



## TIP OF THE MONTH

**August 2016**  
**(Updated October 2017)**

### **HHS Guidance on PSWP**

**Tip:** Understand the patient safety work product (PSWP) guidance issued by the Department of Health and Human Services (HHS) on May 24, 2016, and what it means for information you may be gathering to meet external obligations.

---

One of the many benefits of participating in a patient safety organization (PSO) is that certain information, known as patient safety work product (PSWP), is given privilege and confidentiality protections against disclosure and discoverability in litigation. These protections encourage providers to undertake patient safety activities and drive safer care delivery. Those protections have been subject to challenges in a handful of state court cases. To address some of the questions raised by these cases, the Department of Health and Human Services (HHS) released a document entitled "[Guidance on Patient Safety and Quality Improvement Act of 2005](#)" (the "Guidance").<sup>1</sup>

#### **What is PSWP?**

In general, PSWP is defined as 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. They must either:

- Be prepared by a provider for reporting to a PSO and be reported to a PSO;
- Be developed by a PSO for the conduct of patient safety activities; or
- Identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES.

---

<sup>1</sup> 81 Fed. Reg. 32,655 (May 24, 2016). On the same day that HHS released the Guidance, it also filed a brief with the U.S. Supreme Court urging the Court not to hear an appeal in the case of *Tibbs v. Bunnell*. On that brief, HHS stated that the Guidance was prompted, among other things, by its examination of the *Tibbs* case. On June 27, 2016, the Court declined to hear an appeal in *Tibbs*, letting stand a Kentucky Supreme Court finding that incident reports required by Kentucky law do not qualify as PSWP. Subsequently, the U.S. Supreme Court in October 2017 declined to hear an appeal brought by a Florida hospital (*Charles v. Southern Baptist Hospital*) required to turn over adverse incident reports, letting stand a Florida Supreme Court finding the reports were not PSWP because they were prepared pursuant to Florida law. In both cases, the results of the court cases hinged on state requirements.

The federal regulations exclude certain information from the definition of PSWP. Specifically, PSWP does not include:

- a patient's medical record, billing and discharge information, or any other original patient or provider information; or
- information that is collected, maintained, or developed separately, or exists separately, from a PSES.

In its May 24, 2016 Guidance, HHS seeks to address confusion about the definition of PSWP with respect to external reporting or recordkeeping requirements placed on providers. For example, HHS noted that more than half of all states have adverse event reporting systems. In addition, Medicare Hospital Conditions for Participation require hospitals to track adverse patient events through a Quality Assessment and Performance Improvement (QAPI) program. Freestanding clinics may have additional Medicare or other state or federal requirements. According to HHS, the information required to meet these external reporting or recording keeping requirements cannot be considered PSWP, regardless of whether they require a provider to report certain information, maintain specific records or operate a separate system.<sup>2</sup> HHS maintains that “the Patient Safety Act was intended to spur the development of *additional* information created through voluntary patient safety activities and to provide privilege and confidentiality protections for such *new* information.”<sup>3</sup> **In other words, information that you would have gathered for reasons other than reporting to a PSO is not considered PSWP.** Because state laws and requirements vary from state to state, it is important that you are familiar with these requirements.

#### **HHS Guidance expands the definition of “original records”**

Original records placed in a PSES do not become protected PSWP under the Patient Safety Act. The examples given in the regulations include “a patient’s medical record, billing and discharge information, or any other original patient or provider information.”<sup>4</sup> In the Guidance, HHS expands on the language in the regulations, saying that reports or documents that are required by a provider to meet any Federal, state or local public health or health oversight requirement are “original provider records,” regardless of whether those records are maintained inside or outside the PSES. If copies of these documents are placed in the PSES for further analysis, those documents may be considered PSWP as long as the original documents are maintained outside the PSES. If the original documents are destroyed or are otherwise unavailable, the duplicate copies within the PSES lose their protected status as PSWP and must be treated as original records, thereby not PSWP.

#### **HHS Guidance requires that data is assembled or developed for the purpose of reporting to a PSO**

In order for information to become PSWP, a provider needs to show that the information was assembled or developed for reporting to a PSO. Another way of stating this, according to HHS, is that “the information is prepared *for the purpose of* reporting it to the PSO.”<sup>5</sup> HHS states that some types of information could be PSWP or not depending upon why it was assembled or developed and provided the following chart. Note that in the third column, HHS uses the phrase “prepared solely for reporting to a PSO.”

---

<sup>2</sup> 81 Fed. Reg. at 32,657.

<sup>3</sup> 81 Fed. Reg. at 32,657 (emphasis in original).

<sup>4</sup> 42 C.F.R. § 3.20 (definition of patient safety work product).

<sup>5</sup> 81 Fed. Reg. at 32,656.

<u>Type of information</u>	<u>Not PSWP if prepared . . .</u>	<u>Could be PSWP if information is not required for another purpose and is prepared solely for reporting to a PSO, for example . . .</u> <sup>6</sup>
Information related to the functioning of medical equipment.	For upkeep of equipment (e.g., original equipment maintenance logs), to maintain a warranty, or for an external obligation (e.g., CMS requires some equipment logs).	Following a patient incident, a provider develops information about possible equipment malfunctions for reporting to a PSO. The PSO can aggregate it with other rare events from other reporting providers to identify risks and hazards.
A list of provider staff who were present at the time a patient incident occurred.	To ensure appropriate levels of clinician availability (e.g., routine personnel schedules), or for compliance purposes.	Following the incident, a provider originally assembles the list for reporting to a PSO so the PSO can analyze the levels and types of staff involved in medication errors.
Written reports of witness accounts of what they observed at the time of a patient incident.	For internal risk management (claims and liability purposes).	The provider originally prepares the written reports for reporting to the PSO so that the richness of the narrative can be mined for contributing factors.
Information related to care or treatment provided to the patient.	As part of the patient's original medical record.	The provider documents all patient allergic reactions in the medical record then prepares a list of patients that have exhibited the reaction to determine if newly-instituted procedures for reducing risk were followed specifically for the PSO. The list of patients exhibiting the reaction prepared for reporting to the PSO could be PSWP, but the original patient medical records would not.

Two other recommendations from HHS include:

- Providers should maintain at least two systems or spaces:** a PSES for PSWP, and a separate place for records to meet external obligations. The “drop out” provision -- allowing providers to place information in its PSES and then remove it if the provider determines that information is needed for external reporting -- should be used on a case-by-case basis for providers who are unsure whether information will be needed for an external obligation. In general, the PSES should only contain information that is originally created for reporting to a PSO.

---

<sup>6</sup> 81 Fed. Reg.at 32,657.

- **Providers and regulators should work together**, especially where regulatory requirements are ambiguous or broad, so regulators get the information they need and providers are able to report the additional information to PSOs.

### **Conclusion**

This Guidance from HHS provides new information and, in general, narrows the protections afforded to certain information that is required for purposes other than patient safety activities. The Guidance will affect RO-ILS participants differently, depending upon state and other external requirements as well as internal requirements, including your hospital's QAPI program. Please note that this general analysis is intended to keep you apprised of developments in this area and should not be construed as legal advice. ASTRO encourages providers to confer with qualified legal counsel on these and other matters related to participation in PSOs.

### **Resources**

- ❖ [\*Guidance Regarding Patient Safety Work Product and Providers' External Obligations\*](#). 81 Fed. Reg. 32,655 (May 24, 2016).
- ❖ [\*Final Rule implementing the Patient Safety and Quality Improvement Act of 2005\*](#). 73 Fed. Reg. 70,732 (Nov. 21, 2008).
- ❖ [42 C.F.R. Part 3](#).

*To subscribe to RO-ILS "Tips of the Month", please email [roils@astro.org](mailto:roils@astro.org).  
Previous "Tips of the Month" can be found in the Library area of the RO-ILS portal.*