PATIENT SAFETY ORGANIZATION

THA PSO MEMBER GUIDE

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Tennessee Hospital Association PSO
5201 Virginia Way, Brentwood, TN 37027
www.tnpatientsafety.com/initiatives/patient-safety-organization

Contents

Executive Summary

Tennessee Hospital Association PSO (THA PSO) is pleased to provide this member guide as a resource for optimizing PSO participation and improving patient safety. After joining a PSO, member organizations must become familiar with the PSO legislative framework and terminology and make thoughtful decisions on how they will participate with the PSO. This guide is designed to simplify and assist that process.

THA PSO staff are available to support members in designing their PSO participation plan through on-site or virtual consultation and provision of resources. Members of the THA PSO Advisory Council are also available to share their experiences and advice as needed. Through these efforts, THA PSO strives to support every member in improving patient safety.

Introduction

About Patient Safety Organizations

Patient safety organizations (PSOs) were established by the federal government via the Patient Safety and Quality Improvement Act of 2005 (PSQIA) to help healthcare organizations advance patient safety through learning from adverse events in a legally protected environment. In the PSO program, member organizations voluntarily share adverse event information to a PSO for aggregation and analysis. The reported information, known as patient safety work product (PSWP), receives federal confidentiality and privilege protection. As PSOs analyze adverse event information from multiple organizations, they gain insights into common contributing factors, event trends, and key learnings that are shared with PSO member organizations through personal feedback, development of guidelines, or education offerings such as publications, webinars, and conferences.

About THA PSO

Tennessee Hospital Association PSO is a federally certified patient safety organization under the U.S. Department of Health and Human Services (HHS) through the Agency for Healthcare Research and Quality (AHRQ) serving hospitals and health systems located or headquartered in Tennessee. THA PSO contracted ECRI-ISMP PSO to provide a secure warehouse for reported safety event information and assist with data analysis, member feedback, and education offerings. This gives THA PSO members the benefit of local support and access to resources from a long-standing, well-regarded healthcare safety organization. Because ECRI-ISMP PSO is a contractor for several PSOs, they provide a multi-PSO safety event comparative database.

History and Background of THA PSO

In 2007, the Tennessee Hospital Association, through its not-for-profit, education and research subsidiary, Tennessee Hospital Education and Research Foundation (THERF), launched the Tennessee Center for Patient Safety, which provides education, resources, and other tools to assist hospitals in accelerating their performance on quality and patient safety initiatives.

In January 2009, regulations implementing the Patient Safety and Quality Improvement Act of 2005 (PSQIA) went into effect, providing a roadmap for the creation of patient safety organizations (PSO). Recognizing the value of PSO participation in forwarding its mission,

TCPS sought listing by the U.S Department of Health and Human Services (HHS) for a PSO program.

In July 2009, the TCPS PSO program received federal listing as a component PSO under THERF, the parent organization, and has maintained listing through the Agency for Healthcare Research and Quality (AHRQ) triannual relisting process.

In 2019, TCPS PSO changed its parent organization to the Tennessee Hospital Association and updated its name to the Tennessee Hospital Association PSO (THA PSO).

Mission and Purpose of THA PSO

It is the mission of THA PSO to advance a culture of safety and high reliability; increase knowledge and adoption of best safety practices; and prevent patient harm or risk of harm through protected sharing, analysis, and learning from patient safety information.

The purpose of THA PSO is to make healthcare delivery safer and more effective among member providers through the provision of patient safety activities as defined in the PSQIA.

THA PSO Workforce

Rhonda Dickman, PSO Director
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THA PSO Advisory Council

The THA PSO advisory council represents hospitals and health systems of different types, sizes and regions of Tennessee. The Council meets quarterly to provide input to THA PSO on PSO services, education offerings, and member needs and priorities. Council members also serve as a resource for THA PSO members that are working on developing the PSO program at their facilities.

Becky Day – *Corporate Director, Risk Management*
Ballad Health

DeAnn Berry - *Director, Quality Improvement & Risk Management*
Henry County Medical Center

Katherine Strobel – *Director of Quality Services*
Blount Memorial Hospital

Leanne Bilbrey – *CNO, Risk Manager, Quality & PI Coordinator*
Macon County General Hospital

Lori Paden – *Director, Patient Safety*
Vanderbilt University Medical Center

Olivia Johnson – *Director, Risk Management*
Regional One Health

Rhonda Bennett – *Senior Risk Analyst*
Maury Regional Health System

Sharon Fiveash – *Corporate Director of Clinical Risk Management*
Baptist Memorial Health Care Corporation

Sharon Gilliam – *Director, Quality & Patient Safety*
Williamson Medical Center

Chris Clarke - *Senior Vice President*
Tennessee Hospital Association

Rhonda Dickman – *PSO Director/Clinical Quality Improvement Specialist*
Tennessee Hospital Association

Karizma Whitfield – *TCPS Program Manager*
Tennessee Hospital Association

Services

THA PSO offers services to PSO members directly, as well as through ECRI-ISMP PSO, the Alliance for Quality Improvement and Patient Safety (AQIPS) and the Tennessee Center for Patient Safety. Direct services include the following:

Quarterly All-Member Virtual Meetings

THA PSO hosts quarterly virtual meetings to update THA PSO members on PSO news, educate members on PSO-related topics, and share learnings from PSO data. Registration links for the quarterly meetings are emailed to all members prior to the meeting.

Education Offerings

THA PSO regularly provides webinars and conferences on a variety of patient safety or safety culture topics. Prior topics have included Just Culture, Human Factors Analysis, PSO Bootcamp, Identifying PSWP, Creating a PSES, Case Law Update, and RCA2.

THA PSO Safe Tables

Safe Tables provide a confidential environment in which representatives from PSO member organizations can convene and discuss patient safety topics. Key learnings and recommendations are aggregated from the Safe Table and disseminated to all THA PSO members.

ECRI-ISMP PSO Services for THA PSO Members

ECRI-ISMP PSO services require website login access. THA PSO members may request access for an unlimited number of users. Contact Karizma Whitfield at kwhitfield@tha.com for assistance.

ECRI Community

ECRI Community is an online discussion forum for members of ECRI-ISMP PSO that provides for peer networking and the exchange of patient safety-related resources, ideas, and recommendations.

Education Webinars

ECRI-ISMP PSO offers monthly webinars to THA PSO members on a range of patient safety topics. Slides and recordings of past webinars are available on the ECRI-ISMP PSO website.

Patient Safety Brief

Patient Safety Briefs offer concise reviews of patient safety topics featuring a discussion of contributing factors and recommendations from ECRI-ISMP PSO. Past Patient Safety Briefs are archived on the ECRI-ISMP PSO website.

Patient Safety Evaluation System Toolkit

The Patient Safety Evaluation System Toolkit contains templates, presentations, and documents to guide members in developing their patient safety evaluation system.

Patient Safety Event Data Snapshot

Patient Safety Event Data Snapshots are infographics providing a broad overview of select patient safety event types or related topics drawn from the event database.

Research Requests

THA PSO members can submit questions or topics to ECRI-ISMP PSO analysts for a review of existing literature, guidelines, standards, and best practices. This resource is useful when updating a policy, considering a new procedure or type of equipment, or needing fresh ideas for resolving a persistent patient safety challenge. Research requests are submitted through the PSO secure communication portal on the ECRI-ISMP PSO website. ECRI-ISMP PSO publishes findings of select research requests to benefit all PSO members.

Root Cause Analysis Toolkit & Critique

ECRI-ISMP PSO also offers an RCA toolkit with best practices and RCA resources. THA PSO members can submit one or more RCAs for detailed analysis and feedback of the RCA process by a panel of ECRI-ISMP PSO experts. This resource can revolutionize the way an organization conducts and manages RCAs. The RCAs are submitted through the PSO secure communication portal.

Safety Event Deep Dives

Deep Dives provide a focused analysis of a patient safety topic using reported event data from PSO member organizations. ECRI-ISMP PSO analyzes events and provides key recommendations to help reduce the number of future events. Prior Deep Dives are archived and available to THA PSO members on the ECRI-ISMP PSO website.

Safety Sprints

Safety Sprints allow THA PSO members to join peers in dedicated educational opportunities and Safe Tables on key safety challenges led by subject matter experts that use a suite of process improvement, change management, and communication tools.

Alliance for Quality Improvement and Patient Safety (AQIPS) Services

Education Offerings

AQIPS provides a range of education offerings through safe tables, webinars, case law updates, and summits.

Litigation Center

AQIPS attorneys provide information and guidance on recent Patient Safety Act cases, offer risk management advice related to patient safety evaluation systems, and provide resources to assist member defense counsel.

Tennessee Center for Patient Safety Services for THA PSO Members

Cynosure Learning & Improvement Collaborative (CLIC)

Cynosure Learning & Improvement Collaborative (CLIC) is an on-demand virtual learning platform with courses on improvement science, patient safety topics and more. Each course features short videos, downloadable tools, and other resources. CLIC also provides interactive message boards on topics of interest. THA PSO members may have an unlimited number of CLIC users at no cost. Each user must set up a user account to access the platform. Please contact Rhonda Dickman at rdickman@tha.com for more information.

AHRQ Culture of Safety Survey

The Agency for Healthcare Research and Quality (AHRQ) has developed the Hospital Survey on Patient Safety (HSOPS) that helps hospitals and health care systems assess an organization's culture of patient safety. This survey is available to THA PSO members at no cost. For more information, please contact Jennifer McIntosh at jmcintosh@tha.com or visit https://www.tnpatientsafety.com/initiatives/culture-of-safety-2/.

Resources

Tennessee Hospital Association PSO

The THA PSO website includes information on THA PSO services, resources, and the THA PSO Advisory Council.

ECRI-ISMP PSO

Utilize this secure web portal to report patient safety work product to THA PSO and access PSO member services and resources. A username and password are required and can be obtained from Karizma Whitfield at kwhitfield@tha.com.

Agency for Healthcare Research & Quality

This website contains valuable resources from the federal organization that oversees PSOs. Key items include the list of nationally certified PSOs, a variety of education materials, links to federal legislation and guidance, FAQs, and more.

PSO Privacy Protection Center (PSOPPC)

This website contains specific details on AHRQ Common Formats including downloadable forms that display all data fields. THA PSO uses Hospital Version 1.2 for event reporting.

Michael Callahan, Katten Muchin Rosenman LLP

Mr. Callahan is a Chicago-based attorney familiar with the PSO legal framework and case law. He conducts PSO-related presentations for health care organizations and PSOs across the nation and posts the slides and resources on his website.

Academic Medical Center PSO (AMC PSO)

This PSO posts patient safety resources on their website such as patient safety alerts, white papers, and guidelines.

Collaborative Healthcare Patient Safety Organization (CHPSO)

The Collaborative Healthcare PSO allows others to sign up for their newsletters, webinars, and other educational offerings.

PSO Definitions

AHRQ

Agency for Healthcare Research and Quality. AHRQ is one of 11 operating divisions of the HHS. (www.ahrq.gov)

AQIPS

Agency for Quality Improvement and Patient Safety. AQIPS is the national professional organization for patient safety organizations. (www.aqips.org)

Common Formats

AHRQ created the Common Formats (common definitions and reporting Formats) to help uniformly report patient safety events and to improve health care providers' efforts to minimize and potentially eliminate harm. More information is available on the PSOPPC website. THA PSO uses Hospital Version 1.2 for event reporting.

Confidentiality Protections

The Patient Safety Act provides confidentiality protections for PSWP at 42 U.S.C. 299b-22(b). The confidentiality protections are incorporated into the Patient Safety Rule in Subpart C at section 3.206(a). In addition to reviewing Subpart C of the rule, it may be helpful to review the definitions of *disclosure* and *affiliated provider* in section 3.20

Continued Protection

With few exceptions, PSWP that is disclosed to another individual or entity pursuant to the disclosure permissions (exceptions) in sections 3.206(b) remains confidential and privileged in the possession of the receiving entity or individual. See section 3.208 of the Patient Safety Rule for the general principle and section 3.204 and 3.206 to review the specific disclosure permissions.

Copy

The Patient Safety Rule refers to the term "copy" in two ways in the definition of patient safety work product. First, when information meets all of the applicable requirements for protection as patient safety work product, any copy of the PSWP is also protected. Second, if information is not eligible for protection as PSWP (e.g., it is from the medical record or a report sent to regulatory authorities), the provider can still send a copy of the information to its PSO. While the copy held by the PSO or by the provider's PSES is protected, that protection does not apply to the original information that exists elsewhere (e.g., the medical record or the copy held by the regulator).

De-identification

De-identification is the term used for removing identifiers in protected health information (PHI) pursuant to the HIPAA Privacy Rule. The standard is found at 45 CFR 164.514. For more information, see the OCR website (www.ocr.hhs.gov).

Disclosure

The release, transfer, provision of access to, or divulging in any other manner of patient safety work product by:
(1) An entity or natural person holding the patient safety work product to another legally separate entity or natural person, other than a workforce member of, or a health care provider holding privileges with, the entity holding the patient safety work product; or
(2) A component PSO to another entity or natural person outside the component PSO and within the legal entity of which the component PSO is a part.

Drop-Out Provision

The Patient Safety Rule provides a limited opportunity for a provider to remove information that was PSWP from its PSES. The drop-out provision can be used for any reason, provided that the information has not been reported to a PSO and the provider documents the action and its date. Upon removal, the information is no longer PSWP and is not confidential or privileged under the Patient Safety Act. The drop out provision is described in paragraph (2)(ii) of the definition of PSWP in section 3.20 of the Patient Safety Rule.

ECRI or ECRI-ISMP

ECRI and the Institute of Safe Medication Practices PSO (www.ECRI.org)

Entity

Any organization or organizational unit, regardless of whether the organization is public, private, for-profit, or not-for-profit.

Equitable Relief

The Patient Safety Act prohibits a provider from taking an adverse employment action (specified in the Act) against an individual based upon the fact that the individual in good faith reported information to the provider with the intention of having the information reported to a patient safety organization; or directly to a patient safety organization (42 U.S.C. 299b-22(e)). Equitable relief refers to the relief that an individual may seek in a civil action to redress an adverse employment action that violates this prohibition (42 U.S.C. 299b-22(f)(4)).

Event Reporting

The identification and reporting of occurrences that could have led, or did lead, to an

undesirable outcome, typically from personnel directly involved in the incident or events leading up to the event. Also referred to as “occurrence reporting” or “incident reporting.”

HIPAA Privacy Rule

The HIPAA Privacy Rule sets federal standards for the use and disclosure of individually identifiable health information, referred to as protected health information, held and maintained by covered entities, which are health plans, health care clearinghouses, and certain health care providers. Patient safety work product that contains protected health information (PHI) is subject to the requirements of the HIPAA Privacy Rule as well as the Patient Safety Rule. The HIPAA Security Rule may also apply.

Identifiable Patient Safety Work Product

Identifiable PSWP is PSWP that: (1) is presented in a form and manner that: allows the identification of any provider that is a subject of the work product, or any providers that participate in, or are responsible for, activities that are a subject of the work product; (2) constitutes individually identifiable health information as that term is defined in the HIPAA Privacy Rule at 45 CFR 160.103; or (3) is presented in a form or manner that allows the identification of an individual who in good faith reported information directly to a PSO or to a provider with the intention of having the information reported to a PSO (‘‘reporter’’). Identifiable PSWP is confidential and privileged and may not be disclosed except as permitted by the Patient Safety Rule.

Incident Reporting

The identification and reporting of occurrences that could have led, or did lead, to an undesirable outcome, typically from personnel directly involved in the incident or events leading up to the event. Also referred to as “occurrence reporting” or “event reporting.”

Non-identification

The process of removing identifiers in PSWP pursuant to the Patient Safety Rule’s standard at section 3.212 to render PSWP non-identifiable. Generally, non-identifiable PSWP is no longer privileged or confidential after being disclosed. The non-identification standard incorporates and preserves the HIPAA de-identification standard for application to patient information.

Network of Patient Safety Databases (NPSD)

The NPSD, required by the Patient Safety Act (42 U.S.C. 299b-23), will receive, analyze, and report on non-identifiable and aggregated patient safety event information. The goal of the NPSD is to facilitate aggregation and analyses of patient safety event information to help reduce adverse events and improve health care quality.

NPSG

National Patient Safety Goals - goals established by The Joint Commission to help its accredited organizations address specific areas of concern regarding patient safety. (www.jointcommission.org/standards_information/npsgs.aspx)

Occurrence Reporting

The identification and reporting of occurrences that could have led, or did lead, to an undesirable outcome, typically from personnel directly involved in the incident or events leading up to the event. Also referred to as “event reporting” or “incident reporting.”

Patient Safety

Freedom from accidental or preventable injuries produced by medical care; activities to avoid, prevent or correct adverse outcomes which may result from the delivery of health care.

Patient Safety Act

The Patient Safety Act is an informal name of The Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41), 42 USC 299b et seq

Patient Safety Act Guidance

HHS issues guidance to describe or explain certain aspects of the Patient Safety Act and Rule. Guidance documents may be found at the AHRQ PSO website (http://www.pso.ahrq.gov).

Patient Safety Evaluation System (PSES)

The collection, management, or analysis of information for reporting to or by a PSO. A provider's PSES is an important determinant of what can, and cannot, become patient safety work product. It may be helpful to read the definition of PSES in conjunction with the definition of patient safety work product; they can be found in section 3.20 of the rule.

Patient Safety Rule

The Patient Safety Rule is the set of regulations at 42 CFR Part 3 that implement provisions of the Patient Safety Act.

Patient Safety Work Product (PSWP)

PSWP applies to information that is privileged and confidential under the Patient Safety Rule. For details on what information can, and cannot, become PSWP, the applicable process and purpose requirements, and the important role of the provider's patient safety evaluation system, see the definition of patient safety work product in section 3.20 of the rule. It may be helpful to read the definition of PSWP in conjunction with the definition of a patient safety evaluation system; they can be found in section 3.20 of the rule.

Privilege

The Patient Safety Act provides federal privilege protections for patient safety work product (PSWP) at 42 U.S.C. 299b-22(a). The privilege protections are also included in the Patient Safety Rule for convenience and completeness (see section 3.204(a)); however, HHS does not have authority to enforce breaches of the privilege protections.

Provider

In the private sector, a provider means:
(1) an individual or entity licensed or otherwise authorized under State law to provide health care services and
(2) a parent organization of one or more entities licensed or otherwise authorized to provide health care services.
The definition of provider in section 3.20 of the Patient Rule includes additional language specific to Federal, State, local, or Tribal governments. Consult the definition of provider in section 3.20 of the rule for the complete definition.

Root Cause Analysis (RCA)

A structured process used to identify causal or contributing factors underlying adverse events or other critical incidents, uses a pre-defined protocol for identifying specific contributing factors in various causal categories (e.g., personnel, training, equipment, protocols, scheduling) resulting in a detailed account of the events that led up to the incident to assist in identifying areas of focus for improvement to prevent the event from reoccurring.

Legislative Framework

Federal

Patient Safety and Quality Improvement Act

The Patient Safety and Quality Improvement Act of 2005 (PSQIA) establishes a voluntary reporting system intended to improve patient safety and reduce the incidence of events that adversely affect patient safety. To encourage the reporting and analysis of medical errors, the PSQIA provides Federal privilege and confidentiality protections for patient safety information.

Source: AHRQ and the Government Publishing Office

Patient Safety Rule

The Patient Safety and Quality Improvement Final Rule (Patient Safety Rule), effective January 19, 2009, implements some of the provisions of the PSQIA. It establishes the framework for health care providers to report privileged information to PSOs for the analysis of patient safety events. The Patient Safety Rule defines essential terms, provides requirements for the listing of PSOs, describes the confidentiality and privilege protections—as well as the exceptions, and indicates how HHS ensures compliance with the confidentiality provisions.

Sources: AHRQ and HHS

HHS Guidance

The Department of Health and Human Services released guidance regarding patient safety work product and providers' external obligations in May of 2016. The guidance addresses questions that arose about the Patient Safety and Quality Improvement Act of 2005 and the Patient Safety Rule. It is intended to clarify what information can become patient safety work product.

*Note: The HHS Guidance is **NOT** official HHS policy.

Source: AHRQ

State

THA PSO serves members which are located in Tennessee or are located in other states but are headquartered in Tennessee. The following laws are provided for states of current THA PSO members.

Tennessee

TN Code § 68-11-272 (2012) - *Tennessee Patient Safety and Quality Improvement Act*

Background

Tennessee's original Peer Review law, the Tennessee Peer Review Statute of 1967, existed to protect healthcare facilities from disclosure of their peer review findings. However, in 2010 two Tennessee Supreme Court cases limited many of the previous protections it provided. The first case Powell v. Community Health Systems determined that, "records made in the ordinary course of business are not protected." The second case, Lee Medical v. Beecher, "essentially eliminated the peer review protection for health care facility quality assurance, and limited the statute to matters only involving review of a specific physician's professional conduct." Following these cases, a legislative proposal was designed to restore some of the lost protections. This proposal was known as the "Tennessee Patient Safety and Quality Improvement Act of 2011." It became law on April 12, 2011.

Overview

The TN PSQIA revolves around 3 questions: who is protected? What records are protected? And how does the protection work?

Who is protected?

Under the law, "health care organizations," "health care providers," and "Quality Improvement Committees (QIC)" are protected. The definitions are broad enough to encompass most individuals and organizations involved in quality improvement and healthcare.

What records are protected?

"Records" is defined by the law, and includes, "reports, incident reports, statements, minutes, memoranda, charts, statistics, evaluations, critiques, test results, corrective actions, disciplinary actions, and any and all other documentation generated by or in connection with activities of a QIC."

What records are NOT protected?

No protection is extended to any information, documents, or records that:

1. Are not produced or used by a QIC,
2. Are not produced by persons acting on behalf of a QIC
3. Are otherwise available from original sources.

***General Rule**: If the information is created during or at the direction of the QIC it is protected. If it was created before the QIC meetings and is otherwise a facility business record, it does not gain QIC protection because someone gives it to the QIC.

How does the protection work?
The law protects QIC records and makes them confidential and privileged. This means all QIC records are protected from direct or indirect means of discovery, subpoena, or admission into evidence in any judicial or administrative proceeding.

Source: Christopher C. Puri and Amy D. Hampton. *The New Tennessee Patient Safety and Quality Improvement Act of 2011.* Bradley Arant Boult Cummings LLP. https://www.bradley.com/-/media/files/insights/publications/2011/05/the-new-tennessee-patient-safety-and-quality-imp__/files/health-care-alert/fileattachment/health-care-alert_may-12-2011.pdf

Arkansas

A.C.A § 20-9-503 - Peer Review Committees: Proceedings and Records Confidential – Exception

What records are protected?
The proceedings and records of a peer review committee are not subject to discovery or introduction to evidence in any civil action that arises out of matters that are the subject of review of the committee.

Who can testify in civil actions?
No one who attended the committee meetings will be permitted or required to testify regarding any evidence, findings, recommendations, evaluations, or opinions of the committee and its members.

- No one who testifies before the committee or is a member of the committee will be prevented from testifying on matters within his or her knowledge, but he or she should not be asked about committee testimony or opinions developed following the committee meeting.

What records are NOT protected?
Information, documents, or records otherwise available from original sources are not considered immune from discovery simply because they were presented during the committee meeting.

*__Note:__ Submission of peer review proceedings, minutes, records, reports, or communications to a hospital governing board does NOT operate as a waiver of the privilege.

Source: A.C.A. § 20-9-503 (2010)

Mississippi

M.C.A. § 41-63-9 - *Discoverability and Admissibility into Evidence of Proceedings and Records of Review Committees*

Are review committee records confidential and protected?
Any medical and dental review committee proceedings and records are confidential and not subject to discovery or introduction into evidence in any civil action that arises out of the matters that are the subject of review of the committees.

- However, documents or records that are otherwise discoverable or admissible from original sources are not considered immune from discovery simply because they were presented at the committee meeting.

Who can testify in civil actions?
No one who attended the committee meetings will be permitted or required to testify regarding any evidence, findings, recommendations, evaluations, or opinions of the committee and its members.

- Any person who testifies at the committee meetings or who is a member of the committee should not be prevented from testifying as to other matters within his or her knowledge, but the witness should not be questioned regarding his or her participation on or testimony for a review committee or the opinions he or she developed after the committee meeting.

When does the protection NOT apply?
The provisions of the above statements that limit the discovery of records and proceedings shall not apply in any legal action brought by the review committee to restrict or revoke a physician's license or hospital staff privileges, or in any legal action brought by a physician against any member of the committee or the entity which formed the committee for actions that are alleged to be malicious.

M.C.A. § 41-63-23 - *Accreditation and Quality Assurance Materials*

What records are protected?
Accreditation and quality assurance materials shall be held in confidence and are not subject to discovery or introduction into evidence.

Who can testify in civil actions?
No person involved in the preparation, evaluation, or review of such materials will be permitted or required to testify regarding any evidence or other matters produced or presented during the preparation and evaluation or review of the materials or of any finding, recommendation, evaluation, and opinion of the accreditation or quality assurance or any other person involved.

Any person involved in the preparation, evaluation, or review of materials that are otherwise available from other original sources.

- *However*, the witness should not be asked about any opinions or data given to him or her during the preparation, evaluation, or review of the materials.

What records are NOT protected?
Information, documents, and records that are otherwise available from original sources are not to be considered as unavailable for discovery simply because they were presented or used as accreditation or quality assurance materials.

Sources: MS Code § 41-63-9 (2013) and MS Code § 41-63-23 (2013)

Virginia

VA Code § 8.01-581.17 - *Privileged Communications of Certain Committees and Entities*

What records are protected?

- The proceedings, records, minutes, reports, records and all oral and written communication originating or provided to medical staff committees, quality assurance or peer review committee, physician peer review or accreditation entities, and professional associations of health care providers.
- The analysis, findings, conclusions, recommendations, and deliberative process of these committees.

- Reports or patient safety data in possession of a patient safety organization, together with the identity of the reporter and all related correspondence, documentation, analysis, results or recommendations.
- Reports produced solely for purposes of self-assessment of compliance with requirements or standards of a national accrediting organization granted authority by the Centers for Medicare and Medicaid Services.

Who can testify in civil actions?
A person involved in the work of these entities shall not be made a witness with knowledge of the facts by virtue of his involvement in the quality assurance, peer review, or credentialing process.

What records are not protected?
Information known by a witness with knowledge of the facts or treating health care provider is not privileged or protected from discovery merely because it is provided to a committee, board, group, commission, or other entity.

Sources: VA Code § 8.01-581.17 (2011)

How It Works

Participation with a PSO involves reporting information about patient harm events or near misses to the PSO and receiving feedback to improve safety. The information and feedback are called patient safety work product (PSWP) and receive federal-level confidentiality and privilege protections. PSWP and its protections also include analysis and deliberations of patient safety information. The definition of PSWP is outlined in the Patient Safety Rule, Subpart A - Definitions.

Items that meet the definition for PSWP are not automatically PSWP by law. When joining a PSO, organizations identify the patient safety information, analysis, and deliberations occurring within their organization that meet the definition for PSWP. From those, they choose which ones they will designate, manage, and protect as PSWP and report to the PSO. Helpful considerations in choosing what to designate as PSWP include the following:

- What do we want to protect?
- What do we want to report for PSO analysis and feedback to improve patient safety?
- What do we want to report to the PSO to contribute to broader patient safety knowledge?
- Does this meet the definition of PSWP?
- Do we need this information for an external reporting requirement or disciplinary action that would disqualify it from being PSWP?

Once an organization has decided what it will designate as PSWP, it must distinguish the PSWP from the eligible information, analysis, and deliberations that are not PSWP. This is accomplished by creating a patient safety evaluation system (PSES) and describing it in policy.

Establishing a Patient Safety Evaluation System

The PSES includes the processes and spaces in which PSWP is created, developed, analyzed, managed, and reported to a PSO. A PSES is defined by the organization and is unique to that organization. It can include intangible components, such as deliberations about harm events in committee meetings, as well as tangible components, such as a dedicated hard drive for storing PSWP. The PSQIA requires a process for documenting certain actions regarding the PSES, including when PSWP enters the PSES, when PSWP is removed from the PSES, and if PSWP is disclosed.

Choosing a Reporting Method

The organization must determine the method it will use for reporting PSWP to THA PSO and describe the process in the PSES policy. THA PSO currently offers four reporting options. Organizations may use any or all of them:

- Harm Event/Near Miss Reporting
  - *Manual entry of individual events.* Individual events are manually entered into the ECRI-ISMP PSO event reporting portal using AHRQ Common Formats. Organizations reporting low volumes of events usually find this option to be most convenient.
  - *Upload of event data files.* This option requires mapping your organization's event reporting system data fields to the THA PSO AHRQ Common Formats minimum data set, a service provided by ECRI-ISMP PSO. Event files can then be set for manual or automatic uploads. This option works best for organizations reporting large volumes of events/near misses.
- Document Reporting
  - *Secure communication.* PSWP in the form of RCA, FMEA, meeting minutes, or other documents are submitted through a secure communications tool in the ECRI-ISMP PSO secure web portal which operates like an email. Documents are attached to the secure communication from the member's PSES.
  - *Secure SharePoint folders.* A dedicated, secure folder for the member organization on the ECRI-ISMP PSO SharePoint site allows PSWP documents to be uploaded or drag-and-dropped from the member's PSES.

Deliberations and analyses that the organization designates as PSWP are, by their nature, not reportable to the PSO. Such deliberations should be described in the organization's PSES policy as occurring within the PSES and constituting PSWP. Products of the deliberations, such as an RCA or meeting minutes, may be reported to the PSO through a document reporting option.

Utilizing PSO Feedback and Patient Safety Activities

As a final step, the organization must determine how it will access and utilize PSO feedback and patient safety resources such as education offerings and publications. Decisions must be made regarding who will receive the information and how it will be disseminated and utilized within the organization. PSO feedback is PSWP and should be received into the organization's PSES where a determination is made on how it will be utilized within the organization. A hospital may choose, for example, to bring PSO feedback to a patient safety committee for review and integration into patient safety interventions. PSO patient safety resources are not PSWP and may be widely promoted within the organization. A hospital

may, for example, ensure all clinical department leaders have access and training in using the PSO web portal of education resources and publications.

Timeframe for Implementation

It takes time and consideration to complete these foundational tasks of PSO participation. Depending upon the size and complexity of the organization, members can expect the process to take several weeks or months. However, once established, the organization is well-prepared for PSO participation and legal protection of PSWP. To aide in the process, the following tips may be helpful:

- Clearly understand what your organization wishes to gain from PSO participation.
- Become familiar with the Patient Safety Rule Subpart A (definitions) and Subpart C (confidentiality and privilege protections).
- Consider how patient safety information is utilized by your organization, identifying situations in which confidentiality and privilege protections will be helpful and in which they would be a hindrance.
- Recognize there is no perfect PSES or policy. A PSES usually begins simply and is amended over time as an organization gains experience with PSO participation.

THA PSO staff are available to help member organizations with planning how they will participate with the PSO and can provide for additional support through AQIPS as needed.

The following implementation checklist breaks the planning and implementation process into easy steps.

Implementation Checklist

Step One: Prepare for Participation

- ☐ Identify an individual to serve as the key contact for communications between the organization and THA PSO.

- ☐ Provide THA PSO a list of contacts for announcements of THA PSO education offerings and access to education resources on the ECRI-ISMP PSO website.
    - Provide each person's name, title, and email address

- ☐ Identify an individual to lead implementation of PSO practices within the organization and serve as the organizations' subject matter expert. Typically, this is a Risk or Quality leader and is often the same person as the key contact for communications.

- ☐ Establish a PSO Steering Committee with representatives from Risk and Quality.
    - For small organizations, this role may be filled by one individual.
    - For health systems, this may occur at the system office level.
    - Other representatives may be added or removed, as needed.

- ☐ Contact THA PSO to schedule PSO orientation for the PSO Steering Committee.

Step Two: Lay the Foundation

- ☐ Conduct an inventory of potential patient safety work product within the organization.

- ☐ Make decisions regarding which items on the inventory will be designated and protected as patient safety work product, including which analyses and deliberations will be conducted within the organization's patient safety evaluation system and which information will be reported to THA PSO.

- ☐ Determine the organization's method and process for reporting patient safety work product to THA PSO.

- ☐ Define the organization's patient safety evaluation system.

- ☐ Develop processes/tools to ensure the security of patient safety work product.

- ☐ Develop processes/tools for documentation of the following:
    - patient safety work product entry into the patient safety evaluation system
    - patient safety work product removal from the patient safety evaluation system

- disclosure of patient safety work product

- ☐ Create the organization's patient safety evaluation system policy.

Step Three: Implement

- ☐ Provide staff education on the patient safety evaluation system and PSO.
- ☐ Begin reporting patient safety work product to THA PSO.
- ☐ Promote and participate in THA PSO education offerings and services.
- ☐ Utilize patient safety work product to advance patient safety within the organization.

Step Four: Monitor and Maintain

- ☐ Monitor participation and address unforeseen challenges to the patient safety evaluation system, updating the policy as needed.
- ☐ At least annually, review the organization's patient safety evaluation system and policy. Consider any new sources of patient safety work product.