Patient Safety Evaluation System (PSES) Policies and Procedures for Root Cause Systems Analysis

The Patient Safety and Quality Improvement Act of 2005\textsuperscript{1} (Patient Safety Act) was passed to provide nationally uniform protections for information and analysis, including Root Cause Analysis (RCA), of patient safety events.\textsuperscript{2} Sustained quality improvement was prevented because of the lack of uniform federal standards for confidentiality of information about patient safety events. State peer protections were limited in scope and did not exist in all states and did not cover all health care settings. The limited inconsistent protections resulted in a pervasive fear of legal liability and sanctions among physicians and healthcare organizations.\textsuperscript{3}

Fear of liability continues today as the National Medical Malpractice Trial Lawyers Advocacy Association has pledged to use the political movement calling for the transparency of patient safety events against providers in medical malpractice actions to force health care providers to make zero medical errors.\textsuperscript{4} Over the multiple decades that we have had malpractice actions, medical errors have not been reduced, only hidden. The reality is, so long as there are healthcare providers providing care there will always be errors.\textsuperscript{5}

A second barrier to quality improvement is the inability of health care providers to collect and share data about patient safety events with other facilities locally, within, and across states. This makes it harder for providers and organizations to identify and adopt patterns of practice that reduce the risk of medical errors.\textsuperscript{6}

The national peer protections under the Patient Safety Act are intended to operate similar to state peer protections but on a national level. The national peer protections are stronger than any state peer protections yet are easier to apply. Analysis, including root cause analysis, developed under the national peer protections do not have to be reported to the PSO to gain the privilege protections but are privileged the moment they are created.\textsuperscript{7}

\begin{thebibliography}{9}
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\item \textsuperscript{1} 42 U.S.C. 299b-21 et seq.
\item \textsuperscript{3} Id.
\item \textsuperscript{4} http://www.thenationaltriallawyers.org/2016/03/patient-advocacy-association-announces-medical-malpractice-conference/.
\item \textsuperscript{7} 42 U.S.C. 299b-21(7)(ii).
\end{thebibliography}
The Patient Safety Act was intended to bring together all the components within a system—people, processes and equipment—to evaluate using a sociotechnical systems theory to create a more reliable health care system without fear of liability or professional reputational harm. Follows is a list of quality programs that can be conducted under the root cause systems analysis (RCSA) approach:

- Team huddles immediately following an event;
- Reviewing performance in multiple systems to determine the systems differences for differences in outcomes;
- Connecting the healthcare continuum, conducting analysis among unaffiliated care providers;
- Conducting gap analysis throughout the healthcare continuum, including transitions of care, communication and interoperability gaps;
- Modified peer review in medical groups;
- Performance tools, benchmarks, dashboards, physician scorecards and statistics;
- Centralized or standardized peer review across organizations, including integrated care (ACOs, CINs) or sharing of improved protocols across a specialty;
- Root Cause Analyses and Actions (RCA\(^8\)); or
- Big data analytics and predictive analytics.

Implementing a RCSA program may simply include small changes, for example, including the CMIO, CNIO or CIO (or HIT developer representative) in peer review meetings to identify contributions made by health IT. On the other end of the spectrum, analysis can be conducted among two or more healthcare entities and information can be shared throughout the health care continuum.

Analysis concerning the performance of a provider that is performed under the national peer protections cannot be disclosed expect under a disclosure permission but can be recreated using non-protected information (non-PSWP) under the state peer protections to meet regulatory requirements.\(^9\) In short, the information that is developed using the national peer protections is privileged and confidential. Information contained in a Patient Safety Organization cannot be compelled and the protected information (PSWP) is immune from suit.\(^10\)

The following are draft template Policies and Procedures (P&P) for Root Cause Analysis (RCA) and Root Cause Systems Analysis (RCSA) conducted in the

\(^8\) RCS2 is a trademark of NPSF.
\(^9\) 42 U.S.C. 299b-22(h).
analysis and deliberations pathway. We believe that AHRQ has reviewed these P&P. P&P for the health system or other parent provider are highlighted in yellow. These P&P should be modified to reflect your processes and integrated into your existing policies and procedures for your Patient Safety Evaluation System (PSES) and RCA processes. These P&P do not address the information collected and developed in the reporting pathway or developed in the PSO pathway. In addition, these P&P do not address confidentiality, security, and staffing or other operations.
Patient Safety Evaluation System (PSES) Policies and Procedures for Root Cause Analysis (RCA)/Root Cause Systems Analysis (RCSA) and Other Analysis and Deliberations

I. Purpose

The PSES is the secure and confidential mechanism through which provider facilities can collect, maintain, analyze and communicate confidential and privileged information that is Patient Safety Work Product (PSWP) and use the PSWP to process and analyze patient safety events and other quality data and information. By conducting an RCA and other analysis and deliberations within the PSES, each provider is assured that the full range of information in determining possible contributing factors and/or enhanced practices or systems to improve patient care is PSWP and is privileged and confidential.

II. Policy

It is the policy of ____________________________ to conduct a systems analysis to ensure that the systems, including the providers’ performance, the processes and workflows and the equipment and software, are improved to enhance patient safety and clinical processes through Health IT, when appropriate, and not simply to modify human behavior within the system. The system-wide analysis can include affiliated providers and experts, including the CIMO and CIO, or unaffiliated providers, clinical contractors, Health IT developers, medical device manufacturers, pharmaceutical manufacturers or others within healthcare that contribute to the system of patient care.

It is the policy of ____________________________ that all RCA/RCSA and other patient safety activities is conducted within the PSES. The PSES is designed to follow the activities and not define a specific space. For example, all Quality Committee meetings occur within the PSES no matter where the analysis or discussions physically occur.

All activities conducted within the PSES are protected PSWP under the Patient Safety and Quality Improvement Act, 42 USC. §299b-21(7)(A)(ii).
III. Definitions and Explanation

A. Analysis and Deliberations PSWP.

Any data, reports, records, memoranda, analysis (such as root cause analysis), or written or oral statements, which identify or constitute the deliberations or analysis, including the fact of reporting, of a patient safety evaluation system, is PSWP. 42 U.S.C. §299b-21(7)(A)(ii).

1. The analysis and deliberations can be conducted for any purpose.
2. The statutory protections for deliberations and analysis in a patient safety evaluation system apply without regard to the status of the underlying information being considered (i.e., it does not matter whether the underlying information being considered is patient safety work product or not). A provider can fully protect internal deliberations in its patient safety evaluation system over whether to report information to a PSO. The deliberations and analysis are protected, whether the provider chooses to report the underlying information to a PSO or not. See section 921(7)(A)(i)(1) of the Public Health Service Act, 42 U.S.C. 299b–21(7)(A)(i)(1).

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3. If the underlying information identifies the analysis (e.g., lists of documents that are used in the analysis or list of documents that are PSWP), then the underlying information is PSWP.
4. As provided in the AHRQ rulemaking:
   - All information developed in the PSES is PSWP.
   - All information contained in the PSES shall be presumed to be PSWP.
   - If a document contains PSWP and non-PSWP it will be considered PSWP.

B. Disclosures.

Analysis and the Results of the Analysis in the PSES can only be disclosed through a disclosure permission.

1. Disclosure to Accrediting Bodies.
   Disclosures can be made to Accrediting Body such as The Joint Commission.

2. Disclosure to the PSO. The RCA/RCSA memorandum and any learnings can be disclosed to the PSO for analysis and sharing with other providers.

3. Disclosure to other Providers. RCA/RCSA information can be shared through the provider’s PSES.
C. Investigations and Interviews

Investigations and interviews that are conducted within the PSES are PSWP. Investigations and interviews include:

- A preliminary review to obtain basic information related to a concern or complaint about a physician in order to determine whether an investigation should commence;
- Routine quality assurance, case review, utilization review, and performance improvement activities that take place within a hospital or practice; and
- Collegial interventions, ongoing physician practice evaluations, and focused physician practice evaluations, and other peer-to-peer performance improvement interventions that are not intended to, and do not, impact a physician’s clinical privileges or hospital medical staff membership.

D. Patient Safety Activities

All RCA or RCSA are patient safety activities and are conducted within the Patient Safety Evaluation System. All investigations or committee meetings occur in the PSES.

E. Patient Safety Evaluation System

1. With regard to providers, deliberations and analysis are protected while they are occurring provided they are done within a PSES. To determine whether protections apply, the primary question is whether a PSES was in existence at the time of the deliberation and analysis. Federal Register / Vol. 73, No. 29 / Tuesday, February 12, 2008 / Proposed Rules at 8122.

2. To determine whether a provider had a patient safety evaluation system at the time that the deliberations or analysis took place, these indicia of having a patient safety evaluation system should be considered:
   a. The provider has a contract with a PSO for the receipt and review of patient safety work product that is in effect at the time of the deliberations and analysis;
   b. The provider has documentation of a patient safety evaluation system policy demonstrating the capacity to report to a PSO at the time of the deliberations and analysis;
   c. The provider has reported information to the PSO either under paragraph (1)(i)(A) of the definition of patient safety work product or has disclosed results of deliberations and
analysis under paragraph (1)(ii) of the definition of patient safety work product; or
d. The provider has actually reported the underlying information that was the basis of the deliberations or analysis to a PSO.

A provider may still be able to show that information was patient safety work product using other indications. This includes the labeling of information as Patient Safety Work Product or PSWP. Federal Register / Vol. 73, No. 29 / Tuesday, February 12, 2008 / Proposed Rules at 8123.

F. Patient Safety Work Product (PSWP)

Any deliberations and analysis surrounding patient safety and quality improvement activities by the RCA Team, Safety and Quality Committees and other committees occurring in the PSES and any documentation of such activities is PSWP. PSWP includes all:

1. Root Cause analysis (RCA) notes, minutes, images, edited or analyzed audio, or video media, RCA documents and memorandums, all oral and written communications involved in the execution of the RCA process and RCA deliberations.
2. Recommendations for changes based on deliberations and analysis of PSWP, generated by any provider in the PSES or by the PSO.
3. Data, reports, or records, memoranda, analysis, written or oral statements, deliberations and analyses utilized in and surrounding practitioner-specific peer review activities as governed by the Medical Staff By-laws of the facilities.
4. Performance tools, including Dashboards and physician scorecards.
5. List of reports, records or any information that reveals the analysis or fact of reporting, including any data collection tool for disclosing RCA/RCSA information to a PSO. This includes a list of documents that are PSWP as it could reveal the analysis and fact of reporting.

G. Patient Safety Organization is an organization that collects PSWP for analysis and to create feedback. Strategic Radiology Patient Safety Organization is the PSO(s) that _________________________ may disclose PSWP to under these policies and procedures.

G. Root Cause Systems Analysis (RCSA) means the process that examines the processes and systems relevant to an event with an
adverse outcome or without adverse outcome, which, if occurring again, would pose significant risk of an adverse outcome. The purpose is to bring together all providers, clinical contractors, IT officers, and equipment or technology developers to the learning process to identify those processes and systems that were the “root cause” – how, what and why the event occurred. Subsequently, action plans are developed for each responsible participant, including clinical protocols and recommendations designed to prevent future events of the same or similar nature. In addition to factors identified as proximate and root causes, the RCSA process is an opportunity to examine latent factors that may have indirectly contributed to the conditions that allowed for the safety event to occur; and other indirect factors relevant to patient safety that emerge during the process of event analysis and deliberations. The process may include determining how to modify the systems to prevent future events or to improve patient care through the use of HIT. If the systems cannot be modified a workaround will be developed and shared with the HIT developer, if appropriate. The provider and PSO may monitor the implementation of the plans, and the effectiveness of the actions. RCSA also permits the sharing of RCSA information among providers to learn from.

H. Use of PSWP - The PSQIA and final rule does not regulate “uses” of patient safety work product within a provider (i.e., the legal entity). Therefore, a provider can use PSWP for any purpose; this includes credentialing, disciplinary or peer review purposes. See Patient Safety and Quality Improvement Final Rule, 73 Fed. Reg. at 70779 (November 21, 2008). Also, unless the reporter protections apply (i.e., that the report was reported solely to the PSO and not as part of a regulatory recordkeeping requirement) the report and fact of reporting can be used in a disciplinary action against the provider that is the subject of the analysis. The reporter protections are intended to create a confidential safety culture.

IV. Procedures

A. Governance for Patient Safety Activities
a. __________________________ is responsible for patient safety activities within its facilities. A Parent Patient Safety Evaluation System is established to provide leadership, oversight, and resources for patient safety and quality improvement activities system-wide. This system allows each facility specified to share PSWP, including RCA information between the __________________ and each facility provider. The parent may conduct centralized peer review, may share RCA information or may conduct safe tables within its PSES. Each provider facility maintains a separate PSES.

b. __________________________ Members of the Facility PSES Team includes: [List responsible committee and individuals responsible for safety culture leadership including CEO and legal counsel.]

B. The RCSA Team

1. The RCSA team are the members of the quality committee and meets at least quarterly to review patient safety event information and the analysis, including RCAs/RCSA.

2. The standing members of the RCSA team include: the quality committee. All others are invited depending upon the circumstances of the patient safety event and the analysis. Invited members can include 1) Provider staff: physicians, nurses, pharmacists, therapists, lab personnel, representatives of clinical contractors, caregivers and others ancillary to patient care throughout the healthcare continuum, 2) External providers involved in the patient’s care (EMS, primary care providers) and 3) External laboratories, EHR developers, medical device manufacturers; external labs, external quality consultants; systems engineers, human factors experts and others.

C. RCSA Team Responsibilities

The RCSA team is responsible for PSES integrity and for directing and monitoring all patient safety activities at each facility.

1. Analyzes data and trends and makes recommendations to continuously improve patient safety, healthcare quality and healthcare outcomes.

2. Conducts Root Cause Analysis (RCAs/RCSA), Proactive Risk Assessments, Failure-Mode-Effects Analysis (FMEA), in-depth reviews, and aggregate RCAs.

3. Determines which data will/will not be reported to the PSO on the RCSA PSWP reporting tool.
4. Reviews RCSA or other analysis and feedback from the PSO to improve regarding recommendations for RCAs and other analysis.
5. Coordinates training opportunities with the PSO.
6. Leverages improvement efforts implemented in one facility to other facilities through “safe tables” – a shared communications of experiences, challenges, and improvements among facilities within the Parent PSES, clinical contractors, HIT developers, and other relevant parties. Safe Tables will be conducted in accordance with the Safe table policies and procedures.
7. Identifies patterns and trends across facilities.
8. Identifies system modification needs identified by data analysis, care continuum gap analysis, including Health IT, medical devices and other equipment (including work arounds that are put in place until the modifications can be discussed with HIT developer).
9. Identifies advances in treatment and best practices that would facilitate effective treatment for patients.
10. Oversees PSES processes and activities of the PSES, including investigation, review, and analysis of patient safety events; review of lessons learned; modifications to clinical protocols in facility committee meetings, other meetings and events held by Parent as part of the PSES.

D. PSES RCSA and Other Analysis

1. Triggers to RCA/RCSA – patient safety events, sentinel events, unexpected deaths, unsafe conditions contributed by EHRs, patterns of practice that are chosen for review as a proactive process for quality improvement, unexpected outcomes, and near misses which could have resulted in significant patient harm if not caught.

2. Investigations and Interviews – related to patient safety events or RCA/RCSA are conducted in the PSES and are PSWP.
   a. Investigations and interviews include:
      
      • A preliminary review to obtain basic information related to a concern or complaint about a physician in order to determine whether an investigation should commence;
      • Routine quality assurance, case review, utilization review, and performance improvement activities that take place within a facility; and
      • Collegial interventions, ongoing physician practice evaluations, and focused physician practice evaluations, and other peer-to-peer performance improvement interventions that are not
intended to, and do not, impact a physician’s clinical privileges or hospital medical staff membership.

b. If an investigation uncovers information that suggests a regulatory investigation is warranted, the PSES will provide Feedback to Legal, compliance, and leadership, as appropriate, to raise a legal duty to conduct a regulatory investigation outside of the PSES. The feedback from the PSES may suggest that a provider needs education in the area of concern.

3. Practitioner Specific Peer Review, Practitioner Specific Performance Improvement Activities, Ongoing Professional Practice Evaluation, and Focused Professional Practice Evaluation Activities
   a. Practitioner Specific Peer Review, including Ongoing and Focused Professional Practice Evaluation activities, and Practitioner Specific Performance Improvement Activities are functions of the organized Medical Staff for licensed, credentialed providers. All Ongoing and Focused Professional Practice Evaluation activities and Professional PI Activities shall be conducted according to the facility Bylaws and Policies.
   b. All processes related to Ongoing and Focused Professional Practice Evaluation activities, Peer Review, and Professional PI Activities are part of the PSES and the work product is PSWP.
   c. All physician scorecards or other performance tools are developed within the PSES and are PSWP.

4. Morbidity and Mortality (M&M) Conferences are conducted within the PSES and are designed to provide opportunities to learn from adverse outcome patient safety events in order to facilitate quality and safety improvements in systems and processes of care.
   a. A case is de-identified and then presented to staff (who will benefit from learning about the case).
   b. Staff participating shall adhere to PSWP confidentiality.
   c. Morbidity and Mortality (M&M) Conferences can occur on the department, facility or system level.

5. RCSA –
   a. RCSA can occur on the facility, system (as a PSES standardized, centralized peer review), or PSO level.
   b. RCSA can be a continuous quality improvement process to improve clinical processes and guidelines.

6. FMEA - Defect analysis and Other Processes TBD
7. Any other activities or analysis occurring within the PSES, including inter-facility meetings, peer review/case conferences, grand rounds, multidisciplinary conferences that are educational in nature.

E. Utilization of PSWP for purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk

1. RCSA will focus on a systems performance analysis and not assigning blame.

2. Once an RCA/RCSA analysis is complete, the team will present its findings to the CEO and VP of Operations. The Safety & Quality or designated Committee is then responsible for any data tracking/monitoring required by any resulting action plan and for reporting findings to facility clinical management.

3. Disclosing Results and learnings from the RCA/RCSA to the Strategic Radiology PSO.
   a. The results of RCAs that can contribute to learning shall be reported to the PSO, including best practices for resolving technical errors, quality errors, and excellence.
   b. The action plans for all members of the RCSA may be disclosed to the PSO for tracking/monitoring. Providers may report implementation progress and challenges.

4. If HIT systems cannot be immediately modified; system work-arounds may be shared with the PSO. If appropriate, the PSO will conduct a convening with the HIT developer to spur systems modifications or may make an HIT patient safety event report to the Partnership for HIT Safety.

F. Confidentiality Disclaimers Identifying PSWP

1. All electronic and hard copy documents, meeting minutes and notes, audio and/or video recordings, reports, or other media that is deemed PSWP shall:
   a. Contain, by print or stamp, the disclaimer that identifies the material as PSWP; including:
      i. “PSWP” or
      ii. “PSWP developed within the PSES.” or
      iii. “This interview or RCA/RCSA was conducted with in ______________________ PSES which offers the opportunity to address patient safety issues in an honest, candid, and blame free environment.” and
   b. Specify the scope of confidentiality or other protection under the [insert state peer statute].
2. Provider shall use the PSES Confidentiality Agreement and Attendance form for staff and other unaffiliated parties participating in meetings involving PSWP.

G. Activities related to the operation of a PSES and to the provision of feedback to participants in a PSES

1. Tracking Corrective Actions. When RCSA includes clinical contractors, HIT developers or unaffiliated providers, the corrective actions may be reported to the PSO. The clinical contractors shall report progress and challenges.

2. Working with HIT developer to modify systems or Medical Device manufacturers to improve use of a device. All discussions with HIT developers and Medical device manufactures will occur in the PSES and all discussion will remain confidential. The identity of a HIT developer and their products associated with a patient safety event shall be confidential and shall not be disclosed except under a disclosure permission.

   a. Strategic Radiology PSO shall promote process improvement with participating providers through its analysis of PSWP and associated feedback.
   b. Strategic Radiology PSO shall monitor the process improvements (and their implementation and success) through follow-up contact with providers. At the provider level, the following activities are encouraged by the Strategic Radiology PSO to solidify process improvements learned from PSWP:
      i. The provider shall notify all provider workforce of any changes to provider policy, procedure, processes, or systems that could be implemented as a result of the review.
      ii. If necessary, the appropriate executive in the provider’s administration shall follow-up to assess whether the changes are an appropriate response to improve the quality of health care services.
   c. Strategic Radiology PSO staff shall periodically meet or survey provider to review findings and modifications that have been made to the provider’s policies, procedures, systems, or processes as a result of PSO feedback and the effectiveness of such feedback.