IHA and MAPS PSO Present: How to Respond to Regulators' Request for Privileged Information in an ERA of COVID-19

All attendees can join at:

https://join.onstreammedia.com/go/40986997/pswp2

Attendees will be placed in listen-only mode

Tuesday, June 16, 2020 - 10:00 am- 11:00 am

Help Line Phone: 630-276-5657

Email: MAPSHelp@team-iha.org | web: www.alliance4ptsafety.org

Agenda:

- Welcome
- Overview of MAPS PSO
- Review Educational Credits
- Meet our Presenter – Michael R. Callahan
- Strategies in Response to Regulator Requests
- Question and Answer Session

MAPS PSO Welcomes You!

Today's Housekeeping:

- The webinar is being recorded and available via a link along with the PowerPoint presentation.
- Lines will be muted until the Question/Answers portion which is at end of all presentations.
- Feel free to use the chat feature throughout the webinar.
- You must complete the evaluation survey to fulfill CE and CLE requirements. **For attorneys seeking IL CLE – *You will need to submit opening and closing presentation codes.***
- Educational credits will be emailed within 4-6 weeks of the event

Key Benefits for Joining this Event:

- 60-minute overview of important operational needs for PSO and non-PSO members including: understanding legal protections, designating Patient Safety Work Product (PSWP) and being prepared for regulators.
- Gain better understanding of notifying legal counsel about regulator requests.
- Develop copies of non-regulated information that can be provided to regulators.
- Collaborate with other legal professionals on healthcare law challenges surrounding privileged information during COVID-19.

Today's Objectives

At the end of this presentation, the participants will be able to:

1. Understand the positions taken by CMS and The Joint Commission as to whether providers must disclose PSWP when responding to a compliance investigation or site survey
2. Discuss options on how to respond without disclosing PSWP by providing other documentation to demonstrate compliance with standards
3. Identify permissible disclosure exceptions to permit release of PSWP without waiving the privilege protections

Who is Attending Today's Event?

- In-house legal counsel from IHA and MAPS Members
- External legal counsel for IHA and MAPS Members
- Illinois Association of Healthcare Attorneys (IAHA)
- Directors of Risk Management
- Directors of Patient Safety and Quality
- MAPS PSO Coordinators

Welcome from Karen Harris, Senior Vice President and General Counsel, IHA and IAHA's Executive Director

- Patient safety and improved quality of care are the cornerstones of every healthcare system.

- Your attendance at this webinar will provide you with a solid understanding of the PSQIA so you can provide invaluable counsel to your clients and greatly assist their quality improvement efforts.

- Thank you for your efforts in this crucial area of our healthcare systems.

CE and Disclosure Information

CE Statement: As the sponsor of this didactic lecture with interactive exercises, the Illinois Health and Hospital Association is authorized by the State of Illinois Department of Financial and Professional Regulation (license number 236.000109) to award up to **1.0 hours** of nurse continuing education credit for this program.

By attending "Illinois Health and Hospital Association Presents Basic Law Protections for Healthcare Organizations under the Patient Safety Act and Illinois Medical Studies Act – Part 1" offered by the Illinois Health and Hospital Association, participants may earn up to **1.0 ACHE Qualified Education Hours** toward initial certification or recertification of the Fellow of the American College of Healthcare Executives (FACHE) designation.

This course is approved for **.75 Illinois MCLE general credit hours.**

Completion of the survey will be required to obtain CE credits.

Disclosure

No one involved in the planning or presentation of this activity has disclosed any relevant conflict of interest with any commercial entity.

Midwest Alliance for Patient Safety (MAPS) Representing A Diverse Membership

- **Non-Profit; founded in 2010, certified every year eligible**
- **Component of the Illinois Health and Hospital Association**
- **Offers protections, education, networking, shared learning**
- **Across the continuum focus on all safety events**
- **Simple and easy data mapping and collection**
- **Active national role**
- **Annual fee includes all MAPS PSO offerings**

Illinois Health and Hospital Association

97 MAPS Members and counting:

- Hospitals and Hospital Systems
- Critical Access Hospitals
- Physicians Groups
- Specialty Clinics
- Outpatient Facilities

Patient Safety Listed PSO Organization

Plan a Discussion with Your Teams

- You can distribute the electronic copy of this presentation to your core PSO and legal teams.
- You can review your PSES policies for any gaps or needed updates.
- If you do not have a PSES, you can begin writing your policy to add protection to your organization.
- You can print or distribute any of the legal cases to reinforce PSO training.
- The recording will be available and provided to attendees.

Today's Presenter

Michael R. Callahan, BA, JD, Of Counsel, Katten Muchin Rosenman LLP

A nationally recognized advisor to health care providers across the country, Michael Callahan provides deeply informed business and legal counseling in all areas of hospital-physician relations and health care regulatory compliance and governmental investigations, including the Emergency Medical Treatment and Active Labor Act (EMTALA), the Health Insurance Portability and Accountability Act (HIPAA), Medicare Conditions of Participation (CoPs), hospital licensure and accreditation standards.

EDUCATION

DePaul University College of Law, JD
Northern Illinois University, BA

Katten

Illinois Health and Hospital Association and the Midwest Alliance for Patient Safety

Presents

How to Respond to Regulators' Request for Privileged Information in an ERA of COVID-19

June 16, 2020

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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.

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 is not subject to discovery and is not admissible into evidence in state proceedings but can be used in disciplinary hearings and subsequent judicial review to determine whether the action and proceedings were fundamentally fair and in substantial compliance with the By-laws.
- 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.

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 and likely will not apply to any federal government investigation or complaint.

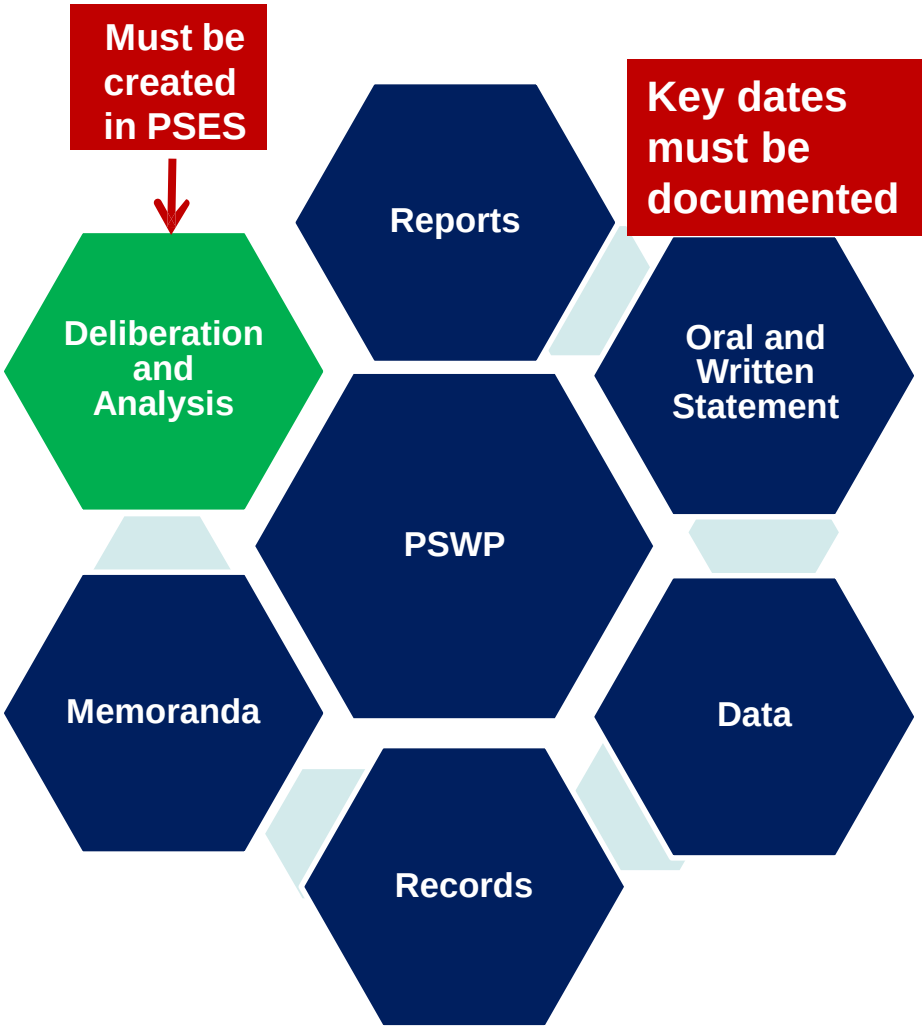
Patient Safety and Quality Improvement Act of 2005

- 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
  - Internal COVID-19 analysis and reports

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

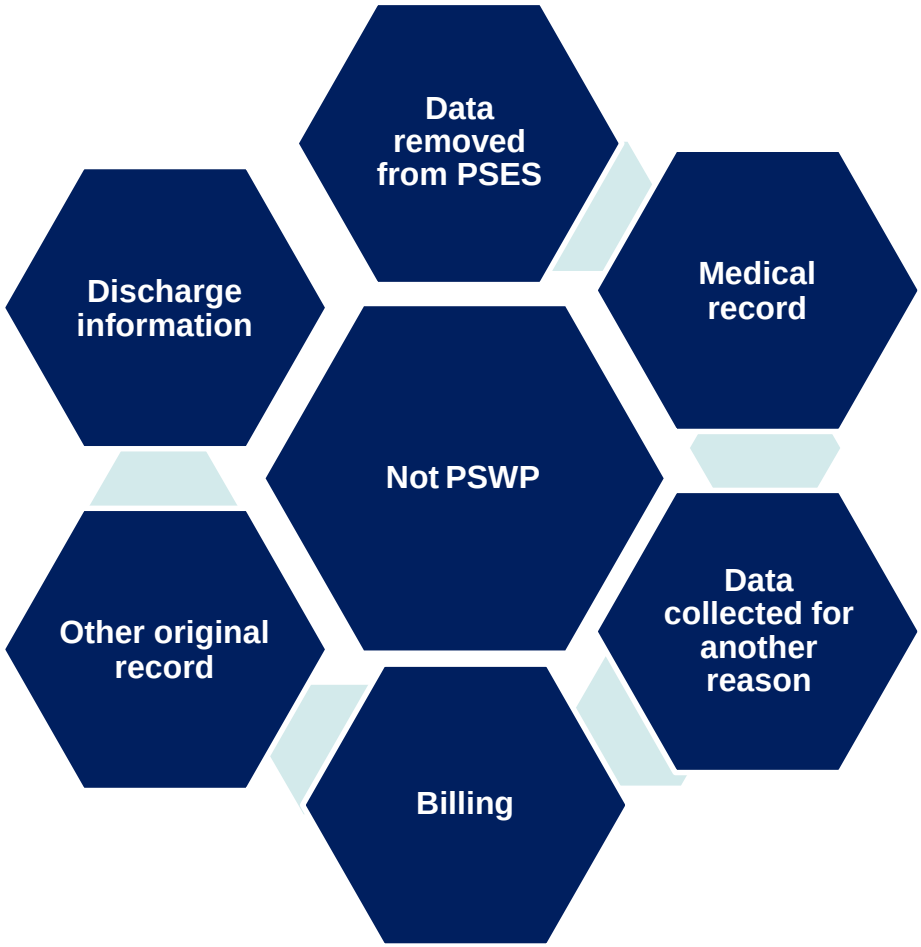
Analysis and deliberations conducted within a PSES

- 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
  - Reports that are the subject of mandatory state or federal reporting or which are collected and maintained pursuant to state or federal laws

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

- 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.

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

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

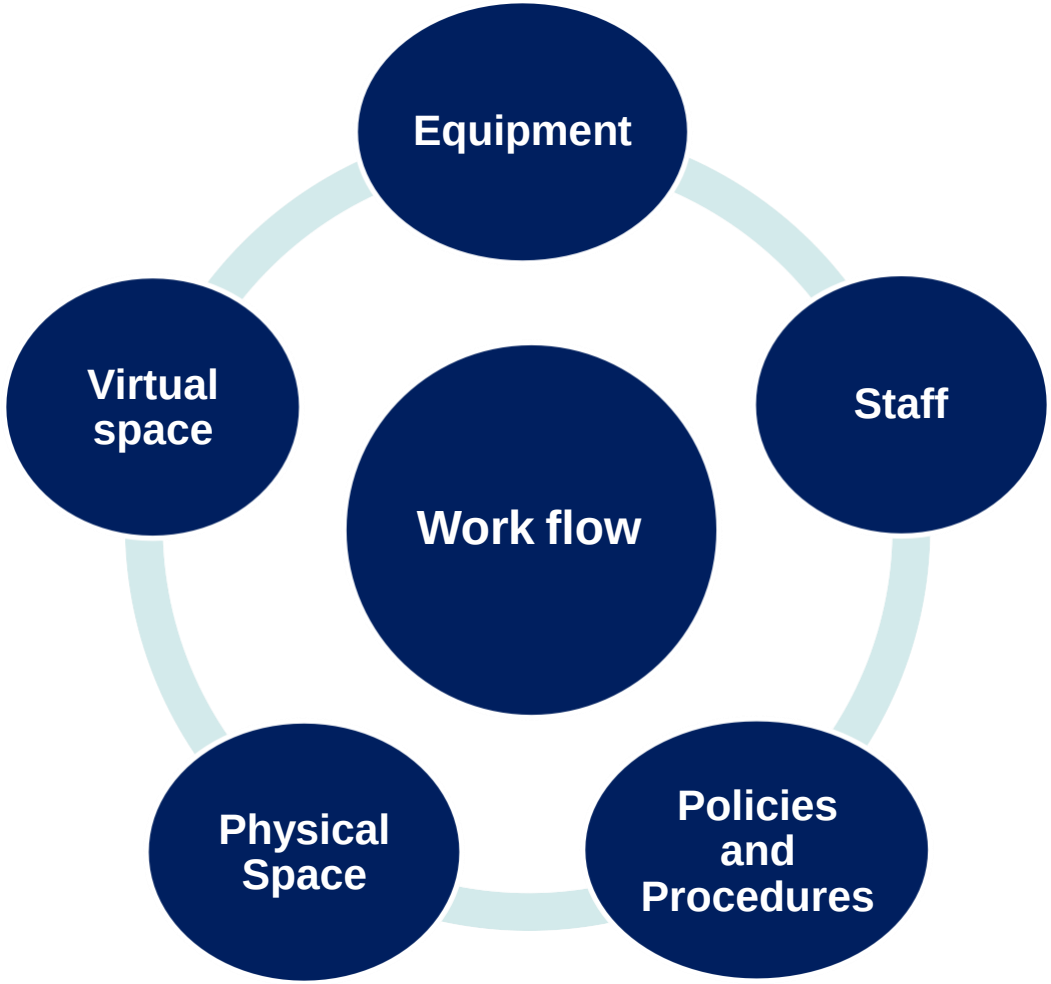
Working with a PSO must be implemented in a way that facilitates a Just Learning Environment while taking advantage of privilege and confidentiality protections.

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.
  - Non-provider corporate parent can be treated as a provider and included in system-wide PSES with provider affiliates it owns, controls, manages or has veto authority over affiliate decisions
  - PSWP can be freely shared by and between and among affiliated providers
  - Privilege protections apply in all federal, state and other governmental proceedings
  - Privilege can never be waived under any circumstances

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

Example Health System PSES

What Comprises the System's Patient Safety Evaluation System (PSES)?

- The PSES includes the collection, management and/or analysis of Patient Safety Concern information recorded in the System's Event Reporting System (ERS) for reporting to a PSO. **It includes information documented in the ERS and also deliberation and analysis of a Patient Safety Concern.**
  - A Patient Safety Concern includes:
    - A patient safety event that reached the patient, whether or not there was harm;
    - A near miss or close call - a patient safety event that did not reach the patient; or
    - An unsafe condition - circumstances that increase the probability of a patient safety event.

Example Health System PSES

— It may also include all activities, communications and information reported or developed by individuals or committees, such as data analyses, Root Cause Analyses, outcome reports and minutes, for the purpose of improving patient safety and/or healthcare quality

Creation of PSWP

- PSWP is created automatically upon filing an event report in the ERS that involves a Patient Safety Concern. All Patient Safety Concern information is collected and/or developed with the intent to report to the PSO.
- If so designated by Authorized Staff, PSWP may encompass the data collection efforts leading up to making the Event report. The date of entry into the PSWP is the date these activities occur.

Example Health System PSES

- **PSWP is created when deliberations and analysis (D or A) related to a Patient Safety Concern is conducted**. The date of entry into the PSES is the date these activities occur. **PSWP protections will apply immediately. Deliberations and analysis cannot be de-designated as PSWP. Documents included in this category include but are not limited to**:
  - Failure Mode Effects Analysis (FMEA)
  - Root Cause Analysis (RCA) not otherwise reported in the ERS
  - Data analysis reports & comparative outcomes
  - Patient Safety Committee minutes
  - Quality Improvement Committee minutes

Example Health System PSES

- Patient Safety Activities
  - Patient Safety Activities may be conducted by any individual, committee or body that has assigned responsibility for any such activities. The workforce includes faculty, staff, trainees, volunteers, and contractors who perform work under the direct control of the System. Committees include but are not limited to:

    - Patient Safety Committees
    - Clinical Performance Improvement Committees
    - Risk Management Committees
    - System Chief Medical Officers/Chief Nursing Officers
    - System Risk Services and/or Committees
    - Audits and Compliances Committee
    - Peer Review Committees
    - Quality Improvement Committees
    - Medication Safety Committees
    - The System's Health Services Committee
    - Center for Healthcare Quality Innovation
    - System Data Management System
    - Other System committees with jurisdiction

Regulators Demand for PSWP: How To Respond

Step by Step Guidance

- Do not prevent surveyors from entering the facility
- Are they there on behalf of CMS, OSHA and/or the state?
- Do not panic
- Make sure that appropriate personnel including legal counsel is contacted and decide who will accompany the surveyors
- Review documents requested by surveyor if in writing or if verbally requested
- Determine whether any of the information requested is PSWP or privileged under the Illinois Medical Studies Act
- If PSWP is requested, provide them the “Information for State and Federal Regulators form (See Attachment A)

Regulators Demand for PSWP: How To Respond

- Information Categories
  - Information subject to mandatory reports to a state or federal governmental entity and not eligible for PSWP or ISMS protections
    - Data Bank Reports
    - Illinois Adverse HealthCare Events Reporting Law of 2005
      - Surgery on wrong body part
      - Surgery on wrong person
      - Unintended retention of a foreign object
      - Intraoperative or immediately post operative death
      - RCAs
      - Action plans
    - OSHA
      - Employers required to report when an employee is killed on the job or suffers a work-related hospitalization, amputation or loss of an eye

Regulators Demand for PSWP: How To Respond

— Information not subject to mandatory reporting nor is there a requirement to be make information available for inspection by a governmental entity

- Information is eligible for PSWP protection if collected in the PSES and reported to the PSO or treated as D or A
- Information may be eligible for ISMS protection if reported by a state regulation but not likely protected from disclosure to a federal regulator

Regulators Demand for PSWP: How To Respond

— Information which must be collected and maintained and/or must be made available for inspection by a governmental entity
  - Grey area
  - HHS PSO Guidance states that such information is not eligible for PSWP protection under the Patient Safety Act
  - One important question is whether the collection and maintenance of information/reports is voluntary or mandatory
  - Guidance is not binding
  - Recommendation is to err on the side of asserting the privilege under state and/or federal law
  - But also need to consider the political impact of denying the request

Regulators Demand for PSWP: How To Respond

- If acting on behalf of CMS, provide them the statement from the following statement is set forth in the HHS Guidance Regarding Patient Safety Work Product and Provider's External Obligations:
  - "As described above, the protected system established under the Patient Safety Act works in concert with the external obligations of providers to ensure accountability and transparency while encouraging the improvement of patient safety and reduction of medical errors through a culture of safety. It is the provider's ultimate responsibility to understand what information is required to meet all of its external obligations. If a provider is uncertain what information is required of it to fulfil an external obligation, the provider should reach out to the external entity to clarify the requirement. HHS has heard anecdotal reports of providers, PSOs, and regulators working together to ensure that the regulators can obtain the information they need without requesting that providers impermissibly disclose PSWP. HHS encourages such communication. Regulatory agencies and other entities requesting information of providers or PSOs are reminded that, subject to the limited exceptions set forth in the Patient Safety Act and Patient Safety Rule, PSWP is privileged and confidential, and it may not be used to satisfy external obligations. Therefore, such entities should not demand PSWP from providers or PSOs." (Emphasis added) (41 Fed. Reg. at 32659 (May 26, 2016))

Regulators Demand for PSWP: How To Respond

- Be prepared to provide a copy of the following:
  - PSO certification letter from AHRQ
  - Copy of PSO member agreement
  - Copy of PSES policy along with pointing out that the information they are seeking is PSWP under the policy
  - Screen shots or blank/redacted forms which are used to report PSWP to the PSO or are treated as D or A
  - Provide copies of non-privileged information
    - Medical/patient care records
    - Relevant policies and procedures
    - Action plan relating to the incident if not PSWP
    - Permit interviews of involved personnel but cannot discuss or disclose PSWP

Regulators Demand for PSWP: How To Respond

- What Should You Do If Providing this Information Does not Satisfy the Regulators?
  - If acting on behalf of CMS, contact the applicable CMS Regional Office 5 to confirm that facility is not required to turn over PSWP
  - If acting on behalf of the state, consider using Provider Authorization to Disclose PSWP form (See Attachment B)
  - Contact legal counsel

INFORMATION FOR STATE & FEDERAL REGULATORS (OR OTHER SEEKING COMPULSORY ACCESS TO PSWP)

The information you have requested is protected by federal law (the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 et. seq., and 42 C.F.R. Part 3, §§ 3.10 et. seq.) as Patient Safety Work Product. Identifiable Patient Safety Work Product may not be disclosed outside of this facility.

The following is a statement set forth in the HHS Guidance Regarding Patient Safety Work Product and Provider's External Obligations:

"As described above, the protected system established under the Patient Safety Act works in concert with the external obligations of providers to ensure accountability and transparency while encouraging the improvement of patient safety and reduction of medical errors through a culture of safety. It is the provider's ultimate responsibility to understand what information is required to meet all of its external obligations. If a provider is uncertain what information is required of it to fulfil an external obligation, the provider should reach out to the external entity to clarify the requirement. HHS has heard anecdotal reports of providers, PSOs, and regulators working together to ensure that the regulators can obtain the information they need without requesting that providers impermissibly disclose PSWP. HHS encourages such communication. Regulatory agencies and other entities requesting information of providers or PSOs are reminded that, subject to the limited exceptions set forth in the Patient Safety Act and Patient Safety Rule, PSWP is privileged and confidential, and it may not be used to satisfy externa obligations. Therefore, such entities should not demand PSWP from providers or PSOs." (41 Fed. Reg. at 32659 (May 26, 2016)) (Emphasis added).

Any questions about access to this information should be directed to (Hospital) General Counsel, attention:

(Hospital)

Attn: General Counsel

(address)

PROVIDER AUTHORIZATION TO DISCLOSE PSWP

Name of Provider _____

The above-named provider hereby authorizes disclosure to:

_____

_____

[Insert name of individual or entity to which PSWP may be disclosed]

Of the following Patient Safety Work Product information:

_____

_____

[Insert description of the information to be disclosed]

_____

_____

Signature: _____

Date: _____

For (Hospital) Use:
Information was disclosed pursuant to this authorization on: [*list below all dates upon which disclosure was disclosure was made]*

Date	Signature of Risk Manager/designee releasing information
_____	_____
_____	_____
_____	_____

This authorization is to be delivered to the (Hospital) Risk Manager and retained for 6 years from the date of the last disclosure made pursuant to this authorization.

INFORMATION FOR LAW ENFORCEMENT OFFICIALS ABOUT PERMITTED USES AND DISCLOSURE OF PATIENT SAFETY WORK PRODUCT

To: [*insert name of law enforcement official and agency to whom PSWP is given]*
The information you have requested is protected by federal law (the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 et. seq., and 42 C.F.R. Part 3, §§ 3.10 et. seq.) as Patient Safety Work Product. These provisions permit your access to this information only in the following circumstances and subject to the following conditions:
42 CFR 3.206:

(b)(10) Disclosure to law enforcement.

(i) Disclosure of patient safety work product to an appropriate law enforcement authority relating to an event that either constitutes the commission of a crime, or for which the disclosing person reasonably believes constitutes the commission of a crime, provided that the disclosing person believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

(ii) Law enforcement personnel receiving patient safety work product pursuant to paragraph (b)(10)(i) of this section only may disclose that patient safety work product to other law enforcement authorities as needed for law enforcement activities related to the event that gave rise to the disclosure under paragraph (b)(10)(i) of this section.

By your signature below, you confirm that your request for access to this information is consistent with the above-cited federal law, and that you will maintain confidentiality of the information as required by federal law.

Date: _____ Signature:_____

Retain signed original for (Hospital) files; a copy of this document should be provided to the law enforcement official who obtains a copy of the PSWP.

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.

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THANK YOU!
Illinois Health & Hospital Association
The Midwest Alliance for Patient Safety Team

Visit our website at www.alliance4ptsafety.org for the latest information

E-mail: ***MAPSHelp@team-iha.org***

Phone Number: **630-276-5657**

Questions?

Please complete the survey that will follow to obtain your CE certificate.

For attorneys seeking IL CLE – ***Attendees will need to submit 2 codes on the evaluation.***