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.

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.