

Patient Safety Work Product



*Presentation to the
CMS Region VIII and
State Survey Agency
Leadership Meeting*

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Presentation Objectives

This presentation will briefly cover Patient Safety Work Product and related issues:

- Definition of terms
- Requirements for hospitals
- How to assess compliance

Authority

Patient Safety Act means the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41), which amended Title IX of the Public Health Service Act (42 U.S.C. 299 *et seq.*) by inserting a new Part C, sections 921 through 926, which are codified at 42 U.S.C. 299b-21 through 299b-26.

- 42 CFR Part 3
- Definitions at 42 CFR §3.20

Definition of Terms 1

Patient Safety Organization (PSO):

- A private or public entity or component thereof that is listed as a PSO by the Secretary in accordance with subpart B. A health insurance issuer or a component organization of a health insurance issuer may not be a PSO. See also the exclusions in §3.102 of this part.

Patient Safety Evaluation Systems (PSES):

- Means the collection, management, or analysis of information for reporting to or by a PSO

Definition of Terms 2

Patient safety activities means the following activities carried out by or on behalf of a PSO or a provider:

- (1) Efforts to improve patient safety and the quality of health care delivery;
- (2) The collection and analysis of patient safety work product;
- (3) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
- (4) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
- (5) The maintenance of procedures to preserve confidentiality with respect to patient safety work product;
- (6) The provision of appropriate security measures with respect to patient safety work product;
- (7) The utilization of qualified staff; and
- (8) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

Definition of Terms 3

Patient safety work product:

- (1) Except as provided in paragraph (2) of this definition, patient safety work product means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material)
 - (i) Which could improve patient safety, health care quality, or health care outcomes; and
 - (A) Which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a patient safety evaluation system for reporting to a PSO, and such documentation includes the date the information entered the patient safety evaluation system; or
 - (B) Are developed by a PSO for the conduct of patient safety activities; or
 - (ii) Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

Definition of Terms 4

Patient safety work product (cont.):

(2)(i) Patient safety work product **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. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered patient safety work product.

(ii) Patient safety work product assembled or developed by a provider for reporting to a PSO may be removed from a patient safety evaluation system and no longer considered patient safety work product if:

- (A) The information has not yet been reported to a PSO; and
- (B) The provider documents the act and date of removal of such information from the patient safety evaluation system.

(iii) Nothing in this part shall be construed to limit information that is not patient safety work product from being:

- (A) Discovered or admitted in a criminal, civil or administrative proceeding;
- (B) Reported to a Federal, State, local or Tribal governmental agency for public health or health oversight purposes; or
- (C) Maintained as part of a provider's recordkeeping obligation under Federal, State, local or Tribal law.

Requirements for Hospitals

§482.21 Condition of participation: Quality assessment and performance improvement program.

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. **The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.**

Surveyor Access

- CMS or SA surveyors conducting Federal surveys are entitled to access information that may be confidential and privileged under State law if it is needed as evidence of compliance.
- Surveyors must take into consideration when making notes that QAPI documents contain sensitive information that should not be identifiable from their notes.

Hospital Response

- Hospitals may tell surveyors some of their QAPI information is confidential and may not be shared with surveyors in accordance with PSQIA.
- If the hospital asserts that a document or other information is confidential and privileged PSWP in a PSES and cannot be disclosed:
 - Surveyors must not demand access to materials classified by the hospital as PSWP.

Survey Process 1

- Request to see the contract or other evidence to confirm the hospital has a contract with a PSO, as listed by AHRQ
- PSO list available at:
<http://www.pso.ahrq.gov/listing/psolist.htm>

Survey Process 2

- If there is evidence to support the hospital's claim that it has a PSO contract and the hospital *asserts* the particular document requested by the surveyor qualifies as PSWP under the AHRQ regulation, ask the hospital if it can provide alternative evidence *of compliance* that is not PSWP.

Survey Process 3

- If the hospital produces alternative evidence, it is within the sole discretion of the survey coordinator to determine whether it provides sufficient evidence with which to assess compliance.
- If the hospital cannot produce alternative evidence or if the alternative evidence is insufficient to determine compliance, the hospital is out of compliance with QAPI, and potentially other CoPs.

Survey Process 4

- Hospitals must be able to demonstrate compliance.
 - If the hospital is refusing to provide the requested information, and are unable to demonstrate compliance in any other fashion, the hospital should be cited with non-compliance.
- The above guidance may apply to other CoPs.
 - For example, if when investigating Patient Rights the hospital refuses to supply PSWP, and the hospital cannot demonstrate compliance otherwise, that CoP is deficient.

Today's Take-Aways

- PSWP can be confidential and protected
 - In PSES
 - If contracting with PSO
- Hospitals must be able to demonstrate compliance, regardless of whether or not they choose to share PSWP

Questions



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