its employees committed malpractice when it failed to adequately monitor the patient's blood glucose levels.
  - The lawsuit further alleged that the patient's subsequent injuries caused by this negligence contributed to her death.
  - During the course of discovery the hospital objected to interrogatories which sought a number of incident reports and complaints arguing that the information was privileged from discovery under both the Illinois Medical Studies Act and the Patient Safety and Quality Improvement Act of 2005 ("PSA").
  - The plaintiff also requested that the hospital produce documents which described any statements made by the decedent, a family member or anyone with knowledge regarding issues addressed in the lawsuit.
  - Upon refusal to produce the documents, the plaintiff filed a motion to compel.

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- Ultimately, only three documents remained in dispute which included two incident reports involving the patient's care and the complaint made by the patient's daughter to a hospital employee regarding the patient's treatment.
- All three documents, which were electronically reported to the hospital's PSO, contained the heading "Healthcare Safety Zone Portal" in addition to the name "Clarity Group Inc. Copyright" at the bottom of each page.
- Each document also included the date on which the documents were created and reported to the PSO.

- **Hospital's Response to Motion to Compel**
  - In support of its response to the motion to compel, the hospital submitted two affidavits from its associate general counsel which contained the following representations:
    - The hospital contracted with Clarity PSO in 2009 to improve the hospital's patient safety and quality of care.

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- The documents in dispute were created, prepared and generated for submission to the PSO.
- The Healthcare Safety Zone Portal provided the means by which the hospital reported this information to Clarity and were prepared “solely” for submission to Clarity.
- The documents were not part of the patient’s original medical records which had already been produced to the plaintiff.
- The documents had never been removed from the hospital’s PSES for any purpose other than for internal quality purposes.
- The documents have not been reported to or investigated by any agency or organization other than Clarity.
- There were no other reports pertaining to the incidents alleged in the plaintiff’s complaint that were collected or maintained separately from the hospital’s PSES.

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- Interestingly and importantly, the plaintiff never filed a response nor did the attorney object or attempt to rebut information contained in the affidavits.

- **Trial Court's Decisions**
  - The trial court ordered and the hospital agreed to submit the disputed documents for an in camera inspection.
  - Upon review of the documents, the court determined that some of the information in the incident reports sent to the PSO should have been included in the patient's medical records and therefore ordered the hospital to turn over to the plaintiff those portions of the incident reports.
  - The hospital refused and was therefore held in "friendly contempt" which allowed for an automatic appeal to the Appellate Court.

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- **Appellate Court's Decision**
  - The Appellate Court began its analysis of the PSA by citing to the 1999 report from the Institute of Medicine entitled "to Err is Human: Building a Safer Health System" which served as the primary basis for the passage of the Act.
  - The PSA identified that the privilege protections that are incorporated into the law are "the foundation to furthering the overall goal of the statute to develop a national system for analyzing and learning from patient safety events".
  - In determining whether the documents in dispute were privileged Patient Safety Work Product ("PSWP") the Court recognized that there are three distinct ways of creating privileged documents, the "reporting pathway", which includes actual "functional reporting", as well as treating information as "deliberations or analysis".

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- Because the hospital argued that the documents were PSWP through the reporting pathway the court examined whether the hospital met all of their requirements under the PSA and further whether any exceptions applied that would prohibit the information from being privileged.
- In determining that the documents did qualify as PSWP, the court made the following findings:
  - The court documents demonstrate “that they are an amalgamation of data, reports, discussions, and reflections, the very type of information that is by definition patient safety or product”.
  - The affidavits established that the documents were assembled and prepared by Ingalls “solely” for submission to Clarity PSO and were reported to the PSO.
  - The information contained in the documents had the ability to improve patient safety and the quality of healthcare.

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- The documents themselves bear the dates information was entered into the patient safety evaluation system as represented in the unrebutted affidavits.
- The Court then responded to the plaintiff's arguments that the documents were not PSWP because one or more exceptions under the Act applied.

- **The information was required to be in the patient's medical record and therefore was not privilege**
  - Under the PSA, "original records" such as a patient's medical record, billing and other related information are not privileged.
  - The trial court ruled that factual information which was included in the reported incident reports contained information which should have been included in the patient's medical record.

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- The plaintiff also argued that there was a significant lack of information in the medical record which had been produced to the plaintiff as well as significant gaps of time during which other information should have been included in the medical record. The hospital, therefore, was trying to hide information under the "guise of patient safety work product".
- The Court recognized the Illinois Hospital Licensing Act requires that a medical record meet certain documentation requirements and that the PSA "does not permit providers to use privilege and confidentiality protections… to shield records required by external record keeping or reporting, and if the hospital in fact failed to meet these requirements there are "associated consequences for such failure".
- This failure, even if it occurred, does not mean that the information loses its privileged status simply because a report may include facts or other information that might also be found in the medical records.

Daley v. Ingalls Memorial Hospital, 2018 IL. App. (1st) 170891

- The Court further noted that the documents in question were created weeks after the patient was treated at the hospital and therefore "nothing in the records lead us to believe that the documents were [patient's] original medical records or contained information that should have been included in the original medical records."
- The Court also pointed out that discovery had not yet been completed and that the Plaintiff was entitled to depose individuals regarding any facts surrounding the patient's treatment.

- **The documents were not collected solely for the purpose of reporting to a PSO.**
  - Under the PSA, documents, reports, analyses, and other information that is collected for a purpose other than reporting to a PSO or which is collected outside of a provider's PSES is not privileged.
  - The affidavit submitted by the hospital indicated that the documents in question were in fact prepared "solely" for submission to the PSO.

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- Because this representation was unrebutted by the Plaintiff the court was obligated to accept the hospital's representation.
- Note: There is nothing under the PSA which makes reference to the word “solely”. This so called standard, which is reflected in the HHS PSO Guidance, and on which plaintiffs and courts have sometimes relied, does not mean that the information collected within the PSES and reported to the PSO or treated as deliberations or analysis cannot be used for other internal purposes. In fact, it is expected that PSWP is used by the hospital to improve patient safety and reduce risk.
- If, however, the information in question was required to satisfy an external obligation or was used for a purpose which is separate from improving patient care or reducing risk and is not identified within the PSES, a provider cannot make an after the fact argument that the information is now privileged and not subject to discovery.

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- **Information was collected to satisfy a reporting requirement and therefore did not qualify as PSWP.**
  - The PSA clearly states that if a report that the hospital claimed as privileged was required to be made to a state or federal government or agency, the hospital cannot try to hide that information within its PSES and claim it was privileged.
  - In this case, the plaintiff cited to the Illinois Adverse Healthcare Events Reporting Law of 2005 which requires the reporting of certain identified adverse events to the Illinois Department of Public Health.
  - The Plaintiff also cited to the Florida Supreme Court's in Charles v. Southern Baptist Hospital as well as other state court decisions to further support its argument that the disputed documents were not privileged.
  - In response, the Court pointed out that the Act in question had never been implemented in Illinois and therefore was not applicable.

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- The plaintiff did not cite to any other statute requiring that the disputed documents had to be reported or had to be collected and maintained and made available to a state or federal agency. Therefore, this argument by the plaintiff was rejected.

- **Allowing the documents to remain privileged will permit healthcare providers to hide valuable information and thus impede the truth seeking process.**
  - This is an argument that was made by both the plaintiff and an amicus brief submitted by the Illinois Trial Lawyers Association. In response to this argument the Court provided the following analysis:
    - "However, nothing about these documents being privileged renders the facts that underline the [PSWP] as also privileged."
    - "Plaintiffs can still obtain medical records, as plaintiff did in this case, have their experts analyze and make opinions about those records, and depose doctors and nurses regarding an incident."

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- "When there is no indication that a healthcare provider has failed to comply with its external record-keeping and reporting requirements and it creates supplementary information for purposes of working with a Patient Safety Organization to improve patient safety and the quality of healthcare, that provider is furthering the Patient Safety Act's objectives while not preventing the discovery of information normally available to a medical malpractice plaintiff. Under these circumstances, that additional information must be protected from disclosure."

- **Preemption Analysis**

  — Under the PSA, the federal privilege protections preempt any state or other law which would otherwise require that the information be subject to discovery and admissible into evidence.

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- This preemption standard was ignored by the Florida Supreme Court in the Charles decision in which it determined a state constitutional amendment, which gives patients broad access to any and all information relating to a hospital or physicians qualifications or past adverse events, preempted the PSA rather than the other way around.
- This decision has been roundly criticized and in fact, HHS has stated in a pending federal case that the PSA preempts all laws including Amendment 7, the Florida constitutional amendment cited by the Florida Supreme Court.
- The Appellate Court agreed with the preemption standard in the PSA and stated as follows:
  - "In other words, when information is patient safety work product, the Patient Safety Act should be construed as preempting any state action requiring a provider to disclose such work product… [c]onsequently, the Patient Safety Act preempts the circuit court's production order"

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019)

- **Background**
  - This is a medical malpractice case arising from a claim that the defendants failed to test or treat him for a MRSA infection which because worse subsequent to an elective procedure.
  - The case was in federal court based on diversity jurisdiction.
  - Plaintiff sought to discover information regarding Guthrie's infection-prevention procedures.
  - Defendant Clinic asserted privilege protections under the:
    - PSQIA
    - Pennsylvania Medical Care Availability and Reduction of Error Act ("MCARE")
    - Pennsylvania Peer Review Protection Act

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019)

- **Disputed Documents and Decision**
  - "A copy of all infection prevention and infection control materials which Defendants' received prior to May 1, 2017 from Vizient PSO and/or any other company"
    - MCARE does not apply to Vizient materials because it only protects documents "solely prepared or created for the purpose of complying with [state law] or of reporting…"
    - MCARE only applies to providers. Vizient is and therefore MCARE did not provide any protection to prevent discovery.
    - The court, however, found that the PSQIA applies to documents produced by a PSO for the purpose of conducting patient safety activities and therefore the Vizient materials were privileged under the Act.

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019)

- "A copy of any and all correspondence and communications between defendant and any federal, state, county or local governmental agency within the past 5 years on the subject of infection prevention, infection reporting, infection management and infection rates"
  - Government correspondence is not part of Guthrie's PSES was bit dusckised to Vizient PSO.
  - Consequently, these communications are not privileged under PSQIA or any other statute.
- A copy of Defendant's agenda, notes and any and all written records of Defendant's monthly (or other than monthly) quality committee meetings…insofar as they discuss infection prevention or infection control"
  - "The is the quintessential example of patient safety work product"
  - "Quality committee meetings are a core aspect of Guthrie's [PSES]"

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019)

- ""Agendas, notes and other written records from these meetings are squarely work product and are 'deliberations or analyses' of a [PSES]"
  - All of these materials are privileged under the PSQIA, MCARE and the Pennsylvania Peer Review Protection Act
- Deposition of Clinic witness about quality committee meetings, knowledge gained through the PSES, how the committee meetings determine infection preparedness, the data used to reach preparedness conclusions and why they collected certain data and not others.
  - This information was privileged because the questions sought information generated within the PSES
  - Policies are not privileged

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019)

- **Impact and Takeaways**
  - — Stresses the importance of a provider's PSES policy and detailed identification of patient safety activities and what is considered and treated as PSWP
  - — Multiple privilege statutes can apply – they are not mutually exclusive
    - First reported case to rely on "deliberations and analyses" standard for creating PSWP
    - Policies are not protected
    - Communications with government officials are not protected
    - Does not rely on the "sole purpose" standard which is a requirement under MCARE although the court did reference that documents were prepared "for reporting to a PSO"

Crawford v. Corizon Health, Inc. (U.S. Dist. Ct. W. Dist. Penn. (July 10, 2018)

- **Background**
  - Plaintiff brought suit on behalf of her son who committed suicide while detained in jail.
  - The allegation was that he was denied necessary medications and their deliberate indifference to his needs was in violation of the 8th Amendment.
  - A lawsuit was brought against Corizon which was contracted to provide medical and health care services to the county jail.
  - Plaintiff sought “any and all reports evidencing any investigation into the death of any inmate at the…jail”
  - Court initially held that eight of the nine disputed documents, including deaths of four other inmates, were not privileged.

Crawford v. Corizon Health, Inc. (U.S. Dist. Ct. W. Dist. Penn. (July 10, 2018)

— In response to a rule to show cause as to why the four documents should not be produced the defendant, for the first time, asserted that they were privileged under the PSQIA.

- **Court's Decision**

— Corizon argued that the reports were submitted to its PSO.

— Affidavit states that documents were placed in Corizon's PSES, were "created for submission into Corizon's PSES" and that it "makes information available and reports information contained in its PSES at the request of its" PSO.

— Court states that under the HHS PSO Guidance, with a citation to the Daley v. Teruel decision, the documents must be created "for the purpose of reporting" to a PSO which, in this case, Corizon did not assert.

Crawford v. Corizon Health, Inc. (U.S. Dist. Ct. W. Dist. Penn. (July 10, 2018)

— "Significantly, the Declaration omits seemingly critical details about the timing of the submission to the PSO, giving rise to a reasonable inference that these documents were reported to the PSO only after plaintiff's requested them in this proceeding. Whether or not this is true, what is certain is that Corizon has failed to demonstrate the necessary element of the claimed PSQIA privilege."

- It did not help that some of the documents were "made for the purpose of security legal advice."
- Court also says that "most of the documents that issued were created in the ordinary course of Corizon's business — providing and improving care."

Crawford v. Corizon Health, Inc. (U.S. Dist. Ct. W. Dist. Penn. (July 10, 2018)

- Court also found that the attorney's client work product privileged did not apply because the documents were created for the purpose of improving patient care and not in anticipation of litigation.

- **Impact and Takeaway**
  - This is an example of needing to meet all substantive and technical PSQIA requirements.
  - In this case, the affidavit was defective because it did not reference that the documents were created for the purpose of reporting to PSO and there was no evidence as to when the reports actually were reported.
  - There is no reference in the opinion as to whether the information was being treated as deliberations or analysis.
  - Be prepared for the "ordinary course of business" argument which, taken to its extreme, would totally undermine the PSQIA protections.
  - Emphasizes the need to educate the court regarding the PSQIA.

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.
  - The details of these activities and the information to be protected should be reflected within the PSES.

Impact and Lessons Learned

- 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 hospitals 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.
  - 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.

Impact and Lessons Learned

- 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.
- 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.

Impact and Lessons Learned

— 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

- **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 maybe required.

Impact and Lessons Learned

— 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

- 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

- 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

- 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

- 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

- 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

Additional Litigation Lessons Learned and Questions Raised

- Advise PSO when served with discovery request.
- Get a handle on how adverse discovery rulings can be challenged on appeal.

Significant Court Decisions

- Schlegel v. Kaiser Foundation Health Plan, No. CIV 07-0520 (E.D. Cal, October 10, 2008)
- KD ex rel Dieffenbach v. U.S., 715. F. Supp. 2nd 587 (D.Del. 2010)
- Morgan v. Community Medical Center Healthcare System, Penn. No. 2008-CV-4859 (Lackawanna Co. June 14, 2011)
- Illinois Department of Financial and Professional Regulation v. Walgreens, 2012 Il. App. (2nd) 110452
- Tibbs v. Bunnell, 532 SW 3rd 658 (Ky. Sup. Ct. 2014, cert. denied, 136 Sup. Ct. 2504 (2016)
- Tinal v. Norton Healthcare, Inc. (C.A. No. 3:11-CV-596-S (W. Dist. Ky., May 8, 2014).
- Johnson v. Cook County (No.15 C 741 (N.D. Ill., August 31, 2015)
- Baptist Health Richmond, Inc. v. Clouse, 497 SW 3d 759 (Ky. Sup. Ct. 2016)
- University of Kentucky v. Bunnell, 532 SW 3d 658 (Ky. Ct. App. 2017)
- Charles v. S. Baptist Hosp. of Fla, Inc. 209 So.3d 1199 (Fla. 2017) cert. denied 136 S. Ct. 2504 (2017)
- Daley v. Teruel and Ingalls Memorial Hospital, 2018 Il. App (1st) 170891

COVID-19: Provider Liability and Protections

Areas of Potential Tort Liability

- Relaxation or waiver of licensing requirements
- Expansion of services beyond scope of practice, license or clinical privileges
- Expansion of acceptable sites of services
- Repurposing beds
- Conducting off-site COVID-19 assessments and testing
- Wrongful exposure to COVID-19
- Failure to use PPE
- Imposition of DNR orders against a patient or family wishes

Areas of Potential Tort Liability

- Sharing or repurposing of equipment
- Using untested or off-label use of non-FDA approved medications
- Expedited appointment/reappointment procedures
- Negligent treatment of non-COVID-19 patients
- Procedure determined to be elective versus necessary
- Product Liability

Disaster Proclamations

- **Illinois**
  - March 1, 2020 – First gubernatorial disaster proclamation
  - April 1, 2020 – Second gubernatorial disaster proclamation
- **Federal**
  - March 13, 2020

CMS Blanket Waivers

- EMTALA – Allows off-site COVID-19 testing
- Verbal Orders – Allows authentication past 48 hours
- Detailed Information Sharing for Discharge Planning
- Medical Staff – Allows for physicians whose privileges will expire to continue practicing at the hospital and for new physicians to be able to practice before full Medical Staff/Governing Body review and approval to address workforce concerns relating to COVID-19
- Patient Self-Determination Act – Allows hospitals to waive a requirement to inform the patient about its advance directive policy
- Telemedicine – Allows for easier telemedicine services to be provided by lifting licensure requirements and expanding reimbursement
- Physician Services – Allows Medicare patients to be under the care of a healthcare practitioner other than a physician if not contrary to the state's emergency preparedness or pandemic plan

CMS Blanket Waivers

- Anesthesia Services – Waives the requirement that a CRNA be under the supervision of a physician depending on what is permitted under state law and by the hospital
- CAH Personnel Qualifications – Waives minimum personal qualifications for clinical nurse specialist, nurse practitioners and physician assistants. Allows CAHs to employ individuals in these roles who meet state licensure requirements in order to provide maximum staffing flexibility if not inconsistent with state plan
- CAH Staff Licensure – Waives the requirement that staff of the CAH be licensed, certified or registered in accordance with applicable federal law but defers to the state requirements and relaxations if not inconsistent with the state's plan

CMS Blanket Waivers

- Temporary Expansion Location – Allows hospitals to change the status of their current provider-based department locations to the extent necessary to address the needs of the hospital's patients as part of the state or local pandemic plan
- Responsibilities of Physicians in CAHs – Waives the requirement that an MD or DO be physically present to provide medical direction, consultation, and supervision for the services provided at the CAH. Allows Physician to perform responsibilities remotely as appropriate through direct radio or telephone communication or electronic communication as well as to allow the use of nurse practitioners and physician assistants to the fullest extent possible

State of Illinois Section 1135 Approved Waiver Request

- EMTALA– Same as CMS blanket waiver
- Physical Environment – Same as CMS blanket waiver
- Verbal Orders – Same as CMS blanket waiver
- Medical Staff – Same as CMS blanket waiver
- Discharge Planning for Hospitals – Same as CMS blanket waiver
- Patient Rights – Same as CMS blanket waiver
- Detailed Information Sharing for Discharge Planning – Same as CMS blanket waiver
- Flexibility and Patient Self-Determination Act – Same as CMS blanket waiver

Selected Illinois Executive Orders

- Executive Order No. 7 – March 19, 2020 – Allows for the expansion and payment of telehealth services
- Executive Order No. 10 – March 24, 2020 – Allows for the waiver of the Healthcare Worker Background Check Act for certified nursing assistants
- Executive Order No. 21 – April 9, 2020 – While recognizing the decision of the IDFPR to increase the number of licensed professionals engaged in disaster response and suspending requirements for permanent and temporary licensure of persons who are licensed in another state as well as modifying the scope of practice restrictions under any licensing act, it reinforces the requirement that the IDFPR work in conjunction with the Illinois Emergency Management Agency and the Illinois Department of Public Health when exercising these relaxed standards
- Executive Order No. 24 – April 16, 2020 – Provides a very broad waiver of numerous statutory provisions of several laws including the Hospital Licensing Act, the Emergency Medical Services Systems Act and the Hospital Report Card Act

Tort Liability Protections

- Illinois Hospital Licensing Act (210 ILCS 85/10.4)
  - "Any hospital and any employee of the hospital or others involved in granting privileges who, in good faith, grant disaster privileges pursuant to this Section to respond to an emergency shall not, as a result of their acts or omissions, be liable for civil damages for granting or denying disaster privileges except in the event of willful and wonton misconduct."
  - "Individuals granted privileges who provide care in an emergency situation, in good faith and without compensation, shall not, as a result of their acts or omissions, except for acts or omissions involving willful and wonton misconduct, be liable for civil damages."
  - Protections only apply to volunteers
  - Hospital must grant disaster privileges in compliance with Illinois Administrative Code, Title 77, Chapter 1, Part 2 Sub-part C, Section 250.310(a)(17)

Tort Liability Protections

- Executive Order No. 17 – April 1, 2020
  - Order cites to various provisions of the Illinois Emergency Management Agency Act (IEMA), the Emergency Medical Services Systems Act (210 ILCS 50/3.150) and the Good Samaritan Act (745 ILCS 49).
  - Provides immunity from civil liability from April 1 through April 30, to "Health Care Facilities", "Health Care Professionals" and "Health Care Volunteers" who are:
    - Providing services at a Health Care Facility in response to the COVID-19 outbreak and are authorized to do so; or
    - Are working under the direction of the IEMA or IDPH in response to the gubernatorial disaster proclamations

Tort Liability Protections

— Health Care Facilities must:

- Cancel or postpone elective surgeries as defined in IDPH's COVID-19 Elective Surgeries Procedures Guidance
- Must include measures such as increasing the number of beds, preserving PPE, or taking necessary steps to prepare to treat COVID-19 patients

Tort Liability Protections

— Health Care Professionals and Health Care Volunteers must:

- Provide services at a Health Care Facility in response to the COVID-19 outbreak
- Work under the direction or work under the direction of IEMA or IDPH in response to emergency proclamations
- Health Care Facilities, Health Care Professionals and Health Care Volunteers are immune from civil liability for any acts or omissions which cause death or injury by providing Health Care services to the COVID-19 outbreak unless it is established that such injury or death was caused by gross negligence or willful misconduct
- The order does not preempt any other applicable civil immunity protections

Tort Liability Protections

- Coronavirus Aid, Relief and Economic Security Act (CARES Act) – Section 3215 – Limitation of Liability
  - Applies only to health care professional volunteers providing health care services during a public health emergency with respect to COVID-19 declared by the Secretary of HHS. Acts or omissions must relate to services that:
    - Are within the scope of volunteer's license, regulation or certification as defined by the state
    - Do not exceed the scope of license, registration or certification of a similarly situated health care professional in the state where services are rendered

Tort Liability Protections

- Acts or omissions must relate to services that are:
  - Provided in the good faith belief that the patient was in need of services
  - Applies to diagnosis, prevention or treatment of COVID-19 patient or the assessment or care of the health of an individual relating to actual or a suspected case of COVID-19
- Protections do not apply if act or omission constitutes willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the harmed individual
- Protections do not apply if the volunteer was under the influence of alcohol or an intoxicating drug
- Act preempts the laws of states which provide less protection

Tort Liability Protections

- Volunteer Protection Act
- Public Readiness and Emergency Preparedness Act
- HIPAA
- Emergency Management Assistance Compact
- Uniform Emergency Volunteer Health Practitioners Act

Impact and Recommendations

- CMS Waivers only apply to Medicare/Medicaid patients
- It is therefore important that a hospital and other health care providers read the detailed State of Illinois 1135 Waiver and Executive Orders which apply to all parties
- As a general rule, hospitals should abide by all existing federal, state and accreditation standards relating to the provision of health care services as well as decisions concerning the appointment, reappointment, privileging and credentialing of health care practitioners including limitations on the scope of practice and clinical privileges which are issued
- The relaxation of these and other standards should only be considered if in fact the hospital is faced with insufficient number of health care practitioners and other professionals, hospital beds, PPE, etc., needed to provide services to COVID-19 patients as reflected in the CMS Blanket Waivers, or the Illinois 1135 Waivers and Executive Orders

Impact and Recommendations

- In the context of privileging and credentialing, hospitals should first decide whether it can adequately and timely undertake these requirements using disaster privileges, temporary privileges and expedited credentialing before relying on the waivers
- To the extent that the hospital is compelled to rely on the relaxed measures afforded under the CMS or state waivers and Executive Orders, it should carefully document why it is deviating from existing legal and accreditation standards in order to support access to the state and federal liability protections
- To that end, it is strongly recommended that either the hospital's board of directors and/or the executive committee of the board adopt a supporting resolution setting forth the actual reasons as well as the documentation to support deviation from existing standards and reliance on the various waivers
- It is also strongly recommended that the hospital check with its insurance carriers to determine whether there is coverage in the event that the hospital takes advantage of any of the waivers

Michael R. Callahan

A nationally recognized advisor to health care providers across the country, Michael Callahan provides deeply informed advice in all areas of hospital-physician relations and health care regulatory compliance including EMTALA, HIPAA the Medicare CoPs and licensure accreditation standards. He is widely respected for his leading work on the Patient Safety Act from a regulatory 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 and peer review investigation and hearings
- PSOs and participating provider policies, compliance and litigation support
- CMS and state departments of health investigations
- Assisting health systems with medical staff integration

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 Michael 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 also provide better and comparative solutions.

Michael R. Callahan

- 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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