

GUIDE TO PATIENT SAFETY ORGANIZATIONS' 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 need to be in place and operational before the entity is listed by AHRQ. This helps to ensure the ability of the organization to operate as a PSO as soon as it is listed.

AHRQ does not create, approve, or endorse model PSO policies and procedures or any other template documents for use by PSOs in their operations. The information in this guide provides suggested practices for entities developing their P&P. While this document is intended to assist PSOs when developing their P&P, it is not meant to address every topic that a PSO may want to include in its P&P given the range of PSO organizations and the variety of services offered by each PSO.

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

AHRQ suggests the PSO's P&P 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. Efforts by the PSO to improve patient safety and quality of health care delivery.
 - b. The PSO's collection and analysis of patient safety work product (PSWP).
 - c. The PSO's development and dissemination of information to improve patient safety, such as recommendations, protocols, or information regarding best practices.
 - d. The PSO's utilization of PSWP to encourage a culture of safety and provide feedback and assistance to effectively minimize patient risk.

- e. The PSO's maintenance of procedures and provision of appropriate measures to preserve the confidentiality and security of PSWP, to include:
 - How the PSO and its workforce ensure compliance with the confidentiality provisions of subpart C of the Patient Safety Rule.
 - Standards, policies and procedures the PSO has in place to address each part of the security framework specified in section 3.106 of the Patient Safety Rule, which may be scalable and suitable for the size and complexity of the particular PSO.
 - How the PSO will ensure notification of each provider that submitted PSWP or data to the PSO if it was subject to an unauthorized disclosure or its security was breached.
 - f. Describe the roles and responsibilities of the PSO's qualified staff and identify staff shared between a component PSO and parent organization, if applicable.
 - g. 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: psa@ahrq.hhs.gov.

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