



## Patient Safety Evaluation System

### Background

The Patient Safety and Quality Improvement Act of 2005 (PSQIA) authorized the creation of Patient Safety Organizations (PSOs) to improve the quality and safety of health care delivery in the United States. PSQIA encourages clinicians and health care organizations to voluntarily report and share quality and patient safety information without fear of legal discovery to improve the quality of patient care. To this end, PSQIA authorized the creation of protected systems called Patient Safety Evaluation Systems (PSES) to process events that are being reported to a PSO. Patient Safety Work Product (PSWP) consists of the reports and analyses generated by a PSO to facilitate quality improvement activities and is part of the PSES. PSWP is considered confidential and privileged and is protected from disclosure or discovery in court. PSWP cannot be

disclosed by recipients, nor can it be used by an institution to initiate sanctions against individual physicians who voluntarily participate in the PSO. (Note that medical record data are not considered to be PSWP and remain discoverable).

Documenting a PSES is not a requirement of PSQIA but it is considered a best practice. There are two components of a PSES: the PSES within the PSO and the PSES within a participating entity. (Participating entities within the SNIS PSO can include hospitals, physician groups, or individual physicians. Since most contracting entities are hospitals, all participating entities are referred to as “Institution” within this document). The Society of NeuroInterventional Surgery (SNIS) PSO has identified and documented the processes and procedures for the PSES within the SNIS PSO. Most processes of a PSES within an institution are likely already in place, so that identifying and documenting these processes would comply with best practice under the PSQIA. Determining who has access to PSWP and the

proper and improper uses of PSWP constitute the majority of documentation for the PSES within an institution.

### M2S’s Clinical Data Pathways and the SNIS PSO

M2S’s Clinical Data Pathways registry platform has been designed to house data from an institution’s medical record, some or all of which may be designated for use by the SNIS PSO to generate PSWP. Since Clinical Data Pathways is used within an institution to collect and manage neurovascular procedure data as well as to generate privileged and confidential PSWP, it is necessary to establish separate processes around data entry and PSWP analysis. The template at the end of this document may be useful to document processes, components, and scope of an institution’s PSES.



## Data Entry

The Institution must contract with M2S for the provision of data management services (via M2S, Inc. Data Management Services Agreement). This contract authorizes M2S to securely house medical data that the Institution chooses to submit to M2S, either for submission to the SNIS PSO or for other purposes designated by the Institution. M2S will configure the Clinical Data Pathways system to only allow those data uses that have been elected by the Institution per these agreements.

Institution shall determine workflow for entering medical data into M2S's Clinical Data Pathways platform.

Institution shall designate those individuals with data entry permission. M2S will set up at least one user at the Institution with PSES manager-level permissions. These permissions include the ability to set up additional users at the Institution for data entry. The PSES Manager at each Institution has the ability to customize the user account permissions of these additional users.

## PSWP Analysis

The Institution executes a Service Agreement with the SNIS PSO. This agreement establishes that the Institution wishes to voluntarily participate in the SNIS PSO's Patient Safety Activities in order to improve the quality of care it delivers.

A suite of standardized PSWP reports has been developed by the SNIS PSO, and implemented by M2S, which are available through Clinical Data Pathways. These reports are labeled as PSWP and are privileged and confidential. Once an Institution elects to

participate in the PSO, PSWP reports are generated, which include benchmarking with other Institutions and providers. PSWP may only be accessed from the SNIS PSO when an authorized user submits an online query for analysis of the Institution's data through use of the standard SNIS PSO PSWP reports referenced above.

Institution shall designate those individuals authorized to access PSWP within the M2S Clinical Data Pathways system.

## Institution PSES Description

Institutions should identify the access their current quality improvement systems and workflows to determine how to best incorporate analysis of SNIS PSO PSWP and other SNIS PSO Patient Safety Activities. Institutions should use this information to define the scope and function of the PSES at their Institution. Recommended policies for Institution PSES include:

- Documentation of who is included in the Institution PSES, and therefore has access to PSWP reports (the PSES Manager has the ability to customize user account permissions to allow or prohibit access to PSWP reports). It is recommended that this group include Institution quality officers, the physicians providing the care being analyzed, appropriate department heads, and representatives of other personnel directly involved in the care of patients being included in PSWP.
- Documentation of the frequency and forum for analysis of PSWP. It is recommended that analysis of PSWP be conducted outside of the normal Quality Assurance and/or Peer Review meetings to ensure that PSWP is being used appropriately.

Analysis of PSWP must not be used to place sanctions upon an individual physician. Due to differences in how PSWP and Quality Assurance data can be used regarding individual physicians, separate meetings to discuss such data are recommended, although the participants do not need to be mutually exclusive, provided that their roles in each deliberation are clear and not overlapping. An example of an established policy for reviewing PSWP includes periodic review of physician-and-center-level comparative reports by a designated group of physicians and quality staff.

- Each Institution should decide how to implement or integrate results of PSWP analysis into the Institution's overall quality improvement operations. It is recommended that the Institution document these policies and procedures, but this is not required.
- Finally, a PSES requires the Institution to train all staff that has permission to access PSWP regarding the privilege and confidentiality limitations of the data. As described in the contract between the Institution and the SNIS PSO, the Institution must take adequate measures to ensure that the privilege and confidentiality of PSWP is maintained. The law provides significant penalties for failure to maintain the confidentiality of PSWP.



# Patient Safety Evaluation System

## Institution PSES Documentation

PSES Manager(s):

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User(s) at the institution who have data entry permission:

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Member(s) of the PSES at the institution who have access to PSWP reports:

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Institution's policy regarding the frequency and forum for analysis of PSWP:

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Mechanism by which the SNIS PSO PSWP analysis will be incorporated into the institution's quality operations:

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List the individual(s) at the institution responsible for ensuring that all individuals who have access to PSWP understand the privileged and confidential nature of the information:

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