The Patient Safety Quality Information Act and Ohio’s Peer Review Privilege

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THEY ARE TWO VERY DIFFERENT LAWS WITH TWO VERY DIFFERENT PURPOSES.
PSQIA

- Creates a program through which health care providers (not less than 2) can voluntarily report information relating to patient safety events to a Patient Safety Organization (PSO) on a privileged and confidential basis for the aggregation and analysis of patient safety events.
PSQIA

- If requirements are met, the Patient Safety Work Product (PSWP) is not subject to discovery in any federal, state, local civil, or administrative proceeding (with some defined exceptions).
PSQIA (exceptions)

- May be subject to discovery in criminal proceedings
- May be waived by providers who want their information disclosed
- May be disclosed for patient safety activities, research, disclosure to FDA, disclosure to an accrediting body, disclosure for business operations (such as to attorneys or accountants in course of business operations)
PSQIA

- The protection may be waived by the affected parties.
- There are no immunity provisions.
Improper disclosure in knowing or reckless violation of the confidentiality provisions is subject to a civil money penalty for each violation ($11,000 each).

- Office for Civil Rights is enforcement agency

PSQIA
Ohio’s Peer Review Privilege

- Creates a privilege for information related to professional credentialing or quality review activities involving the competence of, professional conduct of, or quality of care provided by health care providers (individuals and entities).
Ohio’s Peer Review Privilege

- If requirements are met, information (written and verbal) is not subject to discovery in any state proceeding (with some defined exceptions).
  - It is optional with a federal court as to whether it will apply the privilege in a case based upon federal law (the answer is, “almost never”)
  - Does not apply to criminal proceedings
Ohio’s Peer Review Privilege

- The protection from discovery may not be waived.
- If requirements are met, the participants are entitled to immunity from damages.
Goal of PSQIA

The development of a protected environment in which to assess patient safety events and to submit that information to a PSO in order that it can aggregate the information and report back to its participants as a means of improving care.
Goal of Peer Review Privilege

The development of a protected environment in which to assess patient care and to take action with respect to providers (individuals and entities) at the health care entity level as a means of improving care.
Differences

To understand the differences, you also need to understand how PSQIA works.

- **PSO**: Patient Safety Organization. It can be free standing (such as Ohio Patient Safety Institute) or a component (such as a hospital system that has 3 hospitals and develops an internal PSO).
How does a PSO work?

- A PSO is under the oversight of the Agency of Healthcare Research & Quality (AHRQ). There are 15 distinct statutory requirements that it must meet.
How does a PSO work?

- A PSO is responsible for collecting and analyzing patient safety data; developing and disseminating patient safety information; and maintaining confidentiality and security of patient safety data.
How does a PSO work?

- PSWP: Patient Safety Work Product. Information (e.g., data, reports, memoranda, analysis, written or oral statements) that could improve patient safety, health care quality, or health care outcomes or which identify or constitute the deliberations or analysis of, or identify the fact of, reporting to a PSO.
How does a PSO work?

- PSWP must be either assembled or developed by a provider for reporting to a PSO and must be
  - Reported to a PSO; or
  - Developed by a PSO for the conduct of patient safety activities
How does a PSO work?

The following cannot be PSWP:

• Patient medical records
• Billing or discharge information
• Any “other original patient or provider record”
• Other information that is collected or maintained separately from a PSES
Here is the really hard concept:

PSES: Patient Safety Evaluation System

- All PSWP must be developed, generated, and maintained in a PSES.
Here is the really hard concept:

- A PSES must be separate and distinct from other health care provider processes.
  - This means that the PSWP may not be used for any other purpose.
Here is the really hard concept:

- A determination as to whether PSWP is protected will not be based upon the fact that the information was submitted to a PSO.
  - It will be based upon the PSES and whether the information was developed for the **sole purpose** of submission to a PSO.
To understand the difference between PSQIA and Peer...

You need to understand how Ohio’s Peer Review Privilege works.

- Health care entity: An entity, acting on its own behalf or in affiliation with other health care entities, that conducts as part of its regular business activities professional credentialing or quality review activities involving the competence of, professional conduct of, or quality of care provided by health care providers (individuals and entities) (“Peer Review Activities”).
To understand the differences...

- Peer review committee: A committee that conducts Peer Review Activities on behalf of one or more health care entities.
  - Remember: A committee can only speak through its minutes
To understand the differences...

- Peer Review information does NOT become discoverable from a peer review file if the information is used for another purpose.
  - But the information will be discoverable from that other location (if it is not privileged).
To understand the differences...

- Caveat: If a Peer Review process is simply a feeder to an unprotected source (such as employment purposes), the entire process may be subject to attack as it is not truly engaged in its primary purpose of peer review.
Where Are The Courts?

**Remember:** Courts do not like privileges because they “hide” information. Courts therefore construe privileges very narrowly.
PSQIA

- Enacted in 2005.
- To date, the biggest issue has been deciding whether the information was developed for the sole purpose of reporting to a PSO.
- The courts have not yet delved into the issue of what all can be encompassed into a PSES.
Examples

A state agency demanded medication error incident reports from Walgreens regarding Pharmacist A. Walgreens objected saying that it generated these reports for the sole purpose of reporting them to a PSO. Walgreens stated that it did not use the incident reports for any other purpose (such as corrective action against Pharmacist A). Walgreens won.
Examples

- A medical malpractice plaintiff demanded an incident report. The hospital objected saying that it submitted the incident report to a PSO. The trial court said that, even if this was true, the record established that the incident reports were used for other purposes such as insurance, police reports, risk management, etc. The plaintiff won.
Examples

- If information must be disclosed to a federal, state or local agency to fulfill a mandatory reporting requirement, it cannot be maintained in PSES (or take information from original records that are not in PSES).
Examples

- An employee brought suit alleging she was terminated based upon a disability. She demanded certain documents that had been submitted to a PSO. The court held that the PSQIA privilege applied in federal cases involving the Americans with Disabilities Act and, therefore, documents were not discoverable.
Ohio’s Peer Review Privilege

- Enacted in 1975.
- A primary purpose of the statute is to limit medical negligence actions to ensure the availability of health care.
Ohio’s Peer Review Privilege

The statute was amended in 2003 tightening up and better defining the provisions.

• A medical malpractice plaintiff may not obtain an incident report that is protected by R.C. 2305.253.
Ohio’s Peer Review Privilege

- The privilege extends to an entire process.
  - Receipt of an application for appointment/clinical privileges up to and until a governing body decision.
  - Receipt of a concern related to quality which may be resolved informally or which may go through a fair hearing process.
Examples

- A medical malpractice plaintiff may depose a department chair who spoke with a physician about a case when there was no indication that the department chair ever documented or otherwise reported the information for use by a peer review committee.
Example

- A health care entity cannot be compelled to generate a list of what is contained in a peer review file for the plaintiff to review as this constitutes “discovery” of the file.
Example

- An individual may always testify as to what he/she has personally said, seen or heard.
  - But not what she/he has said, seen, or heard as part of a peer review committee process.
Example

- If information is used for a purpose other than peer review (such as employment or risk management), the information is subject to discovery from the unprotected source.
  - The information may not be obtained from the peer review file.
Some Key Take Aways

- PSOs serve a very important purpose.
  - Independent, external experts
  - Can collect, analyze, and aggregate PSWP locally, regionally, and nationally
  - Capable of working with multiple providers to routinely aggregate the large number of patient safety events that are needed to understand the underlying causes of patient harm
Some Key Take Aways

- PSWP will only be protected if you have a well-established PSES.
- The development of or participation in a PSO should not be used as a means of protecting Peer Review Activities.
Some Key Take Aways

- Incident reports should always start out as protected peer review documents. Take information out of the incident report to populate a PSWP document.
Some Key Take Aways

- What is your goal?
- Do you want to create a PSO (need to have at least 2 of you)?
  - Can you create the infrastructure?
- Do you want to participate in a PSO?
Questions?

(And our sincere thanks!)

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