

**PATIENT SAFETY ORGANIZATION’S POLICIES AND PROCEDURES:**  
**SUGGESTED TOPICS TO ADDRESS**

The Patient Safety Rule, at 42 CFR 3.102(b)(1)(i), requires that an entity seeking initial listing as a Patient Safety Organization (PSO) must certify that it has in place written policies and procedures (P&P) to perform each of the eight patient safety activities defined at section 3.20 of the Patient Safety Rule. The PSO’s P&P needs to be in place and operational before the entity is listed by AHRQ. This ensures the ability of the organization to operate as a PSO as soon as it is listed.

The following information provides suggested practices for entities developing their P&P, to enhance the effectiveness of the P&P once the PSO is operational. We believe this information will be helpful to PSOs in the development of the P&P to ensure the productivity and success of the PSO’s patient safety program.

The PSO’s P&P should be current (reviewed periodically) and outline the “what” (i.e., the Policy) and “how” (i.e., the Procedure) the PSO operates. There should be a systematic step-by-step outline of the activities taking place including the positions responsible for each activity. The P&P should be written in “plain English” to the extent possible to ensure that all workforce members can easily understand and apply the P&P. The P&P should also be readily available and accessible by workforce (e.g., available on the PSO’s intranet and/or in hardcopy).

**AHRQ would expect the PSO’s P&P to address, at minimum:**

1. A brief overview of the PSO’s background and structure.
2. The PSO’s goals, mission, and purposes.
3. A description of the roles and expectations of all PSO workforce members.
4. The eight Patient Safety Activities as defined in the Patient Safety Final Rule (42 CFR 3.20) with a description of how the PSO performs each activity.
  - a. Describe efforts to improve patient safety and quality of health care delivery.
  - b. Provide information about the collection and analysis of patient safety work product (PSWP).
  - c. Provide information about the development and dissemination of information such as recommendations, protocols, and best practices.
  - d. Describe how the PSO uses PSWP to encourage a culture of safety and provide feedback and assistance to effectively minimize patient risk.
  - e. Describe the maintenance of procedures to preserve the confidentiality of PSWP.
  - f. Describe security risk assessment and other measures to protect PSWP, such as, but not limited to, firewall, security, and risk management for a security breach.
  - g. Describe the roles and responsibilities of the PSO’s qualified staff and identify staff shared between a component PSO and parent organization, if applicable.
  - h. Describe the collection, management, and analytic activities related to the operation of the PSO’s patient safety evaluation system (PSES) and the provision of feedback to providers in their PSES.
5. A brief overview of the providers currently working with the PSO:
  - a. Types of services to be performed by the PSO.
  - b. General timeframe for the PSO’s services.
6. A brief overview of the PSO’s independent contractor(s) with a description of the activities performed by each contractor, if applicable.

If you have questions regarding the development of your P&P, please contact: [PSO@ahrq.hhs.gov](mailto:PSO@ahrq.hhs.gov).

AHRQ disclaimer: This document is not meant to address every topic that a PSO may need to include in its P&P given the range of PSO organizations and the variety of services offered by each PSO.

