XXX
POLICY & PROCEDURE

MANUAL: XXX	**SUBJECT:** Patient Safety Evaluation System
NUMBER: XXX **Page** 1 **of** 5	**EFFECTIVE:** 3/1/2017
PREPARED BY: XXX	**REVISED:** **REVIEWED:**
CEO APPROVAL:	

Purpose
To document a Patient Safety Evaluation System (PSES) which provides legal protection from discovery for quality and patient safety information.

Background
To promote improved patient safety and quality of care on a national level, the Patient Safety and Quality Improvement Act of 2005 and its interpreting regulation, the Patient Safety and Quality Improvement Rule, (collectively, the "Act") authorized the creation of a national program through which health care providers may voluntarily report quality and patient safety information on a confidential and privileged basis to independent entities, called Patient Safety Organizations[1] (PSO). PSOs collect, aggregate, and analyze information to help providers understand trends and offer strategies for improving patient safety and healthcare quality. The Act encourages providers to share sensitive information and offers broad protections so that providers can participate without the fear of liability.

To obtain privilege and confidentiality under the Act, quality and patient safety information must meet the definition of Patient Safety Work Product[2] (PSWP). PSWP is any information collected by a provider which could improve patient safety, healthcare quality and healthcare outcomes that is assembled or developed by a provider to be reported to a PSO. The Act treats information that is documented as intended to be reported to a PSO as information that is reported to a PSO. The mechanism by which a provider collects, manages, and/or analyzes information for reporting to a PSO is a PSES. All information documented as contained within a provider's PSES is confidential and privileged and is not subject to disclosure under the Act.

Policy
XXX collects quality/safety information through it PSES as set forth below for the purpose of sharing patient safety events and learning from a system of analysis without the fear

[1] Patient Safety Organization means a private or public entity or component thereof that is listed by the Agency of Healthcare Research and Quality (AHRQ) based upon a self-attestation by the entity of component organization that it meets certain criteria established in the Act. AHRQ certifies PSOs and oversees their compliance with statutory and regulatory requirements. See 42 U.S.C. 299b-21—26 and implementing regulations at 42 CFR Part 3.
[2] PSWP does not include a patient's medical record, billing and discharge information, or any other original patient or provider information; nor does it include information that is collected, maintained, or developed separately, or exists separately, from the PSES. See 42 U.S.C 299b-21-b-26 and implementing regulations at 42 CFR Part 3.

of liability or harm to reputation. XXX may report such information on a confidential and privileged basis to more than one PSO under a contractual arrangement (Contracted PSO)[3]. The activities of the XXX PSES and information and analysis provided by each Contract PSO are confidential and privileged under the Act and not subject to disclosure.

Scope of XXX PSES

The XXX PSES consists of information of XXX Patient Safety Activities[4] including, but not limited to, those listed below:

- Event reports[5] submitted through the
- Investigations;
- Failure Mode and Effect Analyses;
- Root Cause Analyses;
- Apparent Cause Analyses; and/or
- Other documents from quality/safety related activities as outlined in the XXX annual Quality Improvement Plan as amended from time to time including, but not limited to:
    - Deliberations, analyses, reports, and any correspondence pertaining to quality/safety improvement activities including, but not limited to, XXX Patient Safety and Performance Improvement Committee, VCOM/VMG Physician Event Review Meeting, Entity Quality Safety Committee, Entity Medical Staff Quality Committee, Entity Nursing Quality Committee, Entity Environment of Care Committee, Entity Emergency Management Committee, Entity Medical Executive Committee, Entity Pharmacy and Therapeutics Committee, Entity Mortality and Morbidity Committee, Entity Infection Control

[3] Each Contracted PSO will be a business associate of XXX and all Patient Safety activities will be deemed health care operations under the Health Insurance Portability and Accountability Act of 1996 (HIPM) Privacy rule as amended by the Health Information Technology for Economic Clinical Health (HITECH) Act.

[4] Patient Safety Activities are carried out by, or on behalf of a PSO, or a health care provider. These activities are 1) efforts to improve patient safety and the quality of health care delivery; 2) the collection and analysis of PSWP 3: the development and dissemination of information regarding patient safety, such as recommendations, protocols, or information regarding best practices; 4) the utilization of PSWP for the purposes of encouraging a culture of safety as well as providing feedback and assistance to effectively minimize patient risk; 5) the maintenance of procedures to preserve confidentiality with respect to PSWP; 6) the provision of appropriate security measures with respect to PSWP; 7) the utilization of qualified staff; and 8) activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system. See 42 U.S.C. 299b-21-bb-26 and implementing regulations at 42 CFR Part 3.

[5] The web-based occurrence reporting system is an essential component of XXX's PSES. Reports in the system are reviewed and analyzed by appropriate managers and department heads within the XXX PSES.

Committee, Entity Profession Practice Councils, Entity Safety Intelligence Weekly Event Review Meetings; and/or

- Deliberations, analyses, reports and any correspondence pertaining to patient events including, but not limited to, information and formal discussions, meetings, conferences, departmental meetings, departmental case reviews, peer review documents, department reports and action plans. See entity specific addendum.

Notwithstanding the foregoing, information related to Patient Safety Activities needed to fulfill external reporting obligations as well as voluntary reporting activities (e.g., state reporting requirements, adverse drug event information reports, complying with required disclosures pursuant to Medicare Conditions of Participation or Conditions of Coverage, etc.) is not within the scope of the XXX PSES and therefor is not PSWP.

The XXX Director of Patient Safety serves as the primary contact for the Patient Safety Activities. Another designee of the XXX Patient Safety / Quality Department may serve as an alternate contact.

Criteria for PSWP

1. All quality and safety information collected within the XXX PSES is PSWP unless otherwise removed from the XXX PSES and not reported as PSWP. The types of documents that can qualify as PSWP are expansive and include any data, reports, records, memoranda, analyses, or written or oral statements that can improve patient safety, health care quality, or health care outcomes.[6]
2. Documentation created, maintained, or developed separately from the PSES is not PSWP. This includes information such as patient medical records, billing and discharge information, or other original patient or provider information developed for a purpose other than reporting to the Contracted PSO.
3. Once the information is collected within the XXX PSES as PSWP, it may be removed from the XXX PSES and no longer considered PSWP if it has not yet been reported to the Contracted PSO and its removal is documented. Staff must document the date of PSWP entry, removal, submission to PSO and the date when deliberation and analysis is conducted within the PES.

Privilege and Confidentially Protections

[6] Documentation of other information generated within the XXX PSES, but outside of the ?, that contains a date of committee or review, contact person and meeting agenda, as appropriate, are deemed as PSWP within the XXX PSES. It is not necessary to send all information through the Contracted PSO to receive legal protections provided by the Act nor is it necessary to label the information as PSWP.

XXX PSWP is both privileged and confidential under the Act. XXX PSWP should not be disclosed without the prior review and approval of the Legal Counsel.

1. **Privilege.** Except as provided under the Act, PSWP shall be privileged and shall not be: 1) subject to subpoenas, orders, or discovery request issued in a Federal, State, local or Tribal civil or criminal case against a provider; 2) subject to disclosure under the Freedom of Information act or any similar Federal, State, local or Tribal law; 3) admitted as evidence in any Federal, State, local, or Tribal governmental proceeding of any kind, including any such proceeding against a provider; or 4) admitted in any professional disciplinary proceeding established under State law.
2. **Confidentiality.** Excepted as provided under the Act, PSWP shall be confidential and shall not be disclosed.
3. **Exceptions to both Privilege and Confidentiality Protections.** Neither the legal privilege nor confidentiality proections under the Act apply to the following disclosures:
    - Disclosure of relevant PSWP for use in a criminal proceeding; provided, the court determines that the PSWP contains evidence of a criminal act,is material to the proceeding and not reasonably available from anoather source;
    - Disclosure of PSWP to permit equitable relief for reports;
    - Disclosure of PSWP authorized by each provider identified in the PSWP; or
    - Disclosure of non-identifiable[7] PSWP.
4. **Exceptions to Confidentiality Protections[8].** Confidentiality protections do not apply to the following disclosures:
    - Disclosure for patient safety activities including disclosure between a provider and a PSO, disclosure to a contractor of a provider or a PSO, disclosure among affiliated providers, or disclosure to another PSO or provider;
    - Disclosure for research;

[7] Identifiable PSWP means PSWP that is presented in a form and manner that allows identification of any provider that is subject of the work product, or any providers that participate in activities that are a subject of the work product, constitutes individually identifiable health information under HIPM, or is presented in a form and manner that allows the identification of an individual who reported information directly to a PSO or to a provider with the intention of having the information reported to a PSO. See 42 U.S.C. 299b-21-b-26 and implementing regulations at 42 CFR Part 3.

[8] HHS's Office of Civil Rights (OCR) is responsible for the investigation and enforcement of the confidentiality provisions of the Act. OCR will investigate allegations of violations of confidentiality through a complaint-driven system. When information resolution of an indicated violation cannot be achieved through voluntary compliance, the HHS Secretary has the discretion to impose a civil money penalty (CMP) of up to $10,000 against any PSO, provider, or responsible person for each knowing and reckless disclosure that is in violation of the confidentiality provisions. Penalties under the Act may not be imposed in addition to penalties under the HIPM with respect to the same act of omission. See 42 U.S.C. 299b-21-b-26 and implementing regulations at 42 CFR Part 3.

- Disclosure to the FDA;
- Voluntary disclosure to an accrediting body;
- Disclosure for business operations to attorneys, accountants, and other professionals; or
- Disclosure to law enforcement.

5. **Continued Protection after Disclosures.** Disclosure is not treated as an absolute waiver of privilege and/or confidentiality. XXX PSWP may be confidential and privileged after certain disclosures permitted under the Act.

References

Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21-b-26
Patient Safety and Quality Improvement Rule, 42 CFR Part 3