



**The Patient Safety Work Product Privilege:
Evidence and Proof**

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GK Disclosures

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Objectives

- Describe Legal Concept of “Privilege”
- Outline expected effect of the Patient Safety and Quality Improvement Act on state law.
- Discuss Proof of the PSWP Privilege and Case Law to Date
- Consider ramifications for disclosure and use of data that is designated as Patient Safety Work Product (Open for questions).



Lawyers Speak a
Different Language
from Clinicians



Evidence

- Piece of information that supports a conclusion about some matter being reviewed.

- **Fact Evidence**
 - Physical (Physical Object)
 - Testimonial (Witness's Observation, Experience or Intention)
 - Documentary (Business Record, Data, Image)
 - Demonstrative (Representative of Object, e.g., photos, x-rays, recordings, diagrams, maps, etc.)

- **Opinion Evidence**
 - Traditionally Always Testimonial – (Until now?)



Legal Privileges

■ Evidentiary Privileges -

(1) Refuse to be a witness.

(2) Refuse to disclose any matter.

(3) Refuse to produce any object or writing.

(4) Prevent another person from doing (1) – (3).



Waiver of Privilege

- **Voluntary disclosure** of any significant part of the matter or communication
- If communicated with **no** reasonable expectation of privacy (“Loose lips sink ships”)
- **Consent** to disclosure by another

But **no waiver** occurs when the disclosure is itself a **privilege** communication



“Self-critical Analysis” Privileges

- “Peer Review”
- “Risk Management”/”Work Product”
- “Quality Assurance”/“Utilization”

- Problems:
 - Does not cover all types of providers
 - Vary from State to State
 - Kentucky has none



“Immunity” vs. “Privilege”

- Statute provides **absolute immunity from use** of the record in question only **in “any civil or administrative action” against the hospital**, such as the pending medical malpractice action.
- The fact that the hospital **disclosed** the protected record to persons outside the committee **does not remove or waive the limited immunity from use** provided by the statute.

Hillsborough County Hospital Authority v. Lopez, 678 So. 2d 408 (Fla. 2d DCA 1996)



Federal Courts?

Most federal courts did not recognize the “peer review” or “self-critical analysis privilege”

- Dowling v. American Hawaii Cruises, Inc., 971 F. 2d 423 (9th Cir. 1992)
- Adkins v. Christie, 488 F.3d 1324 (11th Cir. 2007)



Federal Courts?

- Also did not recognize the state law peer review privileges except in “diversity cases” like medical malpractice actions filed in federal court. Compare
 - Adkins v. Christie, 488 F.3d 1324 (11th Cir. 2007)
 - Somer v. Johnson, 704 F.2d 1473 (11th Cir. 1983)

- Issued protective orders to limit re-disclosures
 - Scott v. McDonald, 70 F.R.D. 568 (N.D. Ga. 1976)
 - Martinez v. Provident Life & Accident Ins. Co., 174 F.R.D. 502 (S.D. Fla. 1997)



Federal Response

**Patient Safety
And
Quality Improvement
Act of 2005**



Key Definitions: **Patient Safety Work Product**

- Any data, reports, records, memoranda, analysis (such as root cause analysis), or written or oral statements which:
 - “Are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization,”
 - “Are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes”
 - “Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to a *patient safety evaluation system*.”



In other words,

■ **Patient Safety Work Product is:**

- Information created for and actually sent to a PSO
- Information and analysis coming back from the PSO
- Documentation of the deliberations or analysis of your Patient Safety Evaluation System (i.e., documentation of how such information is processed in the Patient Safety Evaluation System, e.g., root cause analysis, minutes of meetings, other analyses)



PSWP does NOT include:

- Patient's medical record
- Billing and discharge information
- Any other original patient or provider information
- Information that is collected, maintained, or developed separately, or exists separately, from a *patient safety evaluation system*.

NOTE: If “separate information” or a copy thereof is reported to a PSO, it does not become patient safety work product.



Key Provision:

Patient Safety

Work Product

is

privileged



PRIVILEGE & CONFIDENTIALITY PROTECTION

- Patient safety work product shall be privileged and shall not be –
- Admitted as evidence in any proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding

NOTE: Same as “IMMUNITY FROM USE”

- Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law



PRIVILEGE & CONFIDENTIALITY PROTECTIONS (Part 2)

- Patient safety work product shall be privileged and shall not be –
 - Subject to a subpoena or order, including disciplinary proceedings against a provider
 - Subject to discovery in connection with a proceeding, including proceedings against a provider
 - Subject to disclosure under the Freedom of Information Act or any other similar law



CONTINUED PROTECTION *AFTER* DISCLOSURE

- In general –
 - Patient safety work product that is disclosed continues to be privileged and confidential!
 - Disclosure is not treated as a waiver of privilege or confidentiality.

GK Disclosures

- Several Exceptions to the Confidentiality Rule set out in 42 C.F.R. § 3.206(b)
- Only as Authorized by Regulation
- Disclosure is Not a Waiver (as if disclosure itself is “privileged”)
- Confidentiality and Privilege Still Apply after Permissible Disclosure

NOTE: “Disclosure of Unanticipated Outcomes” (Joint Commission Standard RI 01.01.01, EP 21-22) is not a “Permissible Disclosure” under the Regulation



Unauthorized Disclosures

Disclosers
Can be
Fined

(similar to HIPAA violations)



Waiver can occur

HOWEVER...

- You will **LOSE** continued protection if:
 - work product is disclosed in a **criminal proceeding**, the confidentiality protections no longer apply to the work product so disclosed
 - work product is disclosed as **non-identifiable** patient safety work product



What does it mean for you?



Benefits?

**Stronger, Farther-reach Legal Privilege Under
Federal Law (“PSWP”)**

supplements

**State Law Privileges
(if any)**



Why Stronger?

- Privilege will apply in Federal Courts

- Supremacy Clause

This Constitution, and the Laws of the United States which shall be made in pursuance thereof; . . . , shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the constitution or laws of any state to the contrary notwithstanding.

- Supplement State laws

- More protective laws prevail. 42 U.S.C. §299b-22(g)



Previous Federal Privileges -

Pierce County Washington v. Guillen,
537 U.S. 139 (2002)

Federal OSHA privilege prevailed over constitutional power of state court to subpoena records

State ex rel. Boone Retirement Ctr. v. Hamilton,
946 S.W.2d 740 (Mo. 1997)

Federal SNF Q/A privilege prevailed over Missouri law



First cases

- *Schlegel v. Kaiser Foundation Health Plan* (not mission and primary activity)
- *Massi v. Walgreen Co.* (not assembled for reporting)
- *Lee Medical v. Beecher* (“peer review” not submitted to PSO)
- *K.D. ex rel. Dieffenbach v. U.S.* (change in federal policy allowed federal court to recognize state law privilege)
- *Illinois Dept. of Financial & Professional Regulations (IDFPR) v. Walgreen Co.* (segregated PSWP data was not discoverable)



First Cases – Lee Medical v. Beecher (Part 1)

Not a PSQIA case, but the discussion is illuminating

Obiter dictum

(Latin, a statement "said by the way")

A remark or observation made by a judge that, although included in the body of the court's opinion, does not form a necessary part of the court's decision.

Statements constituting *obiter dicta* are therefore not binding, although they can be strongly persuasive.



First Cases – Lee Medical v. Beecher (Part 2)

- [P]rivileges present obstacles to the search for the truth.
- They are not designed or intended to facilitate the fact-finding process or to safeguard its integrity. Rather than illuminating the truth, their effect is to “shut out the light.”
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- Privileges protect “interests and relationships which, rightly or wrongly, are regarded as of sufficient social importance to justify some sacrifice of the availability of evidence relevant to the administration of justice.”



First Cases – Lee Medical v. Beecher (Part 3)

CONCLUSION:

Privileges should not be broadly construed



First Cases – Lee Medical v. Beecher (Part 4)

- Congress . . . Create[d] a tightly crafted federal privilege for “patient safety work product” actually reported to a “patient safety organization.”
- Patient safety work product that is not actually reported is not privileged.

NOTE: The court did not consider the other two categories of PSWP because Medical Center never had a system to report data to a PSO



First Cases – K.D. ex rel. Dieffenbach v. U.S.

Not a PSQIA case either.
But compare it with Lee Medical –

K.D. Court applied public policy



First Cases – K.D. ex rel. Dieffenbach v. U.S. (Part 2)

- **Federal Rule of Evidence 501 directs that privileges “shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience.”**

Rule 501 provides federal courts with a measure of flexibility in crafting privilege law.



First Cases – K.D. ex rel. Dieffenbach v. U.S. (Part 3)

EVEN SO:

- Courts have long disfavored the recognition of privileges in federal practice
- Courts are especially reluctant to recognize a privilege “where it appears that Congress
 - has considered the relevant competing concerns but
 - has not provided the privilege itself.”



First Cases – K.D. ex rel. Dieffenbach v. U.S. (Part 4)

- More obiter dictum –
 - Many courts have looked to the Health Care Quality Improvement Act of 1986 (“HCQIA”) and concluded that federal policy is hostile to a medical peer review privilege.
 - [T]he prevailing analysis of the HCQIA is that “Congress spoke loudly with its silence” in not enacting a broad privilege against discovery of peer review materials.



First Cases -- K.D. ex rel. Dieffenbach v. U.S. (Part 5)

- More obiter dictum –
 - HCQIA no longer represents Congress' final word on the issue of medical peer review.
 - The Patient Safety Quality Improvement Act of 2005 announces a more general approval of the medical peer review process and more sweeping evidentiary protections for materials used therein.
 - In contrast to the HCQIA, . . . the PSQIA tackled the larger problem of systemic weaknesses in the delivery of health care resulting in preventable adverse events



First Cases – K.D. ex rel. Dieffenbach v. U.S. (Part 6)

- More obiter dictum –
 - The PSQIA was thus designed to encourage this “culture of safety” by “providing for broad confidentiality and legal protections of information collected and reported voluntarily for the purposes of improving the quality of medical care and patient safety.”
 - While the HCQIA applies only to peer review actions affecting individual physicians, the PSQIA protects all “patient safety work product” a term defined expansively to include any data, reports, records, memoranda, analyses, or written or oral statements which:
 - (1) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization;
 - (2) are developed by a patient safety organization for the conduct of patient safety activities . . . ; or
 - (3) identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.



First Cases -- K.D. ex rel. Dieffenbach v. U.S. (Part 7)

- clearly perform the same functions Congress intended the PSQIA to encourage. . . .
- The NIH review process. . . collects the same *kind* of safety data as enumerated in the PSQIA, within the same organizational structure, to accomplish the same goal (i.e., ensuring participant safety and effectiveness of care).
- The court is confident that protecting otherwise confidential and evaluative materials resulting from this process would not substantially offend the federal policy announced in the PSQIA.



First Cases -- K.D. ex rel. Dieffenbach v. U.S. (Part 8)

- Court recognized a qualified privilege for confidential evaluative materials produced by the NIH review process . . .
■ based on
 - public policy evident in Maryland privilege law
 - intent of Congress in passing the PSQIA
 - the particular circumstances of this case.



First Cases -- K.D. ex rel. Dieffenbach v. U.S. (Part 9)

The new privilege applied only to those materials

prepared with the expectation that they would be kept confidential

and

not, in fact, disclosed.

RESULT:

Same privilege as “self-critical analysis” so “waiver” applies.



SUMMARY

- **Pre-emption** of Less Protective State Laws is Likely
- **Strict Construction** of PSWP is Likely but not Inevitable
- **One of Three PSWP categories** must be Proven to Assert PSWP
- **Evidence of Intent, Structure, and Process** Will Be Needed to Prove Privilege
- **Burden of Proof** is on Provider/PSO



Cultural Challenges

- Major Shift in Disciplinary Process.
- No PSWP can be used in discipline.
- Replace Reaction with Intervention.
- Parallel investigation, after “**trigger**” if necessary.
- Both paths should feature Due Process.
- **How do you keep “*accountability*”?**



Record-keeping Challenges

- **Identify** PSWP and Where PSWP is Kept
- **Segregate** PSWP
- **Secure** PSWP (Particularly Electronic Data)
- **Prevent** Unauthorized Disclosure of PSWP
- **Establish Process** for Evaluating Requests for Disclosure of PSWP



Evidentiary Challenges

- **Witness** for What is PSWP & Where PSWP is Kept
 - **Who** Holds, owns, uses PSWP?
 - **What** Kinds of documents and records are they?
 - **When** Was it collected, sent, or received?
 - **Where** Is it kept now (Separate? Secure?)?
 - **How** Did you intend to use it, send it, receive it?
- **Is** PSWP *discrete* or does it exist separately? (Intent)
- **Has** it been *used/disclosed* elsewhere? (cf. Wikileaks)
- **How** to prove *process* if PSWP is not admissible?