Pharmacist Spotlight: The Importance of Policies & Procedures for Practice and Patient Safety

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 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 analysis and risk control recommendations related to a critical topic impacting quality of care, patient safety, and the ability to effectively defend insureds in the event of a claim or lawsuit: pharmacy policies and procedures (P&P).

Why Policies & Procedures Matter

Pharmacy continues to evolve.

Pharmacists' roles have expanded (e.g., medication management, immunizations, test-to-treat, complex specialty support), and claim severity is edging upward, with the average total incurred (indemnity plus claim expenses) now $136,000 in the 3rd Edition Report. Dispensing the wrong medication remains the top professional liability claim allegation, with "wrong dose/strength" second and rising in associated costs. Compounding-related claims are among the most severe, with an average total incurred of $438,221. License defense costs have climbed as well, with an average defense cost of $7,650. Note that approximately 70 percent of license defense matters result in some type of pharmacy board disciplinary action.

Mitigate the risk of errors and harm.

Compliance with well-written and maintained P&P reduces variation, embeds safety technology (e.g., barcode verification, clinical decision support), raises staff competency, preserves records for patient safety, error investigations and litigation, and is consistent with a culture of safety and quality in the delivery of healthcare services.

Considerations for Developing P&P.

Although specific P&P needs will vary by pharmacy venue and other factors, bear these points in mind:

- Reflect on how the resources, examples and case studies provided in this Spotlight demonstrate ways to help anchor P&P to professional content from recognized sources. Sources may include but are not limited to the American Pharmacists Association (APhA); the Joint Commission of Pharmacy Practitioners (JCPP); the Institute for Safe Medication Practices (ISMP); The American Society of Health-System Pharmacists (ASHP); and government agencies such as the Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA). Individual state and federal requirements also must be considered.
- In the community setting, prioritize high-risk community pharmacy workflows (e.g., two-identifier patient verification for all patient and prescriber interactions; barcode use across fulfillment and at the point-of-sale (POS); oral methotrexate weekly dosing safeguards; etc.).

- Reinforce hospital/institutional controls (e.g., systemwide medication-safety programs; barcode verification during inventory, preparation, and dispensing; high-alert medication safeguards; and sterile compounding procedures).
- Consider implementation of P&P that support a "just culture" framework and approach to prevention and management of medication errors.
- Follow an approved template, style and format.
- Assign specific responsibilities to staff categories rather than named individuals.
- Write at an accessible, non-expert level to maximize readership and understanding.

P&P are your operating system.

P&P translate one's mission into action to specify safe processes and sequences of work, set competency and supervision expectations, and document compliance for regulators and/or accreditors. This information also becomes critical for attorneys, courts, and/or licensing boards in the event of a lawsuit or complaint. Compliance with clear and current P&P bolster standard-of-care defense. On the other hand, the absence of P&P—or divergence from them—creates liability exposure.

Core P&P benefits include but are not limited to:

- Establishing clear lines of authority, oversight, and facilitating delegation of responsibility.
- Reducing variation and error risk in routine as well as high-risk tasks.
- Enabling onboarding and retraining, with role-based job descriptions that address responsibilities and objective performance criteria.
- Supporting compliance and accreditation readiness (e.g., licensing board, The Joint Commission, or other site visit/survey evaluations).
- Preserving defensibility via P&P retention, archiving, and version control (who approved, when implemented, and what changed).
- Supporting defense efforts in lawsuits involving standard of care issues.

Examples of Resources and Standards to Anchor P&P

Depending upon the pharmacy venue and focus areas, consulting resources from industry-leading organizations can help to guide the development of effective P&P. Furthermore, be aware of state and/or federal requirements that may apply. For example, state/federal privacy rules or current federal controlled substances act requirements. Though not a complete list, the following examples with notes on their application are provided for consideration.

- **JCPP—Pharmacists' Patient Care Process (PPCP), May 2025.** Compared to the previous version (2014), the 2025 PPCP (**Figure 1**) includes a stronger emphasis on health equity, social determinants, team-based collaboration, and expanded scopes of practice. The process applies across all pharmacy practice settings. Consider using the PPCP as the spine for clinical P&P (e.g., medication reconciliation, comprehensive medication management, chronic disease protocols). Readers may wish to the review the Pharmacist Spotlight: Documentation for additional perspective on the PPCP.

Figure 1*

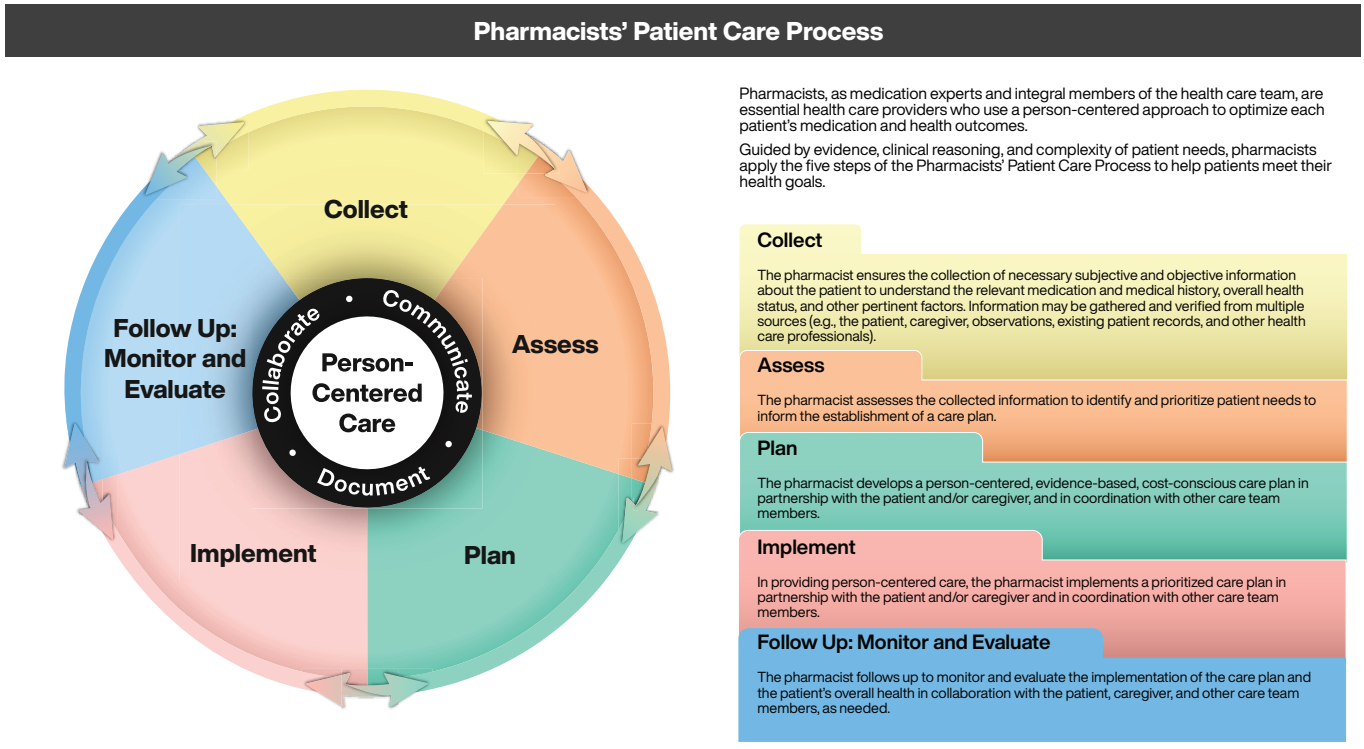


*Image used with permission. *Joint Commission of Pharmacy Practitioners. Pharmacists' Patient Care Process. May 20, 2025.* Available at: https://jcpp.net/wp-content/uploads/2018/10/Pharmacists-Patient-Care-Process-Document-2025.pdf.

- **ISMP Targeted Medication Safety Best Practices.** As one component of pharmacy P&P, consider embedding applicable ISMP Best Practices that support daily workflows and audits. Examples are provided. Please refer to the full Best Practice resources for all topics and full details.

  – **2025-2026 ISMP Targeted Medication Safety Best Practices for Community Pharmacy.** The ISMP Best Practices provide specific actions to help stop recurring serious and/or fatal harm in community practice, including:

  - Use a minimum of two patient identifiers.
  - Implement barcode verification technology.
  - Require a weekly (not daily) default for oral methotrexate in electronic pharmacy systems, along with other safeguards.
  - Use milliliter (mL) for all liquid medications from prescribing to dispensing, and home administration.
  - Institute P&P related to vaccine processes (e.g., vaccine storage, patient consent, counseling, identification, vaccine administration) as well as for required provider education and competency assessments.

  – **2024-2025 ISMP Targeted Medication Safety Best Practices for Hospitals.** These hospital Best Practices are intended to mobilize widespread implementation of effective consensus-based preventions for safety issues that persist in hospital and other institutional settings, causing harmful and fatal medication errors.

  - Dispense vinCRIStine and other vinca alkaloids in a compatible minibag, not in a syringe.
  - Require a weekly (not daily) default for oral methotrexate in electronic pharmacy systems, along with other safeguards.
  - Weigh all patients as soon as possible on admission and for outpatient/emergency treatment visits. Do not rely on historical or estimated weight.
  - Separate and differentiate neuromuscular blocking agents from other medications in all areas where they are stored and available.
  - Implement the use of workflow management systems for sterile compounding. Also refer to additional ISMP Guidelines on the safe use of compounding technology.

  – **ASHP Statements and Guidelines.** The items listed on the ASHP Guidelines and Statements web pages address numerous topics that may apply to pharmacy and/or organizational P&P. Many will aid in the development of an end-to-end medication-safety program, including the use of multidisciplinary teams focused on medication safety and continuous quality improvement. Examples include:

  - Implementing or improving an adverse drug reaction (ADR) monitoring and reporting program. Key definitions, the features of a comprehensive ADR program, and the pharmacist's role in ADR monitoring and reporting will facilitate P&P development.
  - Similar to community/ambulatory pharmacy, the ASHP statement on the use of barcode technology (or other similar/improved technologies that become available) should be an integral part of medication safety and administration systems for hospitals and health systems. It is important that P&P are developed and updated in a multidisciplinary team environment that includes pharmacists, nurses, and other professionals as appropriate.
  - It is encouraging that reports indicate that barcode technology is nearing universal acceptance in the hospital/health system setting, with impressive results in medication error reductions. However, the reports also indicate room for improvement, as some hospitals have not adopted the technology or have not implemented its use in all units that would benefit.
  - The ASHP guideline on preventing medication errors in hospitals is a rich information source for planning appropriate P&P to support safe medication practices. Importantly, it is essential to include risk assessment during the initial P&P planning process and at later times, to identify P&P gaps and improvement opportunities.

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
- Safety Culture
- De-escalation and Crisis Management
- Workplace Issues and Well-being

Visit www.hpso.com/pharmacistclaimreport

Top Claim Drivers

Pharmacist Professional Liability Exposure Claim Report Finding Highlights*

Wrong drug: The most common allegation against pharmacists in the 3rd Edition Report, comprising 41.7 percent of closed claims. The average total incurred increased 16.3 percent since the previous report.

Examples of policy and procedure issues associated with wrong drug claims in the 3rd Edition Report dataset include barcode workarounds, automated warning overrides and inadequate/undocumented staff training.

Wrong dose/strength: The second most common allegation with an average total incurred that rose to $72,972, a 46 percent increase.

A patient's prescription for simvastatin 40 mg was filled in error with the 80 mg strength (3rd Edition Report), resulting in patient injury (weakness, rhabdomyolysis). The pharmacist did not follow the pharmacy's procedure when a computer system alert warned of restrictions for the 80 mg/day dose. The total incurred was more than $350,000.

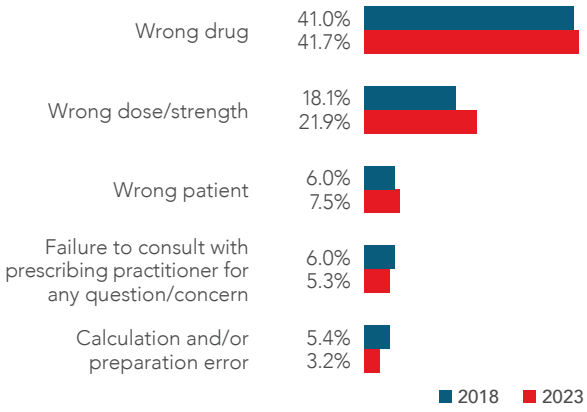
Calculation/preparation errors: Although less common than other top claim allegations, the average total incurred of $413,598 is more than three times the overall average of $136,000.

One 3rd Edition Report claim was associated with a failure to follow the procedure for an independent double-check of the active ingredient compounding calculation. The case resulted in a settlement with a total incurred of more than $450,000.

*Refer to the full 3rd Edition Report for additional details and findings.

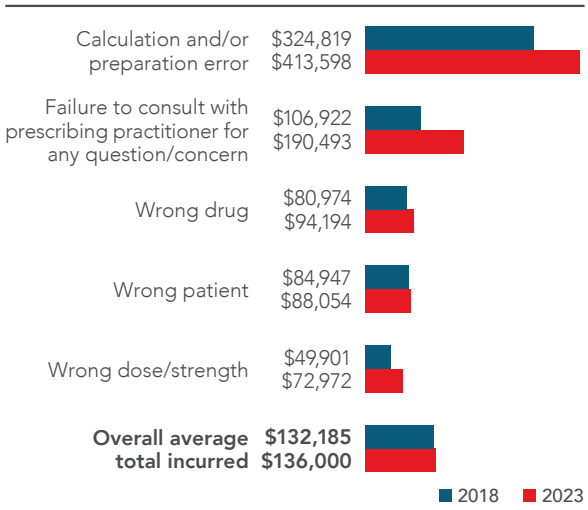
8 Distribution of Closed Claims by Top 5 Most Common Allegations

Closed Claims with Paid Indemnity of ≥ $1



9 Average Total Incurred by Top 5 Most Common Allegations

Closed Claims with Paid Indemnity of ≥ $1



P&P Examples: Error Prevention, Claim Scenarios, and More

The items in this section provide P&P considerations related to two claim scenarios, as well as incident/error response and P&P metrics.

1. Right-Patient, Right-Bag: Two Identifiers at Every Touch

Essential P&P Considerations.

- Require two patient identifiers (e.g., full name plus date of birth) at: intake, callbacks, order transfer, point of sale (POS), home delivery, and immunization. Electronic POS should block completion until verified.
- Prescription bag. Check and review the label and contents with the patient, document counseling or counseling refusal. Conduct periodic quality observations of the patient identification process.

Why: Wrong-patient bag handoffs are a leading consumer-reported error in community pharmacy; two-identifier verification and POS prompts are effective error reduction methods.

CASE STUDY.

A 62-year-old male patient with several health conditions picked up multiple prescription refills at a local pharmacy. Several days later, the patient began suffering epistaxis. The problem worsened, and the patient sought care at the hospital emergency department. Investigation of the patient's medication list and current prescription bottles revealed the problem. In addition to clopidogrel for coronary artery disease, the patient had been taking warfarin in error. The prescription bottle presented was intended for another patient with the same last name. With an INR of more than 10.5, the patient was hospitalized, treated with vitamin K, and released three days later. Total incurred was more than $75,000.

What went wrong?

- The pharmacist was working on more than one prescription at a time. In this case, two patients with the same last name had requested refills and intended to pick them up on the same day.
- The pharmacist became distracted and placed one prescription bottle in the wrong patient's bag.
- No one reviewed the prescription medications and labels with the patient at the POS to confirm that everything was correct. An offer for patient medication review and counseling was not documented.

2. Wrong Drug and Oral Methotrexate Safety (Non-oncologic Indications)

Essential P&P Consideration.

- Require a minimum of five letters of a drug name be entered into the pharmacy electronic medication system.
- Consider judicious use of independent double-checks as one component of risk and error reduction strategies.
- Require an indication on the prescription.
- Default to weekly dosing for methotrexate in the electronic medication system, with hard stops blocking daily frequency for non-oncology use.
- Apply auxiliary labeling for methotrexate such as "Weekly dose—serious harm if taken daily" and documented patient counseling.

Why: As one safety strategy, consider a five-letter policy to significantly reduce the choices presented in electronic system menus, helping to mitigate the risk of selection errors. Selective use of independent double-checks are another method to reduce errors, but should not be relied upon as the sole error prevention strategy. Outpatient oral methotrexate errors continue as an all too frequent source of serious and life-threatening errors in the community setting. A weekly dose hard stop and explicit indication avert common errors.

CASE STUDY.

An elderly hypertensive patient in an assisted living facility received a new prescription for metolazone 2.5 mg. A local pharmacy that supplied most medications for residents of the facility received and filled the order. The assisted living facility staff administered the medication for approximately three weeks. During this time, the patient began to feel ill and became increasingly weak. Complaints of GI distress, nausea, and vomiting occurred , followed by GI bleeding. The patient was hospitalized with severe pancytopenia. Further investigation revealed that the patient's metolazone 2.5 mg prescription was written correctly. However, the pharmacy dispensed methotrexate 2.5 mg. The patient's condition continued to decline, and they expired soon after hospital admission. Total incurred costs were more than $1,000,000.

What went wrong?

- The initial error in a chain of events involved selection of the wrong medication when the technician entered only three letters ("met") into the medication database.
- A pharmacy intern reviewed the filled prescription but did not double-check it against the original prescription order.
- The pharmacist did not review or double-check the filled prescription, having delegated that responsibility to a pharmacy intern, contrary to state preceptor requirements.
- The prescription did not include an indication for use.

3. Incident Response: Disclosure, Just Culture & Root Cause Analysis (RCA)

Principles. Adopt a just culture. Differentiate human error, at-risk behavior, and reckless behavior; respond proportionately; and focus on system defenses and learning. Communicate internally and with patients/families transparently when harm occurs. Document facts, interventions, and followup.

Essential P&P Considerations.

- **Immediate actions.** Address patient harm/stabilize patient, verify facts, sequester products/records, notify leadership, and open an incident record.
- **RCA/learning.** Convene a multidisciplinary team; map the medicationuse process; analyze contributory factors (workload, technology usability, design, environment); implement corrective and preventive actions (CAPA) with effectiveness checks and share learnings.
- **Reporting.** Comply with state board requirements as applicable. Consider incorporation of voluntary reports to FDA MedWatch and patient safety organizations as appropriate.

4. Measurement & Monitoring: Audits and Safety Metrics

Define a balanced scorecard and audit calendar.

Possible P&P compliance/safety metrics: community/ambulatory setting

- Percent of prescriptions with two-identifier verification at POS; barcode mismatch rates and overrides; percent of mL-only labels/devices for liquids; methotrexate weekly hard-stop overrides; vaccine prep deviations; return to stock exceptions resolved within 24h.

Possible P&P compliance/safety metrics: institutional setting

- **Barcode** utilization in inventory, compounding, automated dispensing cabinet restock and dispensing; high-alert compliance measures; compounding personnel competency pass rates; environmental excursions investigated/closed on time; medication reconciliation at admission/discharge.

Programmatic P&P compliance/safety metrics (both settings)

- Near-miss reporting rate; CAPA closure timeliness; staff training completion on revised P&P; audit findings trended quarter-over-quarter.

The Role of P&P in Professional Liability Litigation

Allegations of noncompliance with written P&P may be associated with professional liability lawsuits, especially those involving inadequate training and/or substandard care. On the other hand, healthcare organizations must prioritize safety over adherence to flawed procedures. When P&P are found to be unclear, burdensome or unsafe, it is incumbent upon pharmacists and other affected personnel to speak up and propose changes.

See "*Managing Unsafe Procedures and Work Practices.*"

P&P may be requested during the discovery phase of a trial to determine whether an organization has appropriately addressed safety issues and to determine adherence to its articulated procedures.

In such a situation, the best defense is to prove that the care in question was undertaken in good faith compliance with established procedures. Documentation of the P&P current at the time of the medication error or related adverse event, and of staff training on the established practice(s), will aid in the lawsuit defense. If it is revealed that written policies pertinent to the allegations were not developed and/or implemented, then defending the pharmacist/pharmacy may be more difficult.

At a minimum, be prepared to produce documentation that the P&P in question were:

- Implemented and effective at the time of the incident.
- Approved by leadership and other individuals described in the pharmacy's internal P&P process, such as the pharmacist-in-charge (PIC), pharmacy manager/director, and/or other responsible personnel.
- Included in staff orientation, pre-implementation P&P training sessions, periodic refreshers, and/or professional development programs, and its importance explained to attendees. Track completion and competency sign offs. Maintain personnel files with documented P&P acknowledgment and training.
- Incorporated into staff handbooks, P&P manuals or similar documentation that is readily available to all pharmacy team members.
- Reviewed and revised on a scheduled basis.

In most cases, the defendant is expected to provide an index of pertinent policy manuals, from which the plaintiff requests selected documents. The defendant pharmacist/pharmacy bears the burden of proving that a request for written policies and procedures is unreasonable. Responding that an obsolete policy can no longer be produced weakens the defense position.

To prevent such situations, ensure that outdated or modified P&P are properly archived, preferably in a computerized system and in accordance with specific state retention policies for your organization. Align P&P and training record retention with federal/state requirements and accreditation body expectations.

Organizations should be able to retrieve the following information in a timely manner:

- Dates when the policies and procedures were created and/or revised.
- Location of outdated policies.
- Names of those requesting policy revision or elimination.
- Reasons for policy revision or elimination.

Managing Unsafe Procedures and Work Practices

Consistent with ISMP's Key Elements of the Medication Use System™ and the 2025-2026 Targeted Medication Safety Best Practices for Community Pharmacy, pharmacies should have a defined process for promptly identifying, correcting, and monitoring procedures that are found to be unsafe.

At a minimum, this process should include:

1. Immediate control of the activity deemed as unsafe. Escalate the concern to pharmacy leadership; apply approved temporary safeguards.
2. Documentation of the safety concern, procedure name/number and other details.
3. Performing a system-based risk assessment.
4. Revision of the affected procedure.
5. Leadership approval and staff training.
6. Monitoring for effectiveness and sustainability.

Conclusion

Written policies and procedures serve as an operating framework within which essential clinical and administrative tasks can be accomplished in a systematic and consistent manner. In addition to promoting patient safety, written policies may help defend allegations of negligence by demonstrating an adherence to the standard of care. However, policies also may become a potential source of liability exposure or a challenge to the defense of a claim if they are not aligned with current operational, clinical, and patient safety practices and/or are not consistently followed.

Pharmacists, pharmacy owners, and pharmacy leaders should remain vigilant in monitoring compliance and maintain documentation of all staff training, including orientation of new employees. By adhering to requirements and best practices that meet the standard of care, formal policies and procedures may protect patients, employees, and the organization by providing guidance for decision-making, internal processes, and compliance with laws and regulations.

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

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