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PATIENT SAFETY AND QUALITY IMPROVEMENT ACT

Goal

To review PL 109-41, the PSQIA, and to summarize the key medication error research that contributed to congressional recognition of the need for this legislation.

Objectives

After reviewing this article, the reader should be able to:

1. explain the major recommendations of the IOM report, *To Err Is Human*, and related reports and the influence of the IOM reports on congressional action to adopt the PSQIA;
2. define or describe the following terms related to patient safety and quality improvement: (a) PSWP, (b) PSO, (c) identifiable PSWP, and (d) nonidentifiable PSWP;
3. describe the protections afforded to PSWP under the PSQIA;
4. describe the protections available for pharmacists who report PSWP to their employers or to a PSO;
5. differentiate between PSWP and other patient care data, including protected health information;
6. explain how the PSQIA affects state requirements for mandatory reporting of serious incidents.

Test Questions

1. Which of the following recommendations of the IOM report, *To Err Is Hu-*

man, is fulfilled by Congress in enacting the PSQIA?

- (a) protections against discovery in civil proceedings of PSWP
- (b) establishment of a nationwide mandatory reporting system for the states to collect data on adverse events that result in death or serious harm
- (c) establishment of a network of patient safety databases with a single entry point for patient safety researchers
- (d) funding of the National Health Information Infrastructure
- (e) requiring the FDA to develop standards for safe packaging of medications

2. The terms identifiable and nonidentifiable when related to PSWP refer to identification of:

- (a) the institution involved in the PSWP.
- (b) the providers involved in the PSWP.
- (c) the reporter involved in the PSWP.
- (d) Both b and c are correct.
- (e) All of the above are correct.

3. Which of the following persons' identities are not specifically protected by the PSQIA when a part of PSWP?

- (a) a patient involved in an event
- (b) a provider who is the subject of the PSWP
- (c) a provider who participates in patient safety activities that are the subject of the PSWP
- (d) a person who reports an event in the PSWP
- (e) All of the above persons' identities are protected specifically by the PSQIA.

4. In camera review of PSWP is required before it may be used in:

- (a) civil proceedings.
- (b) administrative proceedings.
- (c) criminal proceedings.
- (d) All of the above are correct.
- (e) None of the above is correct.

5. A pharmacist who reports PSWP to his or her employer or to a PSO is protected from:

- (a) assessment of the quality of his or her clinical performance related to the reported event.
- (b) adverse employment actions by virtue of reporting the event to the institution or the PSO.
- (c) adverse employment actions by virtue of disclosing identifiable PSWP to persons other than providers involved in the event, the institution's authorized personnel involved in patient safety activities, or the PSO.
- (d) claims of negligence filed by a patient who was involved in the event reported in the PSWP.
- (e) All of the above are correct.

6. State-owned hospitals may receive protection for PSWP under the act only if they agree to waive 11th Amendment immunity against lawsuits:

- (a) filed by patients who have been injured in events that are the subject of the PSWP.
- (b) filed by employees who claim adverse employment actions arising from reporting of PSWP to the institution or a PSO.
- (c) filed by third parties seeking information under state open records or freedom of information laws.
- (d) Both a and b are correct.
- (e) All of the above are correct.

7. The following case is loosely based on *Brown vs Southern Baptist Hospital*, 715 So.2d 423 (La. App. 1998), but differs in significant ways from the facts therein. A 46-year-old man was admitted to the hospital for treatment of a severe infection in his finger caused by a work-related injury. An order was written for topical application of Bunnell's Solution (0.49% glacial acetic acid in water and glycerin), and a supply of the solution was prepared by a pharmacy student who was licensed as an intern by the Board of Pharmacy and undergoing an externship rotation at the hospital. In spite of the patient's complaint of severe burning, nurses allowed the solution to drip onto the gauze dressing on his finger for 10 hours. Subsequent removal of the gauze revealed third degree burns to the finger, hand, wrist, and forearm, leading to 6 surgeries, several skin grafts, and amputation of his finger. Following the event, an incident report was prepared, and the patient safety committee investigated the event. Its findings included the following: (1) the student's individual work on this compounding task was not specifically reviewed by her preceptor prior

to administration of the solution to the patient, (2) the solution contained 47% glacial acetic acid, and (3) neither the student nor the preceptor completed the compounding checklist for the solution upon completion of the compounding task, as required by hospital pharmacy policy. The original of the committee's report was circulated only to persons identified in the hospital's peer review policies and procedures in preparation for submission to a PSO; however, a copy of this review was inadvertently placed in the patient's chart. Assuming that this event and its investigation occurred after the effective date of the PSQIA, which of the following best describes the status of PSWP related to the event?

- (a) This PSWP would not be subject to the PSQIA because it is the report of a severe event.
 - (b) The PSWP prepared for the PSO is protected from discovery, but the information in the patient's chart is discoverable and not protected under the PSQIA.
 - (c) All of the information except the student's identity is protected under the PSQIA since the student is not a provider under the terms of the PSQIA.
 - (d) The placement of the report into the patient's chart is an unlawful disclosure of PSWP by the person who placed it there, and the PSWP is protected from discovery.
 - (e) It may be discoverable in a civil lawsuit, but only after *in camera* review by a judge, which establishes certain tests specified in the PSQIA.
8. Which of the following characterizes the findings of medication error and patient safety research over the last 4 decades?
- (a) More than 1 in 30 hospitalizations involve an adverse event.
 - (b) Medication errors account for a small percentage of adverse events in hospitals.
 - (c) A majority of adverse events arise from negligence and/or preventable errors.
 - (d) Both a and c are correct.
 - (e) All of the above are correct.
9. Which of the following cannot be certified as a PSO?

- (a) a company that provides health insurance
 - (b) a subsidiary of a national or state pharmacy association
 - (c) an entity that, within each 24 month period, has patient safety review contracts with fewer than 3 providers
 - (d) Both a and c are correct.
 - (e) Any of the above may be certified as a PSO.
10. Which of the following is *true* when including the name of the patient involved in an event in PHI within PSWP submitted to a PSO?
- (a) It may not be done unless the patient has consented to the disclosure of the information to the PSO.
 - (b) It is an allowable disclosure as part of the provider's healthcare operations.
 - (c) The PSO is treated as a business partner of the provider and may receive PHI as long as it does not further disclose the patient's name and meets other HIPAA requirements.
 - (d) Both b and c are correct.
 - (e) None of the above is correct.
11. Which of the following is *not* an allowed remedy under the PSQIA for an unlawful adverse employment action?
- (a) awards of back pay
 - (b) reinstatement
 - (c) injunction against future adverse employment actions
 - (d) restoration of benefits
 - (e) fines up to \$10 000 per action
12. A nurse misread the label on a vial of a solution for injection and administered 10 vials instead of one. Which of the following notations would be inappropriate to place in the patient's Medication Administration Record or other healthcare record because the information should be treated as PSWP?
- (a) a record in the Medication Administration Record of the number of vials actually administered
 - (b) progress notes that detail specific symptoms observed by practitioners dealing with the patient during the period following the administration of the drug
 - (c) laboratory reports demonstrating a rapid increase in blood urea nitro-

gen following administration of the drug

- (d) a supervisor's note that the administering nurse, designated by name, had worked a double shift just prior to the administration of the drug
 - (e) a note that the patient's physician discussed the event with the patient
13. PSWP is defined to include analyses such as root cause analyses, which are best described as:
- (a) attempts to predict ways in which a system or process can fail, leading to better design.
 - (b) attempts to investigate an event so as to identify the person most responsible for the failure.
 - (c) attempts to investigate a particular event after the fact to identify the basic or causal factors, not just the immediate precursor to the error.
 - (d) attempts to summarize information from several similar events to identify common reasons for the failures.
 - (e) attempts to prove negligence by a provider or a group of providers.
14. How does the PSQIA affect state laws requiring reporting of serious errors or sentinel events?
- (a) State laws are not replaced by any PSQIA requirements.
 - (b) State laws are preempted by the PSQIA to the extent that they result in the disclosure of PSWP.
 - (c) Serious errors reported in accordance with state laws may be disclosed, but such disclosure does not render PSWP related to those errors exempt from other PSQIA protections.
 - (d) Both a and c are correct.
 - (e) All of the above are correct.
15. Administration of the provisions of the PSQIA rests almost entirely within which of the following agencies of the DHHS?
- (a) Centers for Medicare & Medicaid Services
 - (b) US Public Health Service Commissioned Corps
 - (c) Health Resources and Services Administration
 - (d) National Institutes of Health
 - (e) Agency for Healthcare Research and Quality