Pharmacist Spotlight: Safety Culture

Healthcare Providers Service Organization (HPSO), in collaboration with CNA, has published our *Pharmacist Professional Liability Exposure Claim Report: 3rd Edition.* The report includes statistical data and case scenarios from CNA claim files, along with information on where to access risk management resources designed to help pharmacists reduce their professional liability exposures and improve patient safety.

You may access the complete report, and additional Risk Control Spotlights, at: **hpso.com/pharmacistclaimreport**.

This Pharmacist Spotlight focuses on professional liability claims data analysis and risk recommendations regarding one of the most significant topics in the report: Safety Culture. While this Spotlight cannot provide a comprehensive guide to preventing medication errors by implementing a just culture of safety in pharmacies, it can serve as a reference for pharmacy leaders and pharmacists seeking to initiate internal discussion and evaluation of current practices.

Although there is no universally accepted definition of a medication error, the **National Coordinating Council for Medication Error Reporting and Prevention** defines a medication error as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer." This broad definition emphasizes the fact that medication errors can occur due to one--or multiple--failures involving medication nomenclature, labeling, packaging, prescribing, dispensing, administration, and use. Addressing the issue of medication errors requires interdisciplinary collaboration among all professionals whose work touches any aspect of this medication use process. Pharmacists can lead medication error reduction efforts by using their unique combination of clinical, operational, and technological expertise to identify the root causes of error, design and implement solutions, and monitor performance for improvements.

Most Common Pharmacy Errors

The CNA/HPSO *Pharmacist Professional Liability Claim Report: 3rd Edition* identified the following top sources of medication errors for pharmacists:

- **Wrong drug** and **wrong dose/strength** dispensing errors are the most common malpractice allegations involving pharmacists, at 41.7 percent and 21.9 percent, respectively.

  - The most common type of wrong drug dispensing error involves confused drug errors or **look-alike and sound-alike** (LASA) drug errors, accounting for approximately 45 percent of wrong drug errors.

- Errors involving the wrong dose/strength, including the dosing frequency, may be associated with one or more human errors and environmental factors such as: **workplace distractions**, misinterpretation of a prescription (e.g., **due to the use of certain error-prone abbreviations or symbols**), or **selection errors** (e.g., when the pharmacist or pharmacy technician pulls the incorrect medication strength from the shelf, or selects the wrong strength in the computer system).

• Although less common than other top allegations, **calculation and/or preparation errors** continue to be the allegation with some of the most severe claims, with an average total incurred of $413,598 per claim. This is more than three times the overall average for pharmacist claims of $136,000.

Failure to proactively address safety issues in the pharmacy, failure to investigate errors and near misses, and/or attempting to cover up an error may not only lead to patient harm, it also may result in State Boards of Pharmacy taking severe disciplinary action against pharmacists' licenses. Examples of such State Boards of Pharmacy matters include this case study involving a pharmacist who attempted to cover up a wrong concentration dispensing error as well as the following example:

Pharmacist License Protection Case Study: Failure to investigate root cause of dispensing error

The insured pharmacist was the owner, manager, and pharmacist-in-charge of a community pharmacy. A patient presented with a prescription for 40 tablets of carisoprodol 350 mg, which the pharmacist filled the same day. The patient took the medication over the next month and subsequently experienced nausea, vomiting, and diarrhea.

When the patient returned to their physician a month later, the patient showed their physician the remaining 10 tablets. Upon visual inspection of the tablets, the physician determined that the pharmacist had dispensed metformin to the patient instead of carisoprodol. The physician then notified the pharmacist about the error, and later filed a complaint against the pharmacist with the State Board of Pharmacy.

Three months later, in response to the complaint, a Board investigator inspected the pharmacy. The investigator concluded that not only did the pharmacist fail to conduct his own investigation into the medication error in accordance with state regulations, but the pharmacy also failed to implement a medication safety program, as required. The pharmacist was placed on probation for three years, during which time he was prohibited from acting as the pharmacist-in-charge or supervising other pharmacy personnel. In addition, the pharmacy was fined over $5,600.

A Just Culture Approach to Patient Safety

Pharmacy leaders and managers, pharmacists-in-charge, and other key decision makers must appreciate the crucial role that systems, and systems failures, can play in patient safety incidents. Placing blame solely on the individual(s) involved in a patient safety incident will likely fail to effectively minimize the future risks posed by unsafe processes and procedures. For example, while a wrong drug dispensing error may lead to allegations of malpractice against an individual pharmacist, that error may not necessarily originate with the pharmacist. Medication nomenclature, or packaging that looks or sounds similar to that of another medication, understaffing, ineffective processes, and technology lapses may all contribute to a wrong drug dispensing error. Therefore, pharmacists and pharmacy leaders should appreciate how a just culture of safety can support pharmacy professionals and help to reduce the incidence and severity of medication errors.

Organizations that adhere to a just culture safety science framework are guided by five core principles, first outlined by Todd Conklin, a Human and Organizational Performance leader:

1) **Error is normal** – Due to the high-risk nature of pharmacy activities, errors are inevitable, but that does not lessen the determination to achieve consistently safe operations.

2) **Management response matters** –Organizations/pharmacies must commit resources to address safety concerns, and managers and other leaders must be determined to achieve consistently safe operations.

3) **Systems drive behavior** – The context in which individuals work (i.e. organizational processes, culture, systems, and management) drives their behavior, actions, and performance problems.

4) **Blame fixes nothing** – Pharmacy/organizational leaders must foster a blame-free environment, where individuals are able to report errors or near misses without fear of reprimand or punishment.

5) **Learning is vital** – Collaboration across ranks and disciplines is essential to identify solutions to patient safety problems.

These principles emphasize an organizational commitment to sharing responsibility and accountability across all levels and disciplines within the organization and recognize that humans are not infallible.

PHARMACIST SPOTLIGHTS ON RISK MANAGEMENT

For case studies, risk control strategies and more, see additional Pharmacist Spotlights related to:

- Defending Your License
- Documentation
- Vaccination Safety
- Policies and Procedures
- De-escalation and Crisis Management
- Workplace Issues and Well-being

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Organizational/pharmacy leaders should be open regarding the way they deal with professional errors and reported safety incidents. While no system can be truly "blame free", where any and all conduct can be reported with impunity, some actions truly warrant disciplinary action. At the same time, an appropriate, reasonable balance must be struck between the need to take disciplinary action and the need to learn and grow from mistakes and errors.

Addressing Medication Errors Through a Culture of Safety Framework

Addressing medication errors requires that pharmacies and pharmacy systems be designed to discourage human behaviors that may be unsafe and reduce the risk of system failures. To that end, everyone within the organization must be encouraged, and even incentivized, to report errors and near-misses, without retaliation or retribution on the reporter. This way, rather than simply assigning blame to particular individuals involved in an error, lessons can be learned and systems can be improved in such a way that human errors and system failures can be minimized and/or avoided in the future.

Understanding the nuances of behaviors that can contribute to errors can aid pharmacists in reducing medication errors. A just culture framework emphasizes shared responsibility and accountability, focusing on system improvements rather than blaming individuals for errors. It distinguishes between human error, at-risk behavior, and reckless behavior, tailoring responses accordingly (**See table:** *Behaviors that contribute to medication errors*). Human errors stem from inherent fallibility and require system redesigns to mitigate risks, while at-risk behaviors result from intentional choices influenced by workplace norms or inadequate systems. Reckless behaviors involve intentional disregard for obvious risks and may necessitate disciplinary action. Addressing patient safety issues involves transparently discussing error trends and engaging staff in system redesign. It's crucial to reward adherence to patient safety goals and report near-misses, fostering a culture of continuous learning and accountability. Establishing anonymous reporting systems and offering support for behavioral health issues are two examples of policies that can help further promote a just culture in pharmacies, ensuring a focus on patient safety.

BEHAVIORS THAT CONTRIBUTE TO MEDICATION ERRORS

Behavior & Definition	**Human error -** Unintentional lapses in interpretation and judgment.	**At-risk behavior -** Intentional choices based on the assumption that the risk associated with the choice is insignificant or justifiable.	**Reckless behavior -** Intentional, conscious disregard of obvious, substantial, and unjustifiable risk.
Examples	Transposing the numbers in a medication dose or prescription order or selecting the wrong drug from a drop-down menu.	Overriding automated alerts or scanning one container several times for multiple containers of the same drug.	Drug diversion, acts of retaliation, working under the influence of alcohol or drugs on the job, or continuing to engage in at-risk behavior despite coaching.
Motivation	None; these mistakes are not intentional.	Typically believes they are making a relatively "safe" choice based on behaviors that have become the norm in a group, or a genuine desire to help others expeditiously.	Prioritizing individual wants/needs above the safety of others. In some cases, driven by a behavioral health issue such as an untreated substance use disorder.
Recommended Remedy	**Console** the individual(s) involved and engage them in training. Evaluate and redesign systems to implement multiple strategies that reduce or eliminate risk.	**Coach** the individual(s) involved on the risks associated with their behavior. Evaluate and redesign systems to implement multiple strategies that reduce or eliminate risk.	**Punish** reckless behaviors, taking appropriate disciplinary action according to HR policies and statutory requirements, as applicable. In some cases, the response may require legal action.

Adapted from: 1) Rogers E, Griffin E, Carnie W, Melucci J, Weber RJ. A just culture approach to managing medication errors. Hosp Pharm. 2017;52(4):308-315. doi:10.1310/hpj5204-308 and 2) Institute for Safe Medication Practices. The differences between human error, at-risk behavior, and reckless behavior are key to a just culture. 2020. https://www.ismp.org/resources/differences-between-human-error-risk-behavior-and-reckless-behavior-are-key-just-0

Medication Safety Recommendations for Pharmacy Leaders

The following strategies are general in nature and reflect the concept that medication errors are most often traceable to flawed processes, suboptimal workplace conditions, and cultural issues, which can be rectified only through an organization-wide, top-down commitment to safety and quality improvement.

- **Establishing a Safety Culture**
  - **Appoint transformational leaders** who will emphasize shared accountability for medication safety.
  - **Address staff concerns with respect to fear of punishment** when implementing error-reduction programs focusing on systems and process improvements rather than individual human error.
  - **Promote a team culture**, supported by open dialogue with leadership.
  - **Implement weekly safety huddles** to identify system and process failures that contribute to medication safety issues and share the solutions designed to minimize/avoid medication safety issues.
  - **Empower all members of the pharmacy team to "stop the line"** whenever safety concerns arise. Any pharmacy team member should feel empowered to speak up any time they have a safety concern and request that the care process/medication dispensing process be stopped. The phrase "stop the line" is borrowed from the manufacturing industry, where assembly lines have a mechanism, like a big, red button, that can stop the process if something goes wrong or could be about to go wrong.
  - **Train providers and staff to engage the chain of command** whenever unsafe clinical situations arise.

- **Human Factor Principles**
  - **Map out workflows to detect potential problems**, including staff workarounds and process bottlenecks that can lead to at-risk behavior, delays, and errors. Perform workflow assessments on an ongoing basis and reconfigure teams and processes for optimal performance.

- **Design systems and processes that avoid reliance on memory** and which proactively alert providers before an error occurs.
- **Simplify and standardize processes** by using safety checklists, electronic work lists, action queues and other automated, electronic warnings and decision support tools.
- **Build "forcing functions" into IT systems**, requiring users to take appropriate action with respect to medication safety and compliance.
- **Continually monitor error-prone processes** – including documentation, prescription transcription, compounding, and medication dispensing – and identify missteps.

- **Medication Safety**
  - **Adopt automated alerts** for medication allergies, as well as for drug-drug interactions and safe dosing.
  - **Incorporate precautions for look-alike and sound-alike medications** into computer order entry and automated drug dispensing systems.
  - **Implement a secondary labeling and automated warning system for high-alert medications** and permit only appropriately licensed and trained staff members to dispense or administer these drugs.
  - **Employ machine-readable coding** to check patient identify, allergy status, and other pertinent drug data prior to dispensing or administration.
  - **Routinely assess pharmacy staff members' proficiency** in key medication safety issues, such as transcribing and dispensing prescriptions and administering medications, using monitored and documented simulations and provide cyclical training on medication safety.

- **Managing Workflows**
  - **Identify unnecessary regulatory burdens and workplace requirements** that take time away from activities that could improve the safety of patients and the well-being of pharmacy staff and **reallocate administrative and non–patient care tasks to support personnel** (e.g., scheduling, report generation, filing).
  - **Review policies and workflows to decrease interference with pharmacists** and pharmacy support staff in providing patient care and ensure adequate time for necessary documentation in patient-facing hours.
  - **Create clarity and delineation of roles for pharmacy technicians**. Leverage pharmacy technician responsibilities and technology efficiencies to enable pharmacists to focus on high-value pharmacy services.
  - **Implement an appointment-based model as much as possible** (e.g., for vaccines, telehealth, disease state management) to enhance professional status, establish/maintain patient relationships, and support workflow.
  - **Maximize central fill and shared service models, where feasible**, to allow more time for provision of patient care services.
  - **Modify performance metrics to include medication safety**, with proper weighting, as part of overall productivity metrics.
  - **Build models for redundancy, cross-training, and flexibility in staffing** to absorb last-minute and unavoidable schedule and staffing changes and to accommodate people who need to be away or need time for self-care.

PHARMACY INCIDENT RESPONSE GUIDE

This tool is intended to help guide pharmacy leaders through a series of questions regarding an individual's actions, motives, and behavior surrounding a patient safety incident. Recommended actions are then provided for consideration.

(Q1) Intentionality test: Were these actions taken on purpose, with intention to cause harm?	
If the answer is **NO** to Q1, go to the next question.	If the answer is **YES** to Q1, recommendations include: - Punish reckless behaviors, taking swift, appropriate disciplinary action in accordance with HR policies and statutory requirements, as applicable. In some cases, the response may involve legal action. - A wider incident investigation is still recommended to understand how and why patients/staff were not protected from the individual's actions. End Here.

(Q2) Health and wellbeing tests:
     Q2a. Are there any indications of substance abuse?
     Q2b. Are there any indications of illness (e.g., physical or mental health)?	

If the answer is **NO** for Q2a, go to Q2b.	If the answer is **YES** to Q2a, recommendations include: - Console the individual involved and follow organizational/HR guidance regarding suspected or confirmed substance abuse in the workplace. - A wider incident investigation is still recommended to determine if the individual's substance abuse could have been recognized and addressed earlier. - Consider redesigning systems to implement multiple strategies that reduce or eliminate risk. End Here.
If the answer is **NO** for both parts of Q2, go to next question.	If the answer is **YES** to Q2b, recommendations include: - Console the individual involved and follow organizational/HR guidance regarding health issues affecting work. - A wider incident investigation is still recommended to determine if the individual's health issue could have been recognized and addressed earlier. - Consider redesigning systems to implement multiple strategies that reduce or eliminate risk. End Here.

Pharmacy Incident Response Guide

(Q3) Accountability tests:

Q3a. Are there policies, procedures, and/or accepted practices in place that apply to the action/omission in question?

Q3b. Were applicable policies and procedures available, workable, evidence-based, and in routine use?

Q3c. Did the individual knowingly depart from these policies and procedures?

Q3d. Is there evidence that the individual took on unacceptable risk in their conduct?

If the answer is **YES** to all parts of Q3, go to the next question.	If the answer is is **NO** to any part of Q3 recommendations include: - Coach the individual(s) involved on the risks associated with their behavior. Actions signaling out the individual are unlikely to be appropriate. - A thorough incident investigation should indicate the wider actions needed to improve patient safety. Evaluate and redesign systems to reduce or eliminate risk. End Here.

(Q4) Rationality tests:

Q4a. Is there any indication that other individuals who have a comparable level of education, qualifications, and experience would behave in the same way in similar circumstances?

Q4b. Were there any deficiencies in the training or experience of the individual?

Q4c. Did more senior members of the team fail to provide an appropriate level of supervision that normally should be provided under similar circumstances?

If the answer is **NO** to all parts of Q4, go to the next question.	If the answer is **YES** to any part of Q4, recommendations include: - Coach the individual(s) involved on the risks associated with their behavior. Actions signaling out the individual are unlikely to be appropriate. - A thorough incident investigation should indicate the wider actions needed to improve patient safety. Evaluate and redesign systems to reduce or eliminate risk. End Here.

(Q5) Mitigating circumstances tests:

Were there any significant mitigating circumstances that should be considered?

If the answer is **NO** to Q5, recommendations include:	If the answer is **YES** to Q5, recommendations include:
- Follow organizational/HR guidance regarding taking appropriate corrective action. This may involve individual coaching, performance management, competency assessments, role change, increased supervision, suspension, and/or reporting to relevant regulatory bodies. - Wider actions may also be necessary to improve safety for future staff and patients. End Here.	- Coach the individual(s) involved on the risks associated with their behavior. Actions signaling out the individual are unlikely to be appropriate. - A thorough incident investigation should indicate the wider actions needed to improve patient safety. Evaluate and redesign systems to reduce or eliminate risk. End Here.

References and Additional Resources

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Pharmacist Spotlight

The Substance Abuse and Mental Health Services Administration's (SAMHSA's) National Helpline, also known as the Treatment Referral Routing Service, is a source of support for substance abuse issues and is available to provide free, confidential assistance at 1-800-662-HELP (4357) or via FindTreatment.gov.

For resources related to substance use in pharmacy, you can also visit:

- USA Pharmacists Recovery Network (State-specific resources)

- APhA Opioid Resource Center

- APhA-ASP Operation Substance Use Disorders

- APhA Institute on Substance Use Disorders

Pharmacist Professional
Liability Exposure
Claim Report: 3rd Edition

A portion of this information was excerpted from HPSO and CNA's full report, *Pharmacist Professional Liability Exposure Claim Report: 3rd Edition.*
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