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CHART Institute PSO

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How to Maximize Peer Review Protections Under the Patient Safety Act and Responding to Governmental Demand for PSWP

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What is “Peer Review”?

- The process of improving quality and safety in healthcare organizations
- Privileging and credentialing
- Performance of a medical or quality assurance review function
- Utilization review
- Concurrent and retrospective review of medical cases and adverse events
- Root cause analysis
- FPPE and OPPE
- Collegial intervention
- Monitoring, proctoring, consultation requirements and similar remedial measures
- Medical research

What is “Peer Review”?

- Efforts to improve patient care and reduce morbidity or mortality
- Tracking, investigating and managing unacceptable behavior identified in Code of Conduct - Disruptive Behavior Policies
- Physician wellness evaluations and activities
- Evaluating healthcare providers regarding performance, skill, technique, competence, utilization and compliance with hospital and medical staff bylaws, rules, regulations and policies
- Review and establishment of standards of care
- Analyses undertaken for the purpose of reducing the risk of harm
- Peer review investigations and hearings
- All of the discussions, analyses and work product produced by these activates

How to Maximize Peer Review Privilege Protections

- Know your state laws and the Patient Safety Act
 - What is the scope of covered activities?
 - What provider and other entities can assert the privilege?
 - Can the privilege be waived and, if so, how?
 - Can privileged documents be shared by and between affiliated entities whether licensed providers or not?
 - Can identifiable physician Peer Review information be shared among affiliated providers?
 - Is the privileged information protected from discovery and admissibility into evidence?
 - Do the protections apply in both states and federal proceedings?

How to Maximize Peer Review Privilege Protections

- Can the privileged information be shared with third parties and, if so, how?
- How can or how should the privileged information be shared internally?
- Is the information only privileged if it is initiated by or through designated committees?

How to Maximize Peer Review Privilege Protections

- Know how the state and federal courts have interpreted the laws
- Define what you consider to be “Peer Review” activities and what you are treating as privileged information with an eye towards the answers to the questions above as well as the language and interpretation of state laws and the Patient Safety Act
- Create policies and procedures which reflect these standards and decisions and interpretations such as in your Patient Safety Evaluation System (“PSES”) Policy
- Continue to track statutory and case law developments and update your policies and procedures accordingly
- Disclose your policies and procedures as evidence to support your assertion of privileged protections
- Use detailed affidavits to help educate the court as to your compliance with the state and federal privileges including the use of screenshots, redacted PSWP and other related information

How to Maximize Peer Review Privilege Protections

- Remember, the state and the Patient Safety Act privileges are not mutually exclusive – both can be asserted depending on the documents and information in question
- Remember too that the Patient Safety Act provides more protection than the laws in the New York, Pennsylvania and West Virginia and therefore you should lead with the Patient Safety Act privilege
- BUT consult with your legal counsel

Peer Review Questions and Answers

- What should be included in the PSES?
 - Take an inventory of all of your “Peer Review”, quality assurance and patient safety activities and the associated reports, analyses, and committees involved with these activities
 - Remove any reports or other information which you are mandated to report to the state or federal government keeping in mind that copies of the original reports can be reported to a PSO and the copy will be considered PSWP
 - Do not include HR forms or activities or claims in litigation management forms and activities in the PSES
 - What remains should be included in the PSES as well as how the information is collected, managed and maintained
 - Include how information is to be kept privileged, confidential and secure or describe in a separate policy

Peer Review Questions and Answers

- What should be included or referenced in minutes/documentation in order to access the privilege?
 - Make sure the committees or activities producing the minutes are reflected in the PSES
 - Determine whether the minutes/reports are going to be actually reported to the PSO and are reported with the date on which they're reported or are being treated as deliberations or analysis – clarify which method is being utilized for the information in the PSES
 - The language “Privileged and Confidential under the Patient Safety and Quality Improvement Act of 2005 [and the _____ Act]” for those portions of the minutes you are treating as privileged
 - Some hospitals have an email system which includes this or similar language on privileged emails
 - Remember, it is not fatal if this language is not inserted. It is more important that the minutes be identified in the PSES

Peer Review Questions and Answers

- Who can review privileged minutes/documentation?
 - Workforce members who have been identified by the provider – these are the individuals who prepare or need to access PSWP as part of their job responsibilities
- What can be shared from the Peer Review process and who can see it?
 - Workforce members
 - Hospital identifiable PSWP can be shared with affiliated entities, including the parent corporation and their workforce members, who are members of the PSO and are in a single system PSES
 - PSWP can be shared/disclosed if utilizing a permissible disclosure exception, i.e. attorneys, accountants, business associates, accreditation bodies, etc. (See Section 3.206 of the Final Rule)

Peer Review Questions and Answers

- Sharing physician identifiable PSWP generated within a hospital is considered a use and not a disclosure and therefore can be shared with the hospital's workforce members
- In order to share physician identifiable PSWP generated in the hospital with outside entities, including affiliated providers, the physician must sign a written authorization permitting the disclosure of this information
 - Authorization can be included in a separate form or in the appointment/ reappointment application, or an employment agreement.

Peer Review Questions and Answers

- Can Peer Review information be used in a disciplinary action?
 - The short answer is that privileged Peer Review information can and should be used in all Peer Review activities, i.e., monitoring, proctoring, collegial intervention – these are all non-reportable decisions to the Data Bank
 - This information also can be used in disciplinary actions BUT it cannot be introduced into evidence in any subsequent state or federal litigation because the protections from discovery and admissibility into evidence apply to ALL parties
 - There are methods on how to use this Peer Review information, including conducting third party reviews outside the PSES, so that the information can be used in litigation, subject to state laws

Peer Review Questions and Answers

- Regarding HR activities, do NOT include PSWP in an employee's file because the information cannot be introduced into evidence to defend the provider in the event that there is subsequent litigation and because the employment laws allow an employee access to their employment file.
- HR can review PSWP regarding an employee but should prepare separate forms and conduct separate investigations that are not included in and not part of the PSES. These materials can be used for internal HR purposes and are available as evidence in litigation if needed.

Comparison of the New York and Pennsylvania Statutes 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 — protections are not limited to duly appointed committees of qualifying review entities.
 - The scope of what patient safety activities can be protected, generally speaking, is broader than the activities and documents privileged under the New York or Pennsylvania statutes.
 - The scope of what entities can seek protection are very similar.
 - The protections under the PSA apply in both state and, for the first time, federal proceedings. The New York and Pennsylvania statutes only apply in state proceedings and state claims in federal courts.

Comparison of the New York and Pennsylvania Statutes to the Patient Safety Act

- The protections can never be waived under the PSA and probably not under the New York and Pennsylvania statutes.
- PSA pre-empts less protective state law.
- Non-provider corporate parent organization which controls, owns or manages licensed providers can receive and generate privileged information under both the Pennsylvania and PSA if structured correctly but unclear under new York law unless it has been structured under the appropriate committees
- PSWP can be shared among affiliated providers but whether information can be shared under New York and Pennsylvania law is not quite as clear.
- Key to these protections under both laws is the design of the provider's bylaws and policies and its patient safety evaluation system ("PSES").
- See also CHART Institute PSO Program "Maximizing Peer Review Protections under State Laws and the Patient Safety Act" (June 18, 2019) which is attached.

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 New York, Pennsylvania and West Virginia state privilege statutes
 - 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 state privilege protections
 - Data Bank Reports
 - New York Public Health 2801-1, Title 10 New York Code, Rules and Regulations 405 and 751.10, The New York Patient and Occurrence Reporting and Tracking System
 - Pennsylvania Medical Care Availability and Reduction of Error (MCARE) Act, 40 Pa. Stat. § 1303.01
 - West Virginia Medical Harm Reduction Act Disclosure Act - introduced but not passed?
 - 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 state privilege protection from disclosure 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

Regulators Demand for PSWP: How To Respond

- 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 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 external 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)

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.

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.



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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