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Patient Safety Act
Confidentiality Training 2016

Training Overview

- The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) encourages pharmacists to share quality and medication error information to improve the quality and safety of health care delivery without fear of legal discovery or without tarnishing their professional reputations.

- The Patient Safety Act requires that Patient Safety Work Product (PSWP) be confidential and not be disclosed by anyone holding the PSWP, except as permitted by law.

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Training Objectives

- To identify:
  - What is Patient Safety Work Product
  - Exactly what information is confidential
  - Prohibited disclosures to unaffiliated persons
  - Permissible disclosures to unaffiliated persons

- **To understand the penalties for unauthorized disclosure to unaffiliated persons**

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Acronyms and Terms in Patient Safety Act

- **PSO** (Patient Safety Organization)
- **PSES** (Patient Safety Evaluation System)
- **PSWP** (Patient Safety Work Product)
- **Non-identifiable PSWP** (Non-identifiable Patient Safety Work Product)

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PSO - Patient Safety Organization

- ***Alliance of Patient Medication Safety™ (APMS™)***

  – " ... is listed as a PSO by the Secretary of Health and Human Resources."

  – ".... can provide confidential, expert advice to pharmacists in the analysis of patient safety events."

  – "…. can assist pharmacists in identifying ways to improve the practice of pharmacy and patient care".

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PSES: Patient Safety Evaluation System

- Exists anywhere that patient safety activities occur in a pharmacy and includes the process of collection, management, or analysis of information for reporting to or by a PSO (CFR Part 3.20 (b)(2)) which then becomes patient safety work product.

- **Clinical:** Where pharmacists can share information about medication and dispensing errors and how to prevent them to implement lessons learned in the pharmacy.

- **Legal:** Identifies protected information and protected space.

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Your PSES: Patient Safety Evaluation System

- The purpose of your Patient Safety Evaluation System is to provide a process through which your facility and your pharmacy staff can conduct patient safety activities.
    - efforts to improve patient safety and engage in continuous quality improvement activities
    - Information reported into or developed in the PSES is privileged and confidential
    - Each APMS licensee has access to APMS PSES

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What Happens in the PSES?

- **Targeted Patient Safety Initiatives:** Determines what information to collect to improve patient safety, health care quality, and healthcare outcomes.

- **Data Aggregation to Accelerate Improvement:** Reviews data for trends and recommends action when needed to mitigate harm or improve care.

- **Evaluate Recommendations to Implement Improvement:** Analyzes data and evaluates PSO recommendations to continuously improve patient safety, healthcare quality and healthcare outcomes.

- **Root Cause Analysis to Learn from Mistakes:** Conducts Root Cause Analysis (RCAs), Proactive Risk Assessments, in-depth reviews, and aggregate RCAs

- **Reports PSWP to PSO**

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PSWP – The Confidential Data

- PSWP (Patient Safety Work Product) is:
  - Any data, reports, records, memoranda, analysis (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;
  - And that:
    - 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 PSES for reporting to a PSO; or
    - Are developed by a PSO for the conduct of patient safety activities; or
    - which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES.

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PSWP – The Confidential Data

PSWP (Patient Safety Work Product) is:

- PSWP is privileged from administrative, disciplinary, civil, and criminal proceedings and is confidential.

- PSWP may be Personal Health Information (PHI) under HIPAA and subject to other privacy and security regulations.

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When Does Data Become PSWP?

- **Data is PSWP from the moment of collection with the intention to report the information to a PSO.**

- **It is a best practice to mark the information as PSWP when the confidentiality and privilege protections apply. (mark your QA data as confidential)**

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What is NOT PSWP?

- Patient's medical record, billing and discharge information, or any other original patient or provider information.
- Information that is collected, maintained, or developed separately, or exists separately, from a PSES (e.g., developed for licensure or accreditation). PSWP assembled by a provider
  for reporting to a PSO but removed from a PSES is no longer PSWP if:
  - The information had not yet been reported to a PSO; and
  - Provider documents the act and date of removal of such information from the PSES.

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Non-identifiable Data (PSWP)

- PSWP that is presented in a form or manner (e.g.,aggregation) that does not allow the identification of:
  - Any provider that is the subject of the PSWP;
  - The patient or any Personal Health Information; and
  - Any individual who reported the PSWP.

- *PSOs do not release any PSWP that can be identified with any of the above.*

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Non-identification of PSWP

- **Standard:** A qualified expert finds that the risk is very small that the information could be used by an anticipated recipient to identify a provider or reporter and requires:
  - Removal of personal identifiers (provider, patient, reporter and related individuals); geographic identifiers smaller than a state (except the first 3 digits of a zip code if more than 20,000 people live within the code); Dates (except year) of incident or event; and any characterizing code or number (patient code)
  - Removal of information if the information could be used alone, or in combination, with other reasonably available information could lead to identification

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Confidentiality Protections

- Permit providers within a hospital or pharmacy system to share quality information to improve quality of care
- Dovetails with HIPAA privacy rule but also protects information about the person who reported the quality information; the health care providers involved and the institution
- May be strengthened by the pharmacy and disclosures may be delegated
- State laws may provide greater confidentiality protections

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Who is Affected?

Any pharmacist or pharmacy work force who has or may have access to:

- Patient Safety Work Product;
- Patient Safety Evaluation System; or
- Feedback and Recommendations from APMS PSO

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Maintaining Confidentiality

Pharmacies may institute policies and procedures on :

- who and how permitted disclosures may be made; and
- making the confidentiality protections stronger

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Permitted Disclosures

- Disclosure of identifiable PSWP among providers and PSO for Patient Safety Activities (in this case within your pharmacy or pharmacy group)
- Disclosure of non-identifiable PSWP (e.g. non-identified aggregate info for learning purposes)
- Disclosure in a criminal proceeding or criminal activities;
- Disclosure of identifiable PSWP if all providers agree and the disclosure can only be made once then the confidentiality protections reattach; (unique example – pharmacists can share identifiable interaction with other pharmacists such as in a case review)
- Disclosures to FDA; (if reporting is required)
- PSWP may be used within the hospital/pharmacy for any purpose, provided it is not disclosed to third parties.

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Authorized Disclosures

- Release of aggregated information showing a pharmacy has reduced medication errors by a significant amount for marketing purposes
- Pharmacist wants to know the recommendation of the PSES or PSO after an incident was reported
- The pharmacy's risk managers want to use PSWP program management or claims processing

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Unauthorized Disclosures

State Board of Pharmacy Representative asks:

- If an incident was reported to the PSO and what the PSO recommended
- Sharing PSWP with a patient
- Senior Care Center requests to see PSWP concerning a patient

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Practical Issues

Recommend:

- Use secure networks with password protection for transmission of PSWP by e-mails and add a confidentiality disclaimer to the footer;
- Set a protocol to provide for confidential sending and receipt of faxes that contain PSWP and other confidential information;
- Discuss PSWP in secure environments, or in low voice, so that other people do not overhear the discussion.

- Telephone communications
- Email communications
- Disposal of records

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Consequences for Disclosure

- Complaint to APMS
  - Investigation
  - Internal disciplinary action against you

- Complaint to Office of Civil Rights HHS
  - Investigation
  - Sanction against APMS
  - Possible sanctions against you

- Notification to Patient and Providers who were identified in the disclosed information.

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Sanctions for Unauthorized Disclosure

- **General rule:** A person who discloses identifiable PSWP in knowing or reckless violation of the confidentiality provisions is subject to a fine for each disclosure

- Fine is not more than $10,000 per instance

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More Information

- **Health and Human Services Office of Civil Rights www.hhs.gov/ocr**
- **Agency Health Research and Quality www.pso.ahrq.gov**
- **Alliance for Patient Medication Safety www.medicationsafety.org**

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Questions

For questions concerning the confidentiality protections and disclosure of Patient Safety Work Product, contact:

Alliance for Patient Medication Safety™ (APMS ™)

(866) 365-7472

info@medicationsafety.org

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Test

Please complete this True/False test to receive credit for this training: Test found in CQI Compliance section and in Resource Area

1. PSWP (Patient Safety Work Product) is any data, reports, records, memoranda, analysis (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. True or False
2. PSWP assembled by a provider for reporting to a PSO but removed from a PSES is still PSWP even if the provider documents the act and date of removal of such information from the PSES. True or False
3. If a provider can release patient information under HIPAA, he/she can release it under the PSA. True or False
4. A pharmacist or pharmacy work force who has access to Patient Safety Work Product, Patient Safety Evaluation System and Feedback and recommendations from APMS PSO is NOT affected by confidentiality requirements. True or False
5. The identity of the individual who reported the PSWP is considered to be PSWP and is confidential. True or False
6. The Patient Safety Evaluation System (PSES) exists anywhere that patient safety activities occur in a pharmacy and includes the process of collection, management, or analysis of information for reporting to or by a PSO (CFR Part 3.20 (b)(2)) True or False
7. An example of an authorized disclosure would be release of de-identified information determined by the pharmacy institution according to their policies and procedures. True or False
8. A patient's medical record, billing and discharge information, or any other original patient or provider information is PSWP. True or False
9. The PSE does not determine which data will/will not be reported to the PSO. True or False
10. Disclosure of non-identifiable PSWP and disclosure in a criminal proceeding or criminal activities are permitted PSWP disclosures. True or False
11. As a general rule, a person who discloses identifiable PSWP in knowing or reckless violation of the confidentiality provisions is subject to a fine for each disclosure that is not more than $10,000. True or False

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