Developing a Patient Safety Evaluation System

In order to ensure the full protection of Patient Safety Work Product (PSWP) under the law, it is critical to establish a Patient Safety Evaluation System (PSES). A PSES is defined as the mechanism or process through which an organization will collect, maintain, analyze and communicate PSWP. It is the process that the organization will follow to collect PSWP and transmit it to a qualified Patient Safety Organization (PSO), such as the **Mid-Atlantic Patient Safety Organization**.

Although the Patient Safety Act does not require that member organizations formally identify or define their PSES, it is considered a best practice to do so. Formal documentation of the purpose, objectives and procedures for the PSES will provide structure to the PSES to support the privilege and confidentiatliy of the PSWP.

It is important to designate an individual(s) responsible for overseeing the PSES. That individual should have a good understanding of the Patient Safety Act, the regulations, health information privacy and security regulations associated with HIPAA, and state law protections relating to legal privilege. This is often the same individual that is responsible for the organization's safety reporting and data collection systems, and/or professional practice review and credentialing systems. Individuals that may be logical for this role include but are not limited to risk managers, patient safety officers, legal counsel, and quality improvement managers.

In addition to designating responsible staff, an organizational policy should also be developed to formally identify the purpose and objectives of the PSES and the type of patient safety information that will be submitted to the PSO. It is important to note that information that must be reported to the US Food and Drug Administration, the National Practitioner Data Bank and for other federal agency reporting mandates do not gain federal and state protection from disclosure through being reported to a PSES or PSO. It may assist however, in improving accurate data analysis. Remember that PSWO is protected information, and should be labeled and dated as such.

PSES policy should include:

- Processes and activities of the PSES
- Identification of the information that will be collected, maintained, developed or assembled by the organization and entered in to the PSES for submission to the PSO.
- Define procedures regarding disclosure.
- Determine if information should be labeled to avoid risk of inadvertent disclosure.
- Identify what is NOT PSWP

If you would like more information on developing a PSES policy, please contact the Director of Operations at the **Mid-Atlantic Patient Safety Organization**, component of the *Maryland Patient Safety Center*.