Peer Review: Office-Based

What's the Risk?

Reporting, investigating, addressing and learning from patient safety events is an important performance improvement activity. Learning (high-reliability) organizations investigate events that have or could have resulted in patient harm to identify opportunities for improving patient safety, such as the need for system and human performance improvements. These types of activities generally fall under the purview of peer review, which is viewed as a valuable method to improve patient safety and decrease risk. However, failure to follow state and/or federal laws to appropriately protect peer and quality improvement review activities may leave an organization's peer and quality improvement review information vulnerable to discoverability.

When Is This Risk an Issue?

Individual physician performance is often evaluated using peer review, which involves having physicians with similar training experience review each other's patient care practices for appropriateness. Physicians and healthcare workers may be hesitant to participate in these activities for fear the results of the investigation will be used against them in a job action or legal proceeding.

Legal experts recognized that physicians' fear of retaliation (sometimes referred to as "sham peer review") and/or litigation could decrease their participation in and the effectiveness of peer review and patient safety event investigations.

Healthcare Quality Improvement Act (HCQIA)

In an effort to assuage the fear of retaliation and encourage honest peer review, Congress enacted the HCQIA in 1986. The HCQIA applies to hospitals, health maintenance organizations, group practices and professional societies "that follow a formal peer review process for the purpose of furthering quality health care (as determined under regulations of the Secretary)" (42 U.S.C. Section 11151[10]). The HCQIA provides limited immunity for providers who participate in hospital-based professional review activities so long as the participation is for the purposes of determining whether the physician may have clinical privileges or membership; the scope or conditions of such privileges or membership; or to change or modify such privileges or membership (42 U.S.C. Section 11151[10]).

Unfortunately, the HCQIA protections do not provide protection against discovery of peer review activities for the purposes of a legal proceeding, such as in Vimani v. Novant Health, Inc. (as cited by Moore, Pichert, Hickson, et al., 2006).

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The Patient Safety and Quality Improvement Act (PSQIA)

The PSQIA was passed in 2005 in response to the 1999 Institute of Medicine report To Err Is Human: Building a Safer Health System. The report recommended the development of a voluntary system for reporting patient safety issues so that the information could be aggregated and analyzed for educational purposes. The authors recognized that confidentiality and protection of information submitted must be ensured:

> To foster participation in voluntary systems, Congress should enact laws to protect the confidentiality of certain information collected. Without such legislation, health care organizations and providers may be discouraged from participating in voluntary reporting systems out of worry that the information they provide might ultimately be subpoenaed and used in lawsuits (Institute of Medicine, 1999).

The PSQIA outlines a comprehensive approach to ensure the confidential evaluation and management of submitted patient safety and quality improvement information. The approach involves four major components: patient safety organizations, patient safety evaluation system, patient safety activities and patient safety work product.

Patient Safety Organizations (PSOs)

Organizations contract with an established PSO to accept patient safety and quality improvement activity submissions. In addition to receiving the information and maintaining it in a confidential and secure manner, the PSO evaluates individual organizational performance and provides feedback to the submitting organization on improving patient safety. A PSO should also aggregate data, evaluate results and create reports on high-risk concerns including suggestions and actions to reduce risk and improve patient safety. These reports should be shared with PSO members.

Information submitted to a certified PSO is subject to strong confidentiality and discovery protection. PSOs must meet strict certification requirements.

Patient Safety Evaluation System (PSES)

The PSES comprises the collection, management, or analysis of information for reporting to or by a PSO (Patient Safety Rule, 2009). In order to participate in a PSO, an organization must design and implement a PSES that specifies the processes for collecting, preserving and submitting patient safety data. The submitting organization must also clearly identify what information and materials are included and excluded from the PSES.

In order to preserve the confidentiality and protection from discovery of patient safety information submitted to a PSO, it is necessary to ensure the information that is reasonably

expected to be reportable is excluded from the PSES. For example, reports that comply with external regulatory reporting and licensing requirements, such as National Practitioner Data Bank reports, state-mandated significant event reporting and quality reports submitted to third-party payers under pay-for-performance programs, should be created and maintained outside of the PSES.

Patient Safety Activities
Patient safety activities are the data and activities created within a PSES and/or by the PSO.

Patient safety activities means the following activities carried out by or on behalf of a PSO or a provider:

- 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;
- 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 a patient safety evaluation system (Patient Safety Rule, 2009).

Both the organization using a PSO and the PSO itself must have well-defined policies and procedures to address all of the patient safety activities outlined above.

Patient Safety Work Product (PSWP)

> 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) (i) Which could improve patient safety, health care quality, or health care outcomes; and (A) Which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a patient safety evaluation system for reporting to a PSO, and such documentation includes the date the information entered the patient safety evaluation system; or
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> (B) Are developed by a PSO for the conduct of patient safety activities; or

> (ii) Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system (Patient Safety Rule, 2009).

Participation in a PSO provides several benefits for members including protection of patient safety work products that are created, collected and reported according to a strict set of rules and the ability to access aggregated data for research and learning purposes.

It is possible to use a PSO to submit peer review as patient safety work product and thus protect it from discovery.

Peer Review Protection and Quality Improvement Activities

Quality improvement activities tend to be protected from discovery when there are well-defined policies and procedures in place and the quality improvement structure is designed to encompass the work in such a way that the work product is only available to those who need it to perform their duties.

Reports and other work products created strictly for the purposes of peer review are harder to protect. There is no specific federal protection for peer review and state laws vary widely. Some states provide broad protection for professional peer review activities regardless of the care delivery location (e.g., Virginia and Oklahoma). Many states provide protection for physician peer review conducted in a hospital or by a state-recognized professional review body, such as a medical society (e.g., Maine, Michigan, Texas; and Fresno and Modesto, California). Some states offer little or no protection for peer review activities; for example, Squire, Sanders & Dempsey, L.L.P. (2009) noted that Kentucky does not protect the peer review process, although it does protect actions resulting from the process. Finally, states such as Arkansas ("Peer review," 2014) and Florida (Godwin, 2010) have reduced or limited peer review protection, which may encourage providers and healthcare organizations to participate in a PSO.

Physician practices engaged in quality and peer review activities must evaluate which legal protections are available to them and take action to protect their quality, peer review and patient safety work products.

The four basic options for peer and quality improvement review protection in an office setting include attorney-client privilege, applicable state law, the use of external peer review, and participation in a PSO.

Attorney-Client Privilege

According to the Legal Information Institute, attorney-client privilege is a legal privilege that

works to keep communications between an attorney and his or her client secret. The privilege is asserted in the face of a legal demand for the communications, such as a discovery request or a demand that the lawyer testify under oath (Attorney-client privilege).

In most cases, neither the client nor the attorney may be compelled to disclose the discussion. While it may be tempting to invite an attorney to sit in on case discussion for the purposes of peer review, there are risks associated with relying on this approach. The privilege only applies "in the face of a legal demand," so there must be an actual demand or reasonable expectation of one for the privilege to apply.

Attorney-client privilege will apply in very limited situations and should not be relied upon for routine protection of quality and peer review discussions.

State Law

As previously noted, state laws vary widely on the subject of peer review protection, particularly in the outpatient setting.

Hospital or health system-owned practices may have peer review protection based on that relationship, depending on corporate structure. Review the peer review statutes pertinent to your state and work with your risk manager and/or attorney to develop an appropriate strategy. See the **individual state statutes** on the Risk Management Customer Portal for links to pertinent state regulations.

External Peer Review

External peer review is the process of having someone outside the practice review the patient care provided. Common sources of external peer review include professional societies, collaborating healthcare facilities and vendors. Using outside peer reviewers may bring an element of objectivity to the process. Depending on the size of the medical group, it may be difficult for peer providers to review and comment on their coworker's patient care – particularly if they believe the care may not meet standards. Providers may fear damaging the working relationship, causing professional problems for their coworker and reprisals from their coworkers or practice leadership.

External peer review is a good option for challenging situations and may be a solution for the entire process if it is protected under state law. Discuss the possibilities for protecting external peer review with the external peer review organization providing the services and your practice's attorney.

Patient Safety Organization

The PSO was designed to address the limitations of state-based protections, as evidenced by the following quote from the then-proposed, now-final rule:

> Traditional state-based legal protections for such health care quality improvement activities, collectively known as peer review protections, are limited in scope: They do not exist in all States; typically they only apply to peer review in hospitals and do not cover other health care settings, and seldom enable health care systems to pool data or share experience between facilities. If peer review protected information is transmitted outside an individual hospital, the peer review privilege for that information is generally considered to be waived. This limits the potential for aggregation of a sufficient number of patient safety events to permit the identification of patterns that could suggest the underlying causes of risks and hazards that then can be used to improve patient safety (Department of Health and Human Services, 2008).

For providers and organizations that do not fall under other peer review protection rules and regulations, the PSO may be a good option.

A dynamic tension exists between an organization's obligation to investigate and take actions to correct patient safety and quality concerns and an injured patient's need to access information to substantiate the injury for the purposes of litigation. To achieve balance, physician practices must be aware of the protections (or lack thereof) available to them when conducting peer review and quality improvement activities and develop appropriate systems to maximize the available protections so that patient safety activities need not be curtailed due to fear of reprisal.

How Can I Reduce Risk?

Use the following strategies to reduce risk when conducting office-based peer review and quality improvement activities.

Establish Formal Peer Review Processes	
Comply with state law	• Determine if state law peer review protection applies. Review the peer review statutes pertinent to your state and work with your risk manager and/or attorney to develop an appropriate strategy. Links to state regulations and statutes can be found on the Risk Management Policyholder's Page.
Develop policies and procedures	• Develop peer review policies and procedures.

Establish Formal Peer Review Processes	
Establish peer review committee	• When establishing a peer review committee, clarify the following: ○ The definition of peer. Note: a peer should be a provider with similar education who practices in the same discipline or a very similar discipline to the provider under review. For example, a family practitioner may be able to peer review a pediatrician; however, a gastroenterologist should not peer review a cardiologist. ○ The roles and responsibilities of the committee and committee members; ○ The process for settling disputes/disagreements among the members; ○ The process for recusing or removing a member of the committee; ○ The frequency of meetings.
Provide training	• Provide training for committee members. Include: ○ The purpose of peer review; ○ An overview of privilege and the discovery process; ○ Teamwork, coaching and communication skills; ○ Tracking and trending data (data analysis and basic statistical methods).
Establish process for initiating peer review	• Consider the following when establishing a process for initiating peer review: ○ Some organizations identify a set of specific indicators that trigger peer review. Indications for peer review may be practice/specialty-specific, such as low performance on quality indicators and significant adverse clinical outcomes, or generic, such as a pattern of patient complaints and reports/requests from staff. ○ Include periodic record reviews of all providers.
Develop chart review tool	• Consider developing a general chart review tool and/or indicator-specific chart review tools. See the sample ***Physician Chart Review Tool***.

Establish Formal Peer Review Processes

Define investigation procedures	• Define procedures for conducting an investigation and developing a report that includes recommendations and action plans.
Determine when to report	• Determine when adverse peer review actions are subject to reporting to a professional board and/or the National Practitioner Data Bank. • Define the processes for reporting.
Ensure peer review process meets requirements	• Have the entire peer review process, including reporting, policies and procedures, committee structure, reports and documentation, reviewed and approved by legal counsel.

Establish Good Documentation Maintenance Practices

Maintain peer review documents securely	• Maintain peer review documents in secure files separate from routing credentialing and employment files. Maintain paper files in a locked cabinet with limited access to a few key employees, such as the risk or quality manager, a medical staff leader and the practice administrator. Maintain electronic peer review files separate and distinct from the electronic medical record and any patient safety reporting system. Ideally store these files in encrypted and password-protected files with access restricted as defined for paper peer review files.
Be careful developing documentation	• Use caution when developing peer review minutes, reports and recommendations. Document the facts and the decision. Consider asking your attorney to review and provide guidance on peer review documentation practices.
Ensure all documents are collected and shredded	• Number the peer review documents distributed during meetings. Collect the documents at the end of the meeting and make sure to retrieve and shred all copies.
Tag documents subject to peer review protection	• Include a statement on each patient of protected documents that identifies the material as protected and cites the relevant state regulation. For example: This document is the work product of [insert name of physician practice] and was created for

Establish Good Documentation Maintenance Practices

purposes of quality review and improvement within the organization. All information, documents and other materials shall be protected by [insert the state peer review privilege statutes], as may be amended from time to time, to the fullest extent permitted by law. Unauthorized duplication or distribution of this document is strictly prohibited.

Establish Good Meeting Practices

Maintain confidentiality	• Precede every peer review meeting with a reminder that the information is confidential and must not be discussed outside the peer review process. Remind attendees to refer any request for peer review information from an attorney, regulatory or accrediting agent to administration for action.
Be fair and nondiscriminatory	• Ensure that peer review process are fair, nondiscriminatory and are not being used for retaliation or to impede competition.

Use External Peer Review

Determine if external peer review is protected	• Review state regulations to determine if reports created by an external peer review organization or service are protected from discovery in a legal proceeding. • Ask the external peer reviewer or organization to provide written assurance that their process meets state requirements, if applicable. If there is no state protection, seek guidance from an attorney.
Develop an external peer review policy and procedure	• When developing an external peer review policy and procedure, include: ○ Situations that warrant consideration of external peer review in your physician practice; ○ A process for requesting external peer review; that is who authorizes the use; ○ A process for selecting the external peer review company and/or reviewers;

Use External Peer Review	
	○ Notification of the provider(s) subject to the review; ○ A case selection process (single case, representative sample or 100% review).
Define expectations	• Enter into a contract, letter of agreement or memorandum of understanding with the external peer reviewer. In addition to typical language included in every contract, ensure the agreement includes: ○ The HIPAA business associate agreement; ○ The process for maintaining the confidentiality of records sent and materials created; ○ The definition of “peer reviewer”; ○ The peer reviewer selection process: ○ External peer review organizations often provide blinded reviewer CVS to facilitate selection of a reviewer who is close in education, practice type and experience to the individual subject to the review (a “peer”); ○ The process and extent of the review, including the number of records, what will be assessed, how the final product will be presented, and the expected turnaround time; ○ The final disposition of records and materials sent to the reviewer. Options include asking for return of all materials or written confirmation of destruction; ○ The billing process: reviews may be conducted on the basis of a flat fee, an hourly charge or a combination of both; ○ An opportunity for clarification with reviewer and process for clarification, if needed.

Participate in and Select an Appropriate PSO

Determine patient safety needs	• Determine your physician practice's patient safety needs to assist in the PSO selection process. • Look for PSOs that have expertise with the types of activities you intend to use a PSO to protect. For example, if you intend to use a PSO to protect peer review activities, select one that has policies, procedures and staff members who are knowledgeable about protecting peer review. Some organizations, such as large hospital systems, have developed their own PSOs (called a component PSO) for specific purposes, such as collecting specialty data.
Ensure PSO is listed	• Recognize that PSQIA protections apply only to a listed PSO. The Agency for Healthcare Research and Quality (AHRQ) is responsible for listing PSOs and maintains a directory of federally listed PSOs at https://pso.ahrq.gov/listed.
Ensure PSO has policies and procedures	• When selecting a PSO, ensure the PSO has policies and procedures for the following: ○ Maintaining the confidentiality and security of PSWP; ○ Responding to the legal demand for discovery; ○ Facilitating participant submission of PSWP; ○ Ensuring submissions are logged, reported and acted upon in a timely manner; ○ Creating and disseminating patient safety improvement reports, summaries and advisories related to the analysis of submitted PSWP; ○ Ensuring PSO staff are qualified and include licensed medical professionals; ○ Standardizing collection of PSWP data to facilitate case comparisons. ○ NOTE: AHRQ recommend that PSOs use the Common Formats. CMS, NQF and AHRQ have not developed Common Formats specific to ambulatory care. Before entering into an

Participate in and Select an Appropriate PSO

	agreement with a PSO, ensure the PSO has developed standardized reporting processes for the type of patient safety information your physician practice intends to submit (such as peer review).
Ask questions	• When selecting a PSO, ask the following questions: ○ How long has the PSO been certified? ○ Has the PSO ever been denied or lost its AHRQ listing? ○ Has the PSO experienced any HHS or AHRQ sanctions, deficiencies or HIPAA breaches? If so, how were they addressed? ○ How many organizations similar to yours does the PSO include? ○ What types of support can your physician practice expect from participation?
Formalize participation decision	• Formalize the decision to participate in a PSO. Enter into a formal participation agreement, such as a contract or memorandum of agreement. • Enter into a Business Associate Agreement.

Design and Implement a PSES

Establish a PSES	• Determine if your PSO has sample documents and tools and whether they can provide technical assistance with establishing your PSES. If not, consider seeking professional assistance. • Evaluate current risk management, quality and peer review evaluation processes to determine their leverage possibilities. Depending on the purpose for PSO participation, your PSES may be a separate process or a subset of an existing committee. • Define the PSES committee structure and membership. • Consider developing a diagram or organizational chart delineating PSES structure within your

Design and Implement a PSES	
	physician practice. Recognize that PSWP is only protected if it is created within a PSES for reporting to a PSO. Limit PSES activities to material that is being evaluated for patient safety purposes and has the potential to become PSWP.
Develop PSES policy and procedure	• Develop a comprehensive PSES policy and procedure that includes: ○ The purpose for participation in a PSO; ○ The definitions of patient safety organization, patient safety evaluation system and patient safety work product specific to your physician practice; ○ The process for collecting patient safety information and determining if it is patient safety work product; ○ The process for submitting information to the PSES; ○ The format for developing PSWP; ○ The process for submitting patient safety work product from the PSES to the PSO including logging and dating submissions; ○ When and how Common Formats will be used if applicable; ○ Staff members authorized to submit PSWP to the PSO; ○ Staff members authorized to remove information from the PSES when it has been determined that the information does not constitute PSWP and will not be reported to the PSO. ○ NOTE: Restrict the authority to remove PSWP from the PSES and consider the action carefully. Removing information eliminates the protections afforded to PSWP and should only be undertaken when the risk of leaving the information in is greater than the risk of removing it.

Design and Implement a PSES

- A statement that employees are encouraged to report patient safety concerns, events and activities in good faith and good faith reporting will not result in retaliation.
- The process for ensuring the confidentiality and security of PSWP, including where and how the information is stored. If PSWP is created, stored and submitted electronically, specify the program/system used.
- Training and education for staff members and providers.
- The process for auditing compliance with the PQSIA requirements.

- Have your PSES policies and procedures evaluated by an attorney who is familiar with PSQIA requirements.

Identify and Protect PSWP

Identify PSWP

- Include all information created for the purposes of improving patient safety and healthcare quality. Examples might include:
  - Quality indicators for individual providers, departments and the organization as a whole;
  - Patient safety event reports including patient falls, complaints, medication errors, etc.;
  - Significant event investigations, such as root cause analyses (unless state submission of the root cause analysis is required);
  - Proactive patient safety activities, such as failure mode and effect analyses;
  - Peer review, if created for the purposes of submission to a PSO;
  - Information including analysis, conclusions and recommendations received from the PSO; and
  - Documentation, including meeting minutes that identify the date and time of information submittal

Identify and Protect PSWP	

	to the PSES, describe the processes used to evaluate and submit PSWP to the PSO, as well as how information received back from the PSO is evaluated and disseminated.
	• Recognize that peer review-related PSWP might include:
	  ○ Minutes/records of the peer review discussions;
	  ○ Materials created during any investigation;
	  ○ Materials created for/used by the peer review committee.
	• Findings and recommendations.

Develop process for maintaining PSWP	• Do not maintain copies of documents identified as PSWP outside the PSES as doing so waives any privilege and protection applicable to the documents. • Develop a process to remove information that will not be reported to the PSO from the PSES. Document the date and time of information removal from the PSES, that the information was removed voluntarily, and that the organization no longer intends to report the information to a PSO. • Specify PSWP maintenance: Determine where to keep paper documentation and in which system to store electronic PSWP.
Develop security practices for PSWP	• Develop and implement comprehensive security practices for PSWP, whether stored in paper format or electronically. • Log the PSWP into the PSES and out of the PSES. • If a request for PSWP disclosure is received/made after submittal of the PSWP to a PSO, seek the advice of an attorney.
Tag PSWP	• Tag PSWP with the following: This document is the CONFIDENTIAL PATIENT SAFETY WORK PRODUCT of [Insert physician practice name] and was created for purposes of quality review and improvement within the organization. All information,

Identify and Protect PSWP	
	documents and other materials shall be protected under the Patient Safety and Quality Improvement Act. Unauthorized duplication or distribution of this document is strictly prohibited.
Specify what is not PSWP	• Identify what types of information will not be considered PSWP at your physician practice. Examples might include: o Medical records; o Billing information; o Original patient or provider information/communications; o Information/reports created for reporting to an outside agency, such as: • National Practitioner Data Bank reports; • FDA adverse event reports; • Medicare and Medicaid reporting; and • State-mandated reports: e.g., applicable serious reportable events and reports to professional boards. • Establish procedures to exclude information that is not considered PSWP from submission to the PSES.

Additional Resources:
AHRQ PSO Program: https://pso.ahrq.gov/

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