The physician’s guide to patient safety organizations
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Introduction

Under the federal Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), physicians have a defined role in reducing adverse patient events. Taking on this role calls for a clear understanding of the Patient Safety Act, as well as of patient safety evaluation systems (PSES) and patient safety organizations (PSOs).

The American Medical Association (AMA) has produced this guide to further your knowledge of the Patient Safety Act and to optimize physician participation in PSOs. As a physician leader, you can prepare other physicians in establishing PSES as described in the act and in selecting PSOs to which physicians or their hospitals subscribe.

THIS IS NOT A LEGAL DOCUMENT OR LEGAL ADVICE. The AMA guide offers a broad view of the Patient Safety Act. The AMA encourages physicians to further their knowledge of the Patient Safety Act and the Rule that implements this legislation. Your medical society or organization may have legal expertise on staff to assist your understanding of the Patient Safety Act’s benefits and limits. The Patient Safety Act and Rule may be viewed on the PSO website of the Agency for Healthcare Research and Quality under “Legislation and Regulations.”

Why participate in a PSO?

PSO participation enables physicians to learn from the experiences of others, participate in redesigning systems that enhance care delivery, and develop resources and processes needed to enhance safer care, mitigate patient harm and increase care efficiency.

“Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.”

—James Reason
The role of physicians in establishing patient safety organizations and patient safety evaluation systems

Patients and the health care community often view physicians as safety and quality leaders. Within your organization, physicians have various improvement responsibilities. For example, the organized medical staff is responsible for establishing and maintaining patient care standards as well as overseeing safety and the quality of care treatment and services. However, it is important for all physicians to understand the scope of the federal Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), and the safety and quality activities that may be delegated to the patient safety evaluation system (PSES) and patient safety organization (PSO) reporting process. This guide aims to enhance your understanding of the federal Patient Safety Act and assist your participation in the voluntary reporting system established by the act.

As stewards of safety and quality in your hospitals and care settings, your role in the design of the PSES and selection of your organization’s PSO should be recognized and well-defined by your institution. Physicians could consider both oversight and leadership roles as their organization plans and implements its participation in the federal, voluntary reporting system.

In your oversight role:

- Understand the protections afforded by the Patient Safety Act
- Evaluate Agency for Healthcare Research and Quality-certified and -listed PSOs
- Lead the PSO selection process
- Define your organization’s PSES
- Determine which data will or will not be reported to the PSO
- Provide continuous oversight to PSES/PSO activities and update the board of trustees on PSES/PSO progress
- Using the criteria for PSO duties expressed in the Patient Safety Act, assess and determine whether the feedback received from the PSO reflected
  - A valid analysis of the provider’s patient safety work product (PSWP) and existing scientific knowledge
  - Whether the feedback was framed in ways that made it understandable, actionable and appropriate to the nature of the provider’s operation

Physicians may also participate in or lead efforts to:

- Establish policy and the process to implement a PSES
- Inventory data from all sources to determine what can be protected under the Patient Safety Act
- Collect improvement data
- Review and analyze data
- Make improvement recommendations
- Determine actions needed to mitigate harm or improve care

Lead by example: Consider submitting safety event reports to your organization’s PSES and PSO.
The Patient Safety and Quality Improvement Act of 2005: The establishment of a voluntary, confidential and privileged safety event reporting system

Experts have identified a need for patient safety and safety event better data to inform efforts to prevent patient harm, better design systems, advance patient safety science and identify efficient models of care. Currently, safety and quality data reported within an organization are viewed in isolation.

The goals of the federal Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) are to encourage the expansion of voluntary, provider-driven initiatives to improve the safety and quality of health care, promote rapid learning about the underlying causes of risks and harms in the delivery of health care, and share those findings across states within a protected, legal environment to enable the identification and reduction of risks and hazards associated with patient care, thus speeding the pace of improvement.

The Patient Safety Act provides a protected environment to voluntarily report and collect safety event data, and anonymously report patient safety and quality events. Independent patient safety organizations (PSOs) that receive the reported data, or the patient safety work product (PSWP), use it to develop patient safety improvements. The act was designed to strike the proper balance between maintaining confidentiality and legal protections for reporting safety event information and maintaining accountability and patient rights.

Defining “provider”

A provider is defined as any individual licensed or otherwise authorized under state law to provide health care services. Therefore, a provider is a physician or health care practitioner's office, including a group practice, physician assistant, registered nurse, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietician or nutrition professional, physical or occupational therapist, pharmacist and other individual health care practitioners.

Licensed entities are also providers under the Patient Safety Act. These include hospitals, nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, hospices, renal dialysis facilities, ambulatory surgery centers, pharmacies, long-term care facilities, behavioral health residential treatment facilities and clinical laboratories.
The Patient Safety Act protects:

- Information assembled by providers who report to a PSO
- All providers who assemble a safety or quality report to submit to a PSO
- All providers who are named in a safety or quality report submitted to a PSO
- Patient safety and quality information developed by a PSO

The Patient Safety Act:

- Encourages providers to identify and report safety and quality events
- Protects the PSWP submitted by providers directly or through their patient safety evaluation system to PSOs
- Permits PSOs to share information—currently, state laws do not protect safety and quality information if it is shared outside the institution collecting and analyzing these type of data
- Protects patient information under the Health Insurance Portability and Accountability Act (HIPAA)
- Limits the use of patient safety information in criminal, civil and administrative proceedings
- Prohibits accrediting bodies from requiring PSWP or from taking action against providers for participating in PSO activities
- Imposes monetary penalties for violations of confidentiality

What the Patient Safety Act is NOT

- It is not mandatory; the Patient Safety Act does not mandate participation in a PSO
- It is not an error-reporting system; it provides a framework for reporting safety events and quality data to enhance knowledge, advance learning and improve patient care
- It does not preempt stronger state legal privilege and confidentiality protections
- It does not provide for any federal funding of PSOs; PSOs are not federal entities

Scope of the Patient Safety Act

The Patient Safety Act grants privilege and confidentiality to all Patient Safety Work Product:

- Privilege protects against subpoena, discovery or admission into evidence in connection with a legal proceeding or professional disciplinary proceeding and,
  - is not subject to discovery in connection with a Federal, State, local, or Tribal civil, criminal, or administrative proceeding, including a disciplinary proceeding against a provider
  - is not subject to disclosure under the Freedom of Information Act (section 552 of Title 5, United States Code) or similar Federal, State, local, or Tribal law and,
  - may not be admitted as evidence in any Federal, State, local, or Tribal governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider or,
  - may not be admitted as evidence in any Federal, State, local, or Tribal governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider
- Confidentiality protects against any form of disclosure of PSWP to a third party (there are no limits on how information may be used within the entity making the report or a PSO)
Patient safety organizations

The federal Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) provides a framework for the voluntary creation of patient safety organizations (PSOs), which share the goal of improving the safety and quality of health care delivery. Improvement must be the primary activity of the PSO. The Patient Safety Act requires a PSO to have qualified staff, including licensed or certified medical professionals. The AMA suggests each provider assess whether the skill sets of the professional staff employed by or under contract to the PSO are an appropriate match for the specific tasks that led the provider to seek a PSO’s assistance.

Organizations that are eligible to become PSOs include: public or private entities, profit or nonprofit entities and provider entities, such as hospital chains, that establish special components that can seek listing to serve as PSOs. The Patient Safety Act provides privilege and confidentiality protections that enable providers, hospitals and PSOs to create a secure environment where providers, clinicians and health care organizations can collect, aggregate and analyze safety and quality event data that facilitate the identification and reduction of risks and hazards associated with patient care.

Important: Report to a listed PSO

The AMA strongly encourages physicians to determine whether a PSO is listed by the Agency for Healthcare Research and Quality (AHRQ) prior to contract. If a provider submits information to an entity that is not listed on the AHRQ Web page, the confidentiality and privilege protections of the Patient Safety Act will not apply.

The following entities cannot become PSOs:

- Health insurance issuers, a unit or division of a health insurance issuer, or an entity that is owned, managed or controlled by a health insurance issuer (a health insurer cannot establish a component PSO)
- Regulatory entities, either public or private, that oversee or enforce statutory or regulatory requirements governing the delivery of health care services, or entities that serve as the agents of a regulatory entity, e.g., by conducting site visits or investigations for the regulatory entity
- Mandatory reporting systems, such as state mandatory reporting systems, to which some or all health care providers are required by law or regulation to report patient safety information; state health departments that have mandatory reporting systems may establish component PSOs. The Department of Health and Human Services views mandatory reporting requirements established or required by law or regulation, regardless of whether the specific data collected by these systems is anonymous or identifiable, as incompatible with the intent of the Patient Safety Act that aims to foster voluntary patient safety reporting activities; when required by law to report, provider failure to make legally required reports can potentially result in a loss of individual or institutional licensure and the ability to practice or deliver health care services, therefore, the Patient Safety Act Rule excludes mandatory reporting entities or systems from becoming a listed PSO.
- Accreditation or licensure entities
**Component PSOs**

If the Patient Safety Act Rule excludes an entity from becoming a PSO, that entity can designate or established a component organization to seek listing as a PSO. In that case, the parent organization is the legal entity and the component organization is a unit or division within the parent organization.

A component PSO must adhere to strict stipulations written in the Patient Safety Act Rule that include separation of patient safety work product (PSWP) from the rest of the parent organization, restrictions on the parent company’s use of PSWP, nondisclosure and security rules. The component PSO’s establishment must not create a conflict of interest with the parent organization. However, the Patient Safety Act Rule permits the parent company to assist the component PSO conduct its patient safety activities. To protect PSWP from the component PSO’s parent organization, the Patient Safety Act regards sharing of PSWP between a component PSO and the parent company as an impermissible disclosure.

The AMA encourages physicians to review the listed PSO certifications on the [AHRQ PSO website](https://www.ahrq.gov/patient-safety/psos/index.html) where the parent company of a PSO is identified under the name of the listed PSO.

The Patient Safety Act does not require any provider to report data to a PSO. However, the act does not address the issue of whether institutional providers, such as hospitals, or other public entities can impose a reporting requirement on providers. In its efforts to foster a culture of safety, the Department of Health and Human Services has not included any restriction on the ability of a multifacility health care system to require its facilities to report to a designated PSO or of a provider practice, facility or health care system to require reporting data to a designated PSO by those providing health care services under its aegis, whether as employees, contractors or providers who have been granted privileges to practice.

The Patient Safety Act Rule states:

> A patient safety event reporting requirement as a condition of employment or practice can be consistent with the statutory goal of encouraging institutional or organizational providers to develop a protected confidential sphere for examination of patient safety issues.

> While an employer may require its providers to make reports through its patient safety evaluation system, section 922(e)(1)(B) [of the Act] prohibits an employer from taking an adverse employment action against an individual based upon the individual’s reporting information in good faith directly to a PSO.

> Additionally, some institutional providers may make it a condition of employment or privileges that providers agree to the disclosure of patient safety work product to accrediting bodies.
PSO requirements
The Patient Safety Act Rule outlines the requirements entities must meet to become PSOs and the processes by which the secretary of the U.S. Department of Health and Human Services (HHS) will review and accept certifications and list PSOs. For example, the entity must meet the requirement to enter into at least two bona fide contracts within 24 months of its initial listing and meet that test in every subsequent 24-month period. The AHRQ lists PSOs if the applying entity is eligible to be a PSO and attests they meet the requirements stated in the Patient Safety Act Rule.

An entity seeking initial listing by the HHS secretary as a PSO must complete a form which summarizes the 15 statutory requirements all PSOs must certify they meet, the three additional statutory criteria that component organizations must attest they meet and other listing requirements specified in the Patient Safety Act Rule. The secretary will notify the entity in writing of acceptance or nonacceptance of this certification. If this certification is accepted, the secretary will list the PSO for three years beginning on a date and time specified in the PSO’s notification of listing.

To assist physicians in their PSO selection, the AMA encourages PSOs to post on their Web sites a supplementary narrative addressing how the PSO will approach their mission and carry out required patient safety activities, and outline the expertise of their personnel (both employees and contractors) to carry out their mission.
Patient safety evaluation systems

A patient safety evaluation system (PSES) is the process that manages the collection, management or analysis of information for reporting to a PSO. Providers have flexibility in defining and structuring their PSES, as well as determining what information is to become patient safety work product (PSWP) and thus protected from disclosure. A PSES provides a protected space for the candid consideration of quality and safety. Information collected, maintained or developed separately, or that exists separately from a PSES, is not PSWP.

The Patient Safety Act defines a PSES as: “A protected space or system that is separate, distinct and resides alongside, but does not replace, other information collection activities mandated by laws, regulations and accrediting and licensing requirements, as well as voluntary reporting activities that occur for the purpose of maintaining accountability in the health care system.”

In some organizations, the PSES may reside in conjunction with other safety and quality collection activities of that organization. However, a PSES collecting, analyzing and developing information with the intent of submitting that information to a PSO should be distinguishable from other mandatory or voluntary patient safety and quality activities.

Most hospitals and health care organizations have a safety and quality event evaluation process similar to the more formal PSES process as a component of their risk-management program or system’s improvement efforts. Upon joining a PSO, physicians can expect their organizations to formalize or restructure their existing safety evaluation process or create a new PSES that meets the requirements of the Patient Safety Act.

The following are distinguishing characteristics of a PSES established to meet the Patient Safety Act requirements.

- Secure physical and electronic space for the conduct of patient safety activities
- Clear delineation of the various functions of a PSES, especially:
  - When and how information would be reported by a provider to a PSO
  - How feedback concerning patient safety events would be communicated between PSOs and providers
  - Within what space deliberations and analyses of information are conducted
  - How protected information would be identified and separated from information collected, maintained or developed for purposes other than reporting to a PSO

PSES best practices

Experts suggest a PSES should have its own visual and physical space, thus reinforcing its functions are separate from those of a PSO.

To ensure data are protected under the Patient Safety Act, information in the PSES should be documented, or labeled as assembled or developed for the PSES, and should include the date the information entered the PSES.
Patient safety work product

Patient safety work product (PSWP) can be any information based on the medical record, data, reports, records, memoranda, analyses (e.g., root cause analyses), or written or oral statements—or copies of any of this material—collected or developed by a reporter for a patient safety organization (PSO) that could improve patient safety, health care quality or health care outcomes. This includes information managed or analyzed by a patient safety evaluation system (PSES) for reporting to a PSO. PSWP also includes data generated by the PSO for the conduct of patient safety and quality improvement activities.

The federal Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) protects data, reports and other such information including the provider's deliberations or recommendations developed with the intent of generating a report to the PSO. Note that data must be gathered with the intent of providing the information to a PSO to be PSWP and protected by the Patient Safety Act.

To ensure the information is recognized as PSWP within the PSES, a best practice is to label or otherwise properly document with the date that the information collected is intended for reporting to a PSO.

Information that is collected, maintained, or developed separately or exists separately from a PSES is not PSWP.

Data assembled for internal use only, even if for quality improvement activities, do not qualify as PSWP, although such data may be protected under state laws governing peer review.

PSWP does not include:

- Original patient medical records
- Billing information
- Original discharge information
- Information collected, maintained or developed separately, or existing separately from a PSES (e.g., mandatory reporting data or internal improvement records)
- Information on a crime—information on a crime is not privileged or confidential

Because these original documents and information are not PSWP, they are not protected by the privilege and confidentiality protections of the Patient Safety Act.
Submitting data to a PSO

Consider submitting and reporting information that promotes safety and improves care such as the following: safety events, medical errors, failure mode and effects analysis, root cause analysis, proactive risk assessments, outcomes data such as complications, and

- Impressions or subjective evaluations of safety events that are not available in the medical record, e.g., subjective incident report data
- Information that is not required somewhere else, e.g., objective information (facts) that are not required to fulfill mandatory reporting obligations

The overarching aim of the protections in the Patient Safety Act is to encourage voluntary reporting of patient safety events by providers. Therefore, the protections in the act are substantial and broad so that providers can participate in the system without fear of liability or harm to reputation. The Patient Safety Act states that patient safety work product is privileged and cannot be admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under state law.

Determine the effects of the inability to use these reports in disciplinary or legal proceedings:

- Carefully consider state peer review protections at each step of your reporting process
- Discuss and evaluate within your organization the pros and cons of submitting to PSOs ongoing professional practice evaluations, focused evaluations or physician-specific reports

Example of where to report subjective and objective information generated by the same incident: Disclosure of a medical error

First:

- Fulfill your organization’s requirements to disclose information to patients, families or colleagues
- Fulfill your organization’s or state requirements to report certain events

Then consider submitting to a PSO:

- An event report that contains impressions, both yours and the staff’s, on why this event may have occurred
- Additional analysis to determine why the event occurred
- Root cause analysis recommendations
- Findings, conclusions or recommendations from individual case peer review
Submitting copies of original reports, documents and other information to PSOs

The Patient Safety Act Rule recognizes that original documents, including the medical record, are often the major source of factual information about the event you want to report to a PSO. The original medical record and documents cannot become PSWP and, therefore, are not privileged and protected, and cannot be protected or privileged on their own accord or independently.

However, copies of original reports, documents and other information gathered for another purpose, such as a copy of a mandatory report or information gathered for internal risk management or peer review, may be submitted to a PSO, even after they have been submitted to meet your other reporting or internal improvement requirements. Additionally, pages and information copied from the original medical record may be submitted to a PSO. Because you have assembled or developed the copies of these original documents for reporting safety and quality events to a PSO, they are distinguished from other copies of this same information that reside outside of the PSES. Only the copied information assembled and developed for reporting to a PSO is PSWP and, therefore, is privileged and protected under the Patient Safety Act.

Example of submitting copies of documents that are not PSWP

Following a sentinel event, a mandatory sentinel event report is submitted to a state’s reporting system. After submitting the report, a copy of the original document is submitted to the PSO with additional and/or new information about the event that the PSES developed and assembled. This information includes individual impressions of the event given by nurses, doctors and pharmacists, deliberations on factors leading to the event and additional analysis of the event. The original report submitted to the state is not PSWP and is not privileged or protected under the Patient Safety Act. The copy of the information from the original mandatory report and the new information, which was not required or included on the mandatory report, are PSWP and are privileged and protected. Both documents are submitted together, within the same report, which provides the PSO an excellent overview of the event, as well as rich data to advance patient safety science and practices.

View diagram of Model: Safety and quality event information flow in hospitals and clinics

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Improving safety and quality

The Patient Safety Act requires PSOs to demonstrate they have provided feedback to participants in a provider’s patient safety evaluation system. The Patient Safety Act Rule states providers are in the best position to determine whether feedback received by the PSO reflected a valid analysis of the provider’s patient safety work product and existing scientific knowledge, and whether the feedback was framed in ways that made it understandable, “actionable” and appropriate to the nature of the provider’s operation. The AMA encourages physicians to participate in evaluating feedback and support received from the PSO to determine if the information and support enhanced their improvement efforts.
Removal of information from the PSES: The “drop out” provision

Data may be voluntarily removed from or dropped out of the PSES before they are reported to a PSO. If data are removed before they are reported to a PSO, they are no longer PSWP and are not protected from discovery. Institutions may make their decision to remove data from the PSES based on whether the data meet the PSWP criteria or for other reasons. When removing information from the PSES, a best practice is to label the document or data as “voluntarily removed” and note the date of the removal from the PSES. It should be clear to all that information removed from the PSES is not intended to be reported to a PSO.

Electronic submission of reports to PSOs

When preparing reporting forms electronically, be sure that your PSO cannot access the report until it is actually submitted.

“A reporting culture is about protection of people who report.”
—Weick and Sutcliffe
Managing the Unexpected
Protecting patient, reporter and provider information

PSWP protections: PSWP is privileged and confidential
Patient safety work product (PSWP) is privileged and confidential, i.e., protected from use in certain circumstances and from misuse.

PSWP confidentiality protections and use
PSWP is confidential and therefore cannot be disclosed by anyone holding the PSWP, except as permitted or required by the Patient Safety Act. A disclosure of PSWP that is a violation of privilege may also be a violation of confidentiality. A confidentiality violation could result in a civil money penalty.

PSWP privilege protections
Because PSWP is privileged information it:
- Cannot be used in civil, criminal or administrative proceedings, including disciplinary proceedings, against a provider
- Is not subject to discovery
- Is not subject to the Freedom of Information Act or other similar laws
- Cannot be admitted as evidence in any federal, state, local, or Tribal governmental civil or criminal proceeding, including a proceeding against a provider
- Cannot be admitted in a professional disciplinary proceeding of a professional body established or specifically authorized under state law
- Cannot be used for adverse employment action
- Cannot be used for state reporting purposes or any other reporting purposes

HIPAA compliance
The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, which protects patients’ private health information from improper disclosure and misuse, applies to the Patient Safety Act. Therefore, the Patient Safety Act requires providers to comply with the requirements of the HIPAA Privacy Rule when making permissible disclosures of PSWP that include protected health information, e.g., patient information that is confidential, personal or identifiable.

View additional information on HIPAA on AMA Web site.
Permissible disclosures

The federal Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) permits disclosure of PSWP in certain cases and restricts the use of PSWP in these instances.

- **Criminal events: Disclosure to law enforcement**
  The Patient Safety Act permits PSWP to be disclosed to law enforcement in two circumstances. First, if the information in PSWP relates to an event that constitutes the commission of a crime. Second, if a person reasonably believes that the information in PSWP constitutes the commission of a crime and the disclosing person reasonably believes under the circumstances that the PSWP they wish to disclose is necessary for criminal law enforcement purposes.

- **Criminal proceedings**
  Information on a crime is not PSWP and is not considered privileged or confidential. PSWP may be used in a criminal proceeding if the PSWP information is judged relevant to the incident before the court.

  To determine if PSWP is relevant for use in a criminal proceeding, a judge will review the materials in camera, meaning in his/her private chambers or when all spectators are excluded from the courtroom. The judge’s review will determine if the PSWP contains evidence of a criminal act, is material to the proceeding and is not reasonably available from any other source. If the PSWP is found to be relevant to the proceeding, the court will grant permission for its disclosure and use.

- **Permission**
  PSWP may be disclosed through a valid authorization, that is, if permission is obtained in writing from each provider prior to disclosure. Permission must contain sufficient detail to inform each provider fairly of the nature and extent of the proposed disclosure.

- **Business operations**
  PSWP may be disclosed for business operations—e.g., those activities involved in the running of a business—to attorneys, accountants and other professionals who are bound by legal and ethical duties to maintain the confidence of their clients and the confidentiality of client information, including PSWP. Those who receive PSWP for business operation purposes cannot re-disclose the information they receive to others.

- **Voluntary disclosure to an accrediting body**
  The Patient Safety Act permits a provider to disclose PSWP to an accrediting body only if any identified provider—other than the provider making the disclosure—agrees to the disclosure, or if information that identifies patients and providers are removed.

  An accrediting body may not:
  - Further disclose PSWP it receives
  - Take an accrediting action against a provider based on his/her good faith participation in the collection, development, reporting or maintenance of PSWP
  - Require a provider to reveal its communications with any patient safety organization (PSO)
Other permissible disclosures

Under the following circumstances, PSWP may also be disclosed:

- Disclosure to a PSO for patient safety activities
- Disclosure to permit equitable relief for reporters, e.g., a reporter requests that a court issue a restraining order or injunction to prevent the use of protected PSWP
- Disclosure to a contractor of a PSO or provider
- Disclosure among affiliated providers
- Disclosure to another PSO or provider if certain direct identifiers are removed
- Disclosure of non-identifiable PSWP
- Disclosure to the U.S. Food and Drug Administration (FDA) by a provider or entity required to report on the quality, safety or effectiveness of an FDA-regulated product or activity, or a contractor acting on behalf of the FDA
- Disclosure for research to persons carrying out research, evaluation or demonstration projects authorized, funded, certified or otherwise sanctioned by rule or other means by the secretary of the U.S. Department of Health and Human Services for the purpose of conducting research; disclosure for research, if conducted by a HIPAA-covered entity and any personal health information falls under HIPAA exceptions

Sharing patient safety information and PSWP

Providers and PSOs may disclose PSWP to each other, to affiliated providers in a health system, to practitioners who have privileges or to contractors who undertake patient safety activities on their behalf. Disclosure to a second provider is permitted if:

- Written permission is received from everyone named in the PSWP document, including anyone who could be identified in the PSWP document, for example, “the physician in the emergency room at 4 a.m.” or “the nurse on the 7th floor”
- The PSWP is stripped of all identifying information
- The disclosure does not include materials or oral statements that assess the quality of care of an identified provider (the disclosure cannot describe or pertain to one or more patient safety actions or safety event failures that are identifiable or can identify a provider)
- “Affiliated providers” may also share identifiable PSWP (e.g., physicians who work in hospitals affiliated with clinics may share identifiable PSWP with physicians in the clinics and vice versa, and with practitioners having privileges in the hospital system); additionally, affiliated providers may share de-identified data with non-affiliated providers

PSO contracts

The AMA encourages physicians to gain an understanding of the confidentiality provisions in the Patient Safety Act and to participate, when possible, in their organizations’ development of the Patient Safety Organization contract. When developing the terms of agreement in the PSO contract, providers may stipulate limits to the use of their patient safety data by the PSO. For example, a provider may not want their information released to third parties without their written consent.
Reporting to a patient safety organization

Checklist to PSO reporting

Key steps in establishing a process for reporting safety event data to a patient safety organization (PSO):

☐ Identify your organization’s existing safety culture, goals and processes
  ✔ How is patient safety addressed in your mission and vision statements or other key statements of values?
  ✔ What safety data are currently collected?
    a. Patient safety analysis, PRA, RCA, FEMA
    b. Mandatory reports and other required data collection
    c. Incidences and events
    d. Clinical performance measures
    e. Health care outcomes data
    f. Human factors
    g. Teamness
  ✔ What is your current system for evaluating patient safety data?
    a. Are event data analyzed in house or are outside entities involved?

☐ Determine how your organization protects sensitive information through your current reporting and evaluation processes
  ✔ What are your system’s existing security and protection strengths and weaknesses?

☐ Create new policies and structures as needed to support the reporting of safety events to an internal formal, structured system for collection, review, aggregation and analysis of safety event data (i.e., a patient safety evaluation system, or PSES).
  ✔ What physical space(s), equipment and personnel will be used by the PSES?
  ✔ How will information enter the PSES (i.e., who will report data and how)?
  ✔ What internal policies will secure and protect data within the PSES?
  ✔ What other policies might support trust and encourage reporting of safety event data to the PSES?
  ✔ Which personnel or categories of personnel need access to what data to carry out their duties involving operation of or interaction with the PSES?
Select a PSO or PSOs

- Is the PSO AHRQ-listed?
- What type of PSO would best meet your organization’s specific needs or goals?
- Will providers or the organization report to one or multiple PSOs?
- In addition to the AHRQ Common Formats reporting forms, what other types of information would you like your PSO to accept (e.g., pictures, narratives, etc.)?
- What analyses are desired and what can the AHRQ-listed PSOs offer?
- Are you satisfied that the PSO staff is well-qualified and able to assist your patient safety improvement efforts?
- What additional value can AHRQ-listed PSOs provide?

“Learning is stifled when there is insufficient data to stimulate it. Learning is stifled when assumptions already in place seem innocent enough that there is no need for further inquiry.”

—Weick and Sutcliffe

Managing the Unexpected
The interaction of patient safety organization protections with state peer review protections and peer review activities

The patient safety organizations (PSOs) created by the federal Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) benefit from federal confidentiality and privilege protections. The Patient Safety Act also provides protections for patient safety activities and peer review. It is important to remember that patient safety information assembled and collected but not yet reported to a PSO can be withdrawn from the patient safety evaluation system (PSES). Once withdrawn, it will not be considered patient safety work product (PSWP) or be protected by the Patient Safety Act. Once a report is removed from the PSES and used for other purposes, it is no longer PSWP. However, patient safety information used for another purpose may still be protected under state law or have other protections. It is extremely important for physicians to understand the protections offered by their states, state peer review law, and the confidentiality protections and peer review policies of their institutions.
Model: Safety and quality event information flow in hospitals and clinics

1. Safety event
   - Internal Risk Management
     - Protected space for safety event analysis and decisions; peer review; M&M

2. Internal Risk Management
   - Patient safety evaluation system
     - Protected space for patient safety work product (PSWP)

3. Protected space for patient safety work product (PSWP)

4. PSO

5. PSES
**Affiliated provider:** A legally separate provider that is the parent organization of the provider, is under common ownership, management or control with the provider, or is owned, managed or controlled by the provider.

**Confidential:** Information, in this case PSWP, that is intended to be held in confidence or kept secret and cannot be disclosed by anyone holding the PSWP, except as permitted or required by the rule.

**Disclosure:** An unauthorized release, transfer, provision of access to or divulging in any other manner of PSWP by an entity or natural person holding the PSWP to another legally separate entity or natural person outside the entity holding the PSWP.

**Equitable relief:** Equitable relief is granted by a court in the spirit of fairness and justness, and is always directed at a particular person. The two main equitable remedies are injunctions and specific performance. Injunctions may be mandatory (requiring a person to do something) or prohibitory (stopping them doing something). Specific performance requires a person to execute, fulfill or accomplish an obligation according to its terms. Generally, equitable remedies will not be granted where damages (money) would be an adequate remedy.

**Failure mode and effects analysis:** Error analysis may involve retrospective investigations (as in a root cause analysis) or prospective attempts to predict “error modes.” A common proactive investigation is the failure mode and effect analysis, in which the likelihood of a particular process failure is combined with an estimate of the relative impact of that error to produce a “criticality index” thus enabling an organization to prioritize specific processes as improvement targets. Each step in a process is assigned a probability of failure and an impact score so that all steps can be ranked according to the product of these two numbers. Steps ranked at the top (i.e., those with the highest “criticality indices”) would be prioritized for improvement and/or error-proofing.

**Freedom of Information Act:** This act allows for the full or partial disclosure of previously unreleased information and documents controlled by the U.S. government. The act defines agency records subject to disclosure, outlines mandatory disclosure procedures and grants exemptions to the statute. Patient safety work product is granted an exemption to disclosure under this legislation.

**Health care provider:** An individual or entity licensed or authorized by the state to provide health care services. Examples of individual practitioners include physicians, nurses, pharmacists, psychologists, and physical and occupational therapists. Entities include hospitals, skilled nursing facilities, ambulatory centers, physician practice groups, home health agencies, pharmacies and rehabilitation facilities.

**Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule:** The HIPAA Privacy Rule requires physicians to protect the privacy of patients’ medical information. Physicians are required to control the ways in which they use and disclose patients’ “protected health information.” In general, protected health information, or PHI, is health information that contains any of the 18 direct individual identifiers that are listed in the HIPAA definition of de-identified data. In addition, physicians are required to offer patients certain rights with respect to their information, such as the right to access and copying, the right to request amendments and the right to request an accounting. Finally, physicians are required to have certain administrative protections in place (such as a privacy officer, staff training and implementation of appropriate policies and procedures) to further protect the privacy of patients’ information. View more HIPAA information on the AMA Web site.

**In camera inspection:** To determine if PSWP is relevant for use in a criminal proceeding, a judge will review the materials in his/her private chambers or when all spectators are excluded from the courtroom; this judicial procedural is called an in camera inspection.
**Patient safety evaluation system (PSES):** A patient safety evaluation system (PSES) is the body that manages the collection, management or analysis of information for reporting to a patient safety organization (PSO); the PSES determines which data collected for the PSO and submitted to the PSO becomes PSWP, which is then protected from discovery. PSES are also components of PSOs and serve the same function as an organizations PSES.

**Patient safety event:** An event or circumstance which could have resulted or did result in unnecessary harm to a patient; also referred to as an incident.

**Patient safety organizations (PSOs):** The Patient Safety and Quality Improvement Act of 2005 creates patient safety organizations (PSOs). PSOs collect, aggregate and analyze safety event data that enable the identification and reduction of risks and hazards associated with patient care.

**Patient Safety Organization (PSO) Privacy Protection Center:** The PSO Privacy Protection Center was created by the Agency for Healthcare Research and Quality to support the implementation of the Patient Safety and Quality Improvement Act passed by Congress in July 2005 and to provide technical assistance to PSOs.

**Patient safety work product (PSWP):** Patient safety work product (PSWP) is any data, reports, records, memoranda, analyses such as root cause analyses, or written or oral statements (or copies of any of this material) collected or developed by a reporter for the intent of reporting to a patient safety organization (PSO) that could improve patient safety, health care quality or health care outcomes. This includes information managed or analyzed by a patient safety evaluation system for reporting to a PSO.

PSWP includes:

- Data generated by the PSO for the conduct of patient safety activities
- Information not yet reported to a PSO but is documented as being within a provider’s patient safety evaluation system (PSES) and that will be reported to a PSO

Patient safety work product does not include information that is collected, maintained, or developed separately or exists separately from a PSES.

Providers may voluntarily remove, and document the removal of, information from the PSES that has not yet been reported to a PSO, in which case, the information is no longer PSWP.

**Privileged:** Privilege is created by law; the Patient Safety and Quality Improvement Act of 2005 (the Patient Safety Act) creates a privilege that provides a special advantage or rights to PSWP. The privilege created for PSWP prevents its use in civil, criminal or administrative proceedings, including disciplinary proceedings, against a provider. Additionally, PSWP:

- Is not subject to discovery
- Is not subject to Freedom of Information Act or other similar laws
- Cannot be admitted as evidence in any federal, state, local, or Tribal governmental civil or criminal proceeding, including a proceeding against a provider
- Cannot be admitted in a professional disciplinary proceeding of a professional body established or specifically authorized under state law
- Cannot be used for adverse employment action, state reporting or any other purpose

**Proactive risk assessment:** The focus of a proactive risk assessment (PRA) is determining what allows errors to occur rather than discovering who commits errors. A PRA utilizes a failure mode and effect analysis to determine the highest risks to safety and a root cause analysis to analyze the identified risks within the root cause analysis categories. The PRA assists in
determining what protections can be put in place to prevent failures—and subsequent harm—from reaching patients. Additionally, a PRA is helpful in assessing how to mitigate the effects of harm. PRAs are an effective tool to analyze existing processes and the design of new ones. Sources for identifying an organization’s highest risks can be internal improvement data, patient feedback, sentinel event data and data from other organizations or professional literature.

**Redisclosure:** A redisclosure, or “further disclosure” of PSWP, like a disclosure, is the release, transfer, provision of access to, or divulging in any other manner of PSWP by an entity or natural person holding the PSWP to another legally separate entity or natural person outside the entity holding the PSWP.

**Root cause analysis:** A structured process for identifying the causal or contributing factors underlying adverse events or other critical incidents. The key advantage of a root cause analysis (RCA) over traditional clinical case reviews is that it follows a pre-defined protocol for identifying specific contributing factors in various causal categories (e.g., personnel, training, equipment, protocols, scheduling) rather than attributing the incident to the first error one finds or to preconceived notions investigators might have about the case. Though the definition of RCA emphasizes analysis, the single most important product of a RCA is the “descriptive,” which is a detailed account of the events that led up to the incident.