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Texas Hospital Association Foundation

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How to Respond to a Regulator's Demand for PSWP

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Disclaimer

- The opinions expressed in this presentation do not reflect the official position of the Agency for Healthcare Research and Quality (AHRQ), the Office of Civil Rights (OCR) or the Texas Hospital Association Patient Safety Organization.

Comparison of Texas and Patient Safety Act Peer Review Protections

Scope of Protected Activities

- Texas
  - “Medical Peer Review” is defined as:
    - The evaluation of medical and healthcare services
    - Evaluation of the qualifications and professional conduct of professional healthcare practitioners of patient care provided by those practitioners
    - The merits of a complaint relating to a healthcare practitioner and a determination or recommendation regarding the complaint
    - Accuracy of the diagnosis
    - Quality of the care provided by a healthcare practitioner
    - Report made to a medical peer review committee concerning activities under the committee’s review authority

Scope of Protected Activities

- Report made by a medical peer review committee to another committee or to the board as permitted or required by law
- Implementation of the duties of a medical peer review committee by a member, agent, or employee of the committee

Scope of Protected Activities (cont'd)

- Patient Safety Act
  - "Patient Safety Activities" mean the following:
    - Efforts to improve patient safety and the quality of healthcare delivery
    - The collection and analysis of patient safety work product
    - The development and dissemination of information with respect to improving patient safety such as recommendations, protocols or information regarding thus practices
    - The utilization of patient safety work product for the purpose of encouraging a culture of safety and the providing of feedback and assistance to effectively minimize patient risk
    - The maintenance of procedures to preserve confidentiality with respect to patient safety work product
    - The provision of appropriate security measures with respect to patient safety work product

Scope of Protected Activities (cont'd)

- The utilization of qualified staff
- Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in the patient safety evaluation system

Scope of Covered Entities

- Texas
  - A “Medical Peer Review Committee” is defined as:
    - A committee of a healthcare entity
    - A governing board of a healthcare entity
    - The medical staff of a healthcare entity that operates under written bylaws approved by the policy making body or governing board of the healthcare entity and is authorized to evaluate the quality of medical and healthcare services or the competence of physicians including evaluation of the performance of those functions set forth above
  - A “Healthcare Entity” is defined as:
    - A hospital

Scope of Covered Entities

- An entity including an HMO, group medical practice, nursing home, health science center, university medical school, hospital district, hospital authority or other healthcare facility that:
  - Provides or pays for healthcare or healthcare services
  - Follows a formal peer review process to further quality medical care of healthcare

Scope of Covered Entities (cont'd)

- Patient Safety Act
  - "Provider" means:
    - An individual or entity licensed or otherwise authorized under state law to provide healthcare services
    - Agencies, organizations and individuals within the federal, state, local or tribal governments that deliver healthcare
    - A parent organization of one or more licensed provider

Scope of Privileged Protections

- Texas
  - The records and proceedings of a medical committee are confidential and are not subject to court subpoena
  - A record or determination of or a communication to a medical peer review committee is not subject to subpoena or discovery and is not admissible as evidence in any civil, judicial, or administrative proceeding without waiver of the privilege executed in writing by the committee

Scope of Privileged Protections (cont'd)

- The Patient Safety Act
  - "Privileged Patient Safety Work Product" means:
    - Any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements or copies of any of this material
      - which could improve patient safety, healthcare quality or healthcare outcomes and
      - which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO that is document as within a patient safety evaluation system for reporting to a PSO
      - which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant a PSES
- Original records cannot be considered PSWP

Application of Privileged Protections in State, Federal or other Proceedings

- Texas
  - Texas privileged statutes only apply in state, judicial or administrative proceedings. The protections will not be used in federal court to preempt a federal cause of action.
- Patient Safety Act
  - Privileged PSWP is not admissible nor discover in all proceedings, including state and federal

Waiver

- Texas
  - Generally speaking the privilege protections cannot be waived unless a medical peer review committee expressly authorizes waiver of the protections in writing
  - There is case law which states that a voluntary disclosure by a committee or impermissible disclosure arguably could constitute a waiver
- Patient Safety Act
  - The privilege protections under the Patient Safety Act are not waived under any circumstances

Disclosure of Privileged Information within a Healthcare System

- Texas
  - The scope of protected activities in Texas is more limited than the Patient Safety Act
  - It is not clear whether privileged peer review information can be freely shared across a healthcare system as opposed to one medical peer review committee to another committee
- Patient Safety Act
  - PSWP can be shared among affiliated providers
  - Affiliated providers can include a non-licensed corporate parent or parent organization that owns, controls, manages or has veto authority over a licensed healthcare facility or provider

Regulators Demand for PSWP: How To Respond

- Information Categories
  - Information subject to mandatory reports to a state or federal governmental entity
    - Not eligible for PSWP protection
  - Texas requires mandated reports for 48 Preventable Adverse Events (“PAE”) and healthcare associated infections (“HAIs”) effective 1/1/20 by licensed – not comprehensive medical rehab hospitals or special hospitals that do not provide surgery or OB services
  - PAE Questions include:
    - Record Type
    - Preventable Adverse Event
    - Date Event Occurred or Discovered
    - Medical Record Number or Patient ID

Regulators Demand for PSWP: How To Respond

- Level of Harm
- Do You Want DSHS to Delete This Record

— What about additional root cause questions?

- Optional or encouraged but not required

— If participating and reporting to a PSO are the reports still required?

- Yes

— 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 which must be collected and maintained and/or must be made available for inspection by a governmental entity

Regulators Demand for PSWP: How To Respond

- 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

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 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 Texas law
  - If PSWP is requested, provide them the “Information for State and Federal Regulators form (See Attached A)

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 6 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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