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Texas Hospital Association Patient Safety Organization Orientation and Collaborative Workshop

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Design and Implementation of your PSES: A Dialog About Maximizing Protection and Improving Patient Care

Michael R. Callahan
Partner, Katten Muchin Rosenman LLP
+1.312.902.5634
michael.callahan@kattenlaw.com

Speaker Bio

Michael R. Callahan, Partner - michael.callahan@kattenlaw.com

Michael R. Callahan assists hospital, health system and medical staff clients on a variety of health care legal issues related to accountable care organizations (ACOs), patient safety organizations (PSOs), health care antitrust issues, Health Insurance Portability and Accountability Act (HIPAA) and regulatory compliance, accreditation matters, general corporate transactions, medical staff credentialing and hospital/medical staff relations.

Michael's peers regard him as "one of the top guys […] for credentialing—he's got a wealth of experience" (Chambers USA). Additionally, his clients describe him as "always responsive and timely with assistance," and say he is "informed, professional and extremely helpful" and "would recommend him without reservation" (Chambers USA). Michael's clients also commend his versatility, and say "He is willing to put on the hat of an executive or entrepreneur while still giving legal advice," according to Chambers USA.

He is a frequent speaker on topics including ACOs, health care reform, PSOs, health care liability and peer review matters. He has presented around the country before organizations such as the American Health Lawyers Association, the American Medical Association, the American Hospital Association, the American Bar Association, the American College of Healthcare Executives, the National Association Medical Staff Services, the National Association for Healthcare Quality and the American Society for Healthcare Risk Management.

Michael was recently appointed as chair of the Medical Staff Credentialing and Peer Review Practice Group of the American Health Lawyers Association. He also was appointed as the public member representative on the board of directors of the National Association Medical Staff Services.

He was an adjunct professor in DePaul University's Master of Laws in Health Law Program, where he taught a course on managed care. After law school, he served as a law clerk to Justice Daniel P. Ward of the Illinois Supreme Court.

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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.

Topics to be Covered

1. Brief Overview of the Industry Movement Towards Reimbursing Providers Based on Value versus Volume
2. Overview of the Patient Safety Act and What is PSWP and a PSES
3. Overview of the HHS Guidance
4. Impact of the Guidance on PSES design – What Are Your Options?
5. Discussion of Clouse and Pending PSO State Supreme Court Cases
6. Comparison of Texas and Patient Safety Act Privilege Practice Protections

Health Care Reform and PSOs

- Medicare/Medicaid and private payers are now reimbursing providers based on documented compliance with established quality metrics and outcome measures.
- Examples of this shift from volume to value as a condition of payment include:
  - Medicare Shared Savings ACOs
  - Value-based purchasing outcome standards
  - Pay for performance standards
  - Readmission rate penalties
  - Hospital acquired condition/Infection penalties
  - Medicare's goal to base 70% of its payments on compliance with quality standards by 2018

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Health Care Reform and PSOs (cont'd)

- In order to meet these ever evolving standards, clinically integrated networks, hospitals and other providers will need to implement these standards into their appointment, reappointment, ongoing monitoring and similar processes in order to track performance and implement remedial measures, including disciplinary action for non-compliance not only because of the potential adverse impact on patients but also because it will result in reduced reimbursement.
- The result of these efforts will be the creation of very sensitive quality, risk and peer review analyses, reports, studies, and other information, most of which may not be protected under existing state laws.

Health Care Reform and PSOs (cont'd)

- As will be discussed during this presentation, participation in PSOs therefore play a very important role in being able to conduct these patient safety, quality and risk activities in a protected space in order to continue to improve patient care services.

The Patient Safety and Quality Improvement Act of 2005

- The goal of the Act was to improve patient safety by encouraging voluntary and confidential reporting of health care events that adversely affect patients. To implement the Patient Safety Act, the Department of Health and Human Services issued the Patient Safety and Quality Improvement Rule (Patient Safety Rule).
- The Patient Safety Act and the Patient Safety Rule authorize the creation of PSOs to improve quality and safety through the collection and analysis of aggregated, confidential data on patient safety events. This process enables PSOs to more quickly identify patterns of failures and develop strategies to eliminate patient safety risks and hazards.

The Patient Safety and Quality Improvement Act of 2005 (cont'd)

- Provides privilege & confidentiality protections for information when providers work with Federally listed PSOs to improve quality, safety and healthcare outcomes
- Authorizes establishment of "Common Formats" for reporting patient safety events
- Establishes "Network of Patient Safety Databases" (NPSD)
- Requires reporting of findings annually in AHRQ's National Health Quality / Disparities Reports

Key Components of Patient Safety Act

- **PSOs** – Almost any entity can be or have a PSO.
- PSOs serve as independent, external experts who can collect, analyze, and aggregate Patient Safety Work Product to develop insights into the underlying causes of quality and patient safety events.
- **Providers –** An individual or entity licensed or otherwise authorized under State law to provide health care services and/or a parent organization of one or more entities licensed or otherwise authorized to provide health care services.
- **Patient Safety Events –** Incidents or near misses or unsafe conditions
- Any type of event that adversely effects healthcare quality, patient safety or healthcare outcomes
- **Common Formats –** Provide a uniform way to measure patient safety events clinically & electronically and to permit aggregation & analysis locally, regionally, & nationally.

Patient Safety Activities

- Efforts to improve patient safety and the quality of health care 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 best practices;
- The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;

Patient Safety Activities (cont'd)

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

PSES Operations

Establish and Implement Your PSES to:

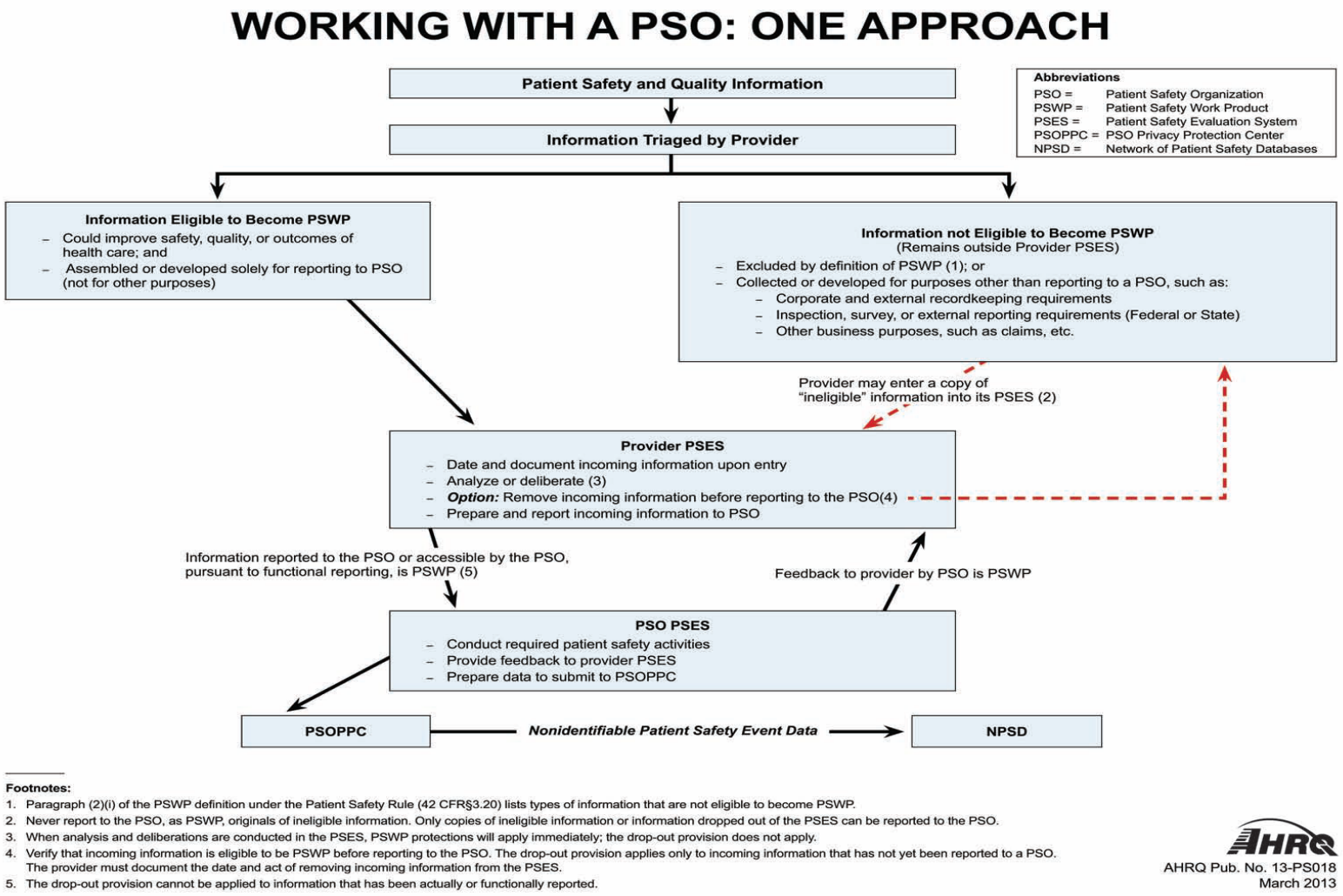
- **Collect** data to improve patient safety, healthcare quality and healthcare outcomes
- **Review** data and takes action when needed to mitigate harm or improve care
- **Analyze** data and makes recommendations to continuously improve patient safety, healthcare quality and healthcare outcomes
- Conduct RCAs, Proactive Risk Assessments, in-depth reviews, and aggregate RCAs
- Determine which data will/will not be reported to the PSO
- Report to PSO
- Conduct auditing procedures

PSES Operations (cont'd)

Examples in PSES for collecting and reporting to a PSO:

- Medical Error investigations, FMEA or Proactive Risk Assessments, Root Cause Analysis
- Risk Management - incident reports, investigation notes, interview notes, RCA notes, notes from risk recommendations via phone calls or conversations, notes from PS rounds which relate to identified patient safety activities
- Outcome/Quality - may be practitioner specific, sedation, complications, blood utilization etc.
- Peer Review
- Committee minutes – Those portions of Safety, Quality, Quality and Safety Committee of the Board, Medication, Blood, Physician Peer Review relating to identified patient safety activities

PSO Participation Schematic



Footnotes:

1. Paragraph (2)(i) of the PSWP definition under the Patient Safety Rule (42 CFR§3.20) lists types of information that are not eligible to become PSWP.
2. Never report to the PSO, as PSWP, originals of ineligible information. Only copies of ineligible information or information dropped out of the PSES can be reported to the PSO.
3. When analysis and deliberations are conducted in the PSES, PSWP protections will apply immediately; the drop-out provision does not apply.
4. Verify that incoming information is eligible to be PSWP before reporting to the PSO. The drop-out provision applies only to incoming information that has not yet been reported to a PSO. The provider must document the date and act of removing incoming information from the PSES.
5. The drop-out provision cannot be applied to information that has been actually or functionally reported.

AHRQ Pub. No. 13-PS018
March 2013

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Overview of HHS PSO Guidance

- Title is “Guidance Regarding Patient Safety Work Product and Providers’ External Obligations”.
- Published in Federal Register on May 24, 2016 (81 FR 32655) at the same time the U.S. Solicitor General filed its amicus curie brief in Tibbs v. Bunnell.
- PSOs and providers have recognized that information and records that must be legally reported to a state and/or federal agency, such as mandated adverse event reports or a Data Bank report, cannot be collected in a PSES and reported to a PSO.

Overview of HHS PSO Guidance (cont'd)

- The Guidance, however, goes further by stating that information which is subject to "external record keeping requirements, even if not required to also be reported, cannot qualify or is not eligible to be treated as PSWP.
- PSWP cannot be used to meet external obligations.

Overview of HHS PSO Guidance (cont'd)

Expansion of What Constitutes an "Original Record"

- HHS also has "clarified" that "original patient or provider information" such as a "medical record, billing or discharge information" now applies to the following:
  - "Original record (e.g., reports or documents) that are required of a provider to meet any Federal, state, or local public health or health oversight requirement regardless of whether such records are maintained inside or outside of the provider's PSES; and
  - Copies of records residing within the provider's PSES that were prepared to satisfy a federal, state, or local public health or health oversight record maintenance requirement if such records are only maintained within the PSES and any original records are either not maintained outside of the PSES or were lost or destroyed.

Overview of HHS PSO Guidance (cont'd)

- HHS identifies hypothetical examples to illustrate what it considers to be original provider records that are not PSWP-eligible:
  - Original records maintained separately from the PSES;
  - Original records maintained outside of PSES, if lost or destroyed, then duplicate records in the PSES for reporting to a PSO for further analysis are no longer considered PSWP;
  - The provider only maintains original records in the PSES. Such records are not PSWP eligible.

Overview of HHS PSO Guidance (cont'd)

"Sole Purpose" Reference

- In its effort to clarify whether the purpose for which the information being collected in a PSES can be treated as PSWP, the Guidance created a chart which has three categories. The third category of the examples (see page 32655 in attached HHS guidance) states are as follows:
  - "Could be PSWP if information is not required for another purpose and is prepared solely for reporting to a PSO" (emphasis added).
  - This confusing and ambiguous term appears nowhere in the Act or the Final Rule. Nor does HHS attempt to clarify this term.
  - PSO's have sent questions asking ARQ to clarify this term.
  - PSO Work Group has requested opportunity to provide its position on "sole purpose" before AHRQ responds.

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Overview of HHS PSO Guidance (cont'd)

Possible responses

- Only logical interpretation is that information and records which must be reported or collected and maintained pursuant to Federal, state or local laws are not and cannot be collected for the sole purpose of reporting to a PSO.
- All other patient safety activity information collected in a PSES for reporting to a PSO for the purpose of improving quality and reducing risk is PSWP.

Overview of HHS PSO Guidance (cont'd)

Available Options When Government Requests Disclosure of PSWP

- HHS identifies the following options if records, which the provider in good faith believes were not created and maintained to fulfill an external obligations, are now sought by an agency even though they have been reported to a PSO and are PSWP.
  - If mistakenly treated as PSWP and you determine that it was not eligible, it can be removed or dropped out because it was not PSWP eligible in the first place.
  - Consider use of disclosure exceptions:
    - Identified provider's written authorization
    - FDA disclosure permission
    - Voluntary disclosure to an accrediting body
  - Conduct a separate analysis on non-PSWP, i.e., medical records, outside of the PSES.

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Summary

Guidance issues	Guidance clarifications	Supplemental Brief
The providers reporting pathway (PSPW and non PSWP)	Not PSWP if prepared for purposes other that reporting to a PSO expanded to “sole” purpose	Privilege exceptions authorize use of info for a variety of purposes Use of “solely” inserted by the government
Meeting external obligations	Expands definitions “original record” to include recordkeeping obligations	Expansion interjects state law above statute
Separate systems	Two systems or spaces: (1) PSES for PSWP (2) separate place where it maintains records for external obligations	Leverage existing infrastructure
Options for PSWP that can’t be dropped out	Providers should work with regulatory bodies to provide information needed. An option is to exercise a disclosure exception.	Disclosure of PSWP must have applicable disclosure permission and a State may not require that PSWP be disclosed

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What To Do Now?

- Wait for Future Developments before modifying PSES
  - U.S. Supreme Court met on June 23rd and denied the petition in Tibbs v. Bunnell case.
  - Three state supreme court cases:
  - Charles v. Southern Baptist in Florida -- to be argued in October
  - Carron v. Newport Hospital in Rhode Island;
  - Baptist Redmond Hospital v. Clouse -- decision could be issued any day
  - PSOs sent questions to AHRQ seeking further clarification
  - PSO Work Group also requested and AHRQ agreed to schedule "listening sessions" to address the issues of "sole purpose" language, peer review as PSWP, and AHRQ Guides

What To Do Now? (cont'd)

- PSOs sent questions to AHRQ seeking further clarifications
- PSO Work Group also requested opportunity to address PSO issues and AHRQ

- Attempt Good Faith Compliance with Guidance

What to Do Now (cont'd)

- Attempt Good Faith Compliance under the Guidance

What To Do Now? (cont'd)

Bucket 1

- Mandated Reports

Bucket 2

- External Obligations
  - Need to review Medicare CoPs, in particular QAPI standards.
  - Need to review other applicable Federal, state and local record keeping requirements.
  - Compare these laws to what you are currently collecting and reporting or functionally reporting to the PSO.
  - Modify PSES if necessary.

What To Do Now? (cont'd)

- Where laws on what records you need to collect and maintain are not clear or are ambiguous, you can:
  - Keep in your PSES and not report in order to remove if necessary;
  - If reported to PSO you can utilize the written authorization disclosure exception, information is still PSWP
  - If the laws identify a record that must be collected and maintained but there is no required form and the law does not identify what must be included, develop your own form.

Bucket 3

- What is not in Bucket 1 or 2 and is collected in the PSES for reporting to a PSO and is reported is PSWP – Reporting Pathway

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What To Do Now? (cont'd)

- Deliberation or Analyses – Can include reports, analyses (RCA) which are the product of deliberations and analyses. D or A automatically becomes PSWP and does not need to be reported. Cannot drop out.
- Treat the Guidance as Non-Binding.
  - Rely on supportive state and/or federal court decisions.
  - Prepare for possible legal challenges knowing that attorneys and courts may or will look to the Guidance to support the challenge.
  - You always have the option to drop out if not reported or to use written authorization to disclose.

Baptist Health Richmond v. Clouse

- Factual Background
  - A medical malpractice case was filed against Baptist Health Richmond ("Hospital") following the death of a patient who died following a laproscopic procedure
  - In addition to seeking original hospital and medical records relating to the patients records, the plaintiff brought the following:
    - All incident reports
    - Investigation reports
    - Sentinel event reports
    - Root cause analysis reports
    - Joint Commission reports
    - Medicare/Medicaid reports
    - Peer review reports
    - Copies of and all documentation reviewed, analyzed, used, utilized or referenced regarding these reports

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Baptist Health Richmond v. Clouse

- Hospital objected to the production of these documents because they were collected within its PSES for reporting to the Kentucky Institute for Patient Safety and Quality ("PSO") and included a supporting affidavit
- In response to the plaintiff's motion to compel the trial court ruled that:
  - "The hospital shall produce any and all said material requested by Plaintiff, except for those specific documents certified by the hospital as having been collected, maintained or developed for the sole purpose of disclosure to a [PSO] pursuant to the [Act]. Specific documents collected, maintained, or developed for any additional purpose beyond PSO disclosure, such as compliance with the requirements of [Kentucky statutes], are not privileged under the [Act] and must be produced."

Baptist Health Richmond v. Clouse

- The Hospital's petition for writ of prohibition to the Court of Appeals was denied as the basis that the trial court's "sole purpose" interpretation "largely applied the principles set forth in the Tibb's decision."
- The Kentucky Supreme Court granted the Hospital's direct appeal and issued its decision on September 22, 2016

- Decision
  - The Court initially noted that the Tibbs decision was a plurality opinion meaning less than a majority agreed on the reasoning of the case, although a majority agreed with the outcome it was not binding on the courts in Kentucky.
  - The Tibbs decision concluded that the incident report in question, which the hospital had collected and reported to its PSO, did not qualify as patient safety work product "since its collection, creation, maintenance, and utilization is mandated by the Commonwealth of Kentucky as part of its regulatory oversight of its healthcare facilities".

Baptist Health Richmond v. Clouse (cont'd)

- The plurality opinion, however, also concluded that the matter be remanded to the trial court to separate the information "normally contained…in state mandated incident reports" from "material properly privileged under the Act" so as to permit discovery of the non-privileged information.
- While the case was still pending on appeal, the Court noted that HHS issued its PSO guidance which expanded the interpretation of "original provider records" and takes the position that such records which "are required of a provider to meet any Federal, state, or local public health or health oversight requirements regardless of whether such records are maintained inside or outside of the provider's patient safety evaluation system" did not qualify as PSWP.

Baptist Health Richmond v. Clouse (cont'd)

- Consequently, the Court determined that "reports that are required by the Commonwealth do not become privileged because the provider puts them in its patient safety evaluation system" and "permitting hospitals to place and leave otherwise discoverable information in the [PSES] in order to shield it from discovery is equally unacceptable…."
- At the same time, the Court agreed with the dissenting opinion in Tibbs that allowing a trial court to invade a hospital's PSES every time there is a discovery dispute would "discourage participation in the patient safety system by Kentucky's health care providers" (quoting from the dissenting opinion in Tibbs).

Baptist Health Richmond v. Clouse (cont'd)

- The Court made the following rulings:
  - A hospital "may collect information within it's [PSES] that complies with the Act and that also complies with state statutory and regulatory requirements."
  - That being said, the hospital must still comply with record reporting and recordkeeping requirements and if "information collected in the provider's internal [PSES] is needed to comply with those state requirements, it is not privileged."
  - If the hospital fulfills these statutory obligations the trial court "has no reason to review the information in the provider's [PSES]"
  - It is only when a provider does not meet these statutory obligations that the Court can conduct an in-camera review of the PSES documents.
  - "In conducting that review, the Court should separate the information that is usually contained in state-mandated reports from information that is not usually contained in those reports and therefore can be treated as PSWP."

Baptist Health Richmond v. Clouse (cont'd)

  - The hospital bears the burden of proving that it complied with the statutory and regulatory requirements.
  - If the provider fails in meeting this burden, the parties seeking the information then must establish that the information requested is generally contained in state-mandated reports.

- Based on the Court's holding, the trial court's order to require the Hospital to produce documents was vacated with instructions to "undertake the review" set forth in the decision.

Baptist Health Richmond v. Clouse (cont'd)

- Analysis and Impact:
  - Although the Guidance simply reflects the government's interpretation of the Patient Safety Act, and its view that mandated reports and recordkeeping reports cannot be considered PSWP and therefore is not binding on the courts, the Kentucky Supreme Court clearly accepted and relied on the Guidance to support its decision.
  - Although the Clouse decision is only binding on Kentucky courts, we expect that other courts may be more likely than not to follow the decision and the Guidance when faced with discovery disputes under the Patient Safety Act.

Baptist Health Richmond v. Clouse (cont'd)

- Interestingly, the Court made absolutely no reference to, nor did it rely on a "sole purpose" theory to support its decision. One can therefore argue that the Court rejected this so-called standard or certainly did not need to accept or rely on the position of the trial and appelate courts in reaching its decision.
- The decision, however, does not answer all of the questions which providers will face because, despite the Court's comments, a hospital's "recordkeeping" obligations are not very clear.
- For example, the Kentucky statutory reference to "incident investigation reports" does not specify a particular form nor does the statute explain what information must be contained in such reports.
- Where a lack of clarity exists and the state has not taken any action to further identify what falls into the Bucket 2 recordkeeping category, the hospital can produce its own report to meet these statutory obligations.

Baptist Health Richmond v. Clouse (cont'd)

- Under these circumstances, the mandated reports and recordkeeping reports can then be made available to the Federal and state agencies in a format that does not contain written analyses, impressions and other information which the provider can therefore treat as PSWP.
- If other courts follow the Kentucky Supreme Court method of assessing burdens of proof, the hospital should be prepared to demonstrate that it has complied with its external requirements through forms, reports, etc., that have not been collected and treated as PSWP which must be reported and/or collected and maintained pursuant to state or Federal law. The burden will then shift to the plaintiff to establish that the reports which the hospital is seeking to treat as PSWP contain mandated record reporting and recordkeeping information.

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
    - 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
    - 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 these 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
    - 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
    - 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 providers

Scope of Privilege 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 Privilege 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 documented 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 Privilege 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 such as an alleged violation of Federal antitrust or discrimination laws.
- Patient Safety Act
  - Privileged PSWP is not admissible nor discoverable 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 never 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

Katten Muchin Rosenman LLP Locations

AUSTIN
One Congress Plaza
111 Congress Avenue
Suite 1000
Austin, TX 78701-4073
+1.512.691.4000 tel
+1.512.691.4001 fax

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

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

HOUSTON
1301 McKinney Street
Suite 3000
Houston, TX 77010-3033
+1.713.270.3400 tel
+1.713.270.3401 fax

IRVING
545 East John Carpenter Freeway
Suite 300
Irving, TX 75062-3964
+1.972.587.4100 tel
+1.972.587.4109 fax

LONDON
125 Old Broad Street
London EC2N 1AR United Kingdom
+44.0.20.7776.7620 tel
+44.0.20.7776.7621 fax

LOS ANGELES – CENTURY CITY
2029 Century Park East
Suite 2600
Los Angeles, CA 90067-3012
+1.310.788.4400 tel
+1.310.788.4471 fax

LOS ANGELES – DOWNTOWN
515 South Flower Street
Suite 1000
Los Angeles, CA 90071-2212
+1.213.443.9000 tel
+1.213.443.9001 fax

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

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

SAN FRANCISCO BAY AREA
1999 Harrison Street
Suite 700
Oakland, CA 94612-4704
+1.415.293.5800 tel
+1.415.293.5801 fax

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

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

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Katten Muchin Rosenman LLP
www.kattenlaw.com