**UC Patient Safety Evaluation System & Patient Safety Organization Reporting: Reference Guide**

**Background:**

* Congress enacted the Patient Safety and Quality Improvement Act of 2005 and subsequent regulations, (collectively referred to as “The Act”) in response to the Institute Of Medicine (IOM) report “To Err is Human” to address national concerns over the number of preventable errors and deaths that were occurring in this country.
* By granting privilege and confidentiality protections to providers engaged in identified patient safety activities, including discussions, reports, and analyses, who contract with a federally-listed Patient Safety Organization (PSO), the Act was intended to nationally enhance health care quality and safety.
* PSOs are required to collect and analyze data in a standardized manner received from participating providers using the Agency for Healthcare Research and Quality (AHRQ) Common Formats to identify safety improvement opportunities, and share the lessons learned from these reviews.

**The Act:**

The goal of the Act was to improve patient safety by encouraging voluntary and privileged reporting of health care events that adversely affect patients.

Requirement: Under the Act all hospitals with greater than 50 beds and which provided care to insureds in the state insurance exchanges were required to have a Patient Safety Evaluation System (PSES) by January 1, 2017, which was interpreted as being obligated to participate in a PSO. Although there are now other ways to satisfy the requirement, the privilege and confidentiality protections are only afforded to licensed providers that are in a PSO.

**UC Policy Highlights:**

At the direction of the Office of General Counsel (OGC), a system wide PSES Policy has been developed. The policy was derivative from an approved template that was reviewed and modified by outside legal counsel, a recognized subject matter expert, UCSF Legal Counsel and UCSF Patient Safety Leadership. The Policy was submitted to the office of Risk Services and the OGC for review and comment, and approved by the UCOP Policy Committee. Ongoing revisions are expected as more information and comments from other campuses are received.

### The PSES is a virtual system as well as a physical system. It directs how our organization handles Patient Safety Concerns. It also identifies what data is considered privileged Patient Safety Work Product (PSWP).

### A Patient Safety Concern is:

### Information recorded and/or reported via the Incident Reporting System. The date the Patient Safety Concern becomes PSWP is the date the Patient Safety Concern is recorded in the incident reporting system.

### With few exceptions all activities, communications and information reported and/or developed by individuals or committees, such as but not limited to, data analyses, Root Cause Analyses, outcome reports and minutes, for the purpose of improving patient safety and/or healthcare quality are treated as PSWP.

**Examples of Patient Safety Concerns:**

* Incident—a patient safety event that reached the patient, whether or not there was harm;
* Near miss or close call—a patient safety event that did not reach the patient; or
* Unsafe condition—circumstances that increase the probability of a patient safety event.

 **PSWP:**

The Act defines PSWP as data that may improve patient safety, health care quality, or health care outcomes, that are assembled or developed by a provider for reporting to a PSO and are reported to a PSO.

* Any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material), which could improve patient safety, health care quality, or health care outcomes, that are assembled or developed by a provider for reporting to a PSO and are reported to a PSO.
* It can also include information that is documented within a patient safety evaluation system that will be sent to a PSO and information developed by a PSO for the conduct of patient safety activities.
* Analysis and deliberations when conducted in the PSES, PSWP protections will apply immediately; the drop-out provision does not apply.

PSWP does not include:

* A patient’s medical record, billing and discharge information, or any other original patient or provider information; nor does it include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system.
* Information that is collected or developed for purposes other than reporting to a PSO, such as;
	+ To justify actions in peer or personnel review
	+ Mandatory reports to regulatory or accrediting bodies (State and Federal)

PSWP can only be disclosed in very specific circumstances and subject to very specific restrictions.

De-Designated: Pertains to the Drop-Out Provision - The Patient Safety Rule provides a limited opportunity for a provider to remove patient safety work protections from information that the provider entered into its PSES for reporting to a PSO. The drop-out provision can be used for any reason, provided the information that the provider had placed in its PSES has not been reported to a PSO and the provider documents the action and its date.

For example: A medication error affecting an inpatient is found to be due to a staff member not adhering to policy. The event report may be removed from the PSES before reporting it to the PSO and then used for remedial or disciplinary actions.

**Initial data to be reported to CHPSO:**

Recommend continued reporting on a quarterly basis.

Data is uploaded to Next Plane, CHPSO’s data intermediary database vendor.

The initial reported cases are closed incident reports, related to patients or hazardous conditions