Pharmacist Spotlight: Documentation

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: www.hpso.com/pharmacistclaimreport.

This Pharmacist Spotlight focuses on analysis and risk control recommendations for one of the most significant topics related to patient safety and the defense of malpractice claims: **Documentation**.

Introduction

Accurate and comprehensive documentation and consistent record retention practices align with the ongoing professional evolution of pharmacy practice. Although safely dispensing medication is at the core of pharmacy practice, today's pharmacists provide a range of safe and consistent medication-related patient care services. The Pharmacists' Patient Care Process and the ongoing digital transformation to the interoperable Pharmacist eCare Plan standard support greater access to patients' electronic healthcare records. These initiatives will increase the value and impact of pharmacy services across all practice settings.

As pharmacy practice continues to evolve, documentation will remain essential to safe care, whether for patient consultation/education and dispensing activities, or for an expanding list of pharmacy patient care services such as medication optimization, prevention and wellness activities, chronic case management, or acute care management. From a risk management and legal perspective, documentation will continue to form the basis of an effective case defense, in the event of a claim or litigation.

Irrespective of the setting in which a pharmacist is working, inadequate documentation may lead to serious patient safety issues and adverse events. Moreover, if an adverse event leads to the assertion of a claim, lawsuit, or licensing board complaint, inadequate documentation may significantly hinder a pharmacist's legal defense and/or result in board sanctions. Actions taken by a pharmacy board may range from a reprimand and/or civil monetary penalty, up to and including license suspension or revocation.

Allegations Involving Pharmacist Documentation

Professional liability and license defense claims rarely involve only one allegation or concern. Claim reviews and board investigations often reveal documentation issues that contribute to deviations from accepted professional practice. As a result, documentation-related issues may frequently be considered as contributory to the primary allegation and adverse outcome, rather than the primary allegation.

For professional liability (i.e., negligence) claims, inadequate or incomplete documentation is one of the most common recordkeeping issues. For example, missing information about a drug allergy or an incomplete medication list are two scenarios that may lead to significant patient injury and professional liability. Other documentation errors and inaccuracies may occur at any point in the medication use process or patient care process and may lead to an adverse event or injury in the absence of adequate safety controls. In contrast and as previously noted, comprehensive documentation may form the basis for an effective defense, as in the following example.

Alleged Wrongful Death—Documentation Results in a Successful Defense

A 63-year-old male patient with multiple, serious health conditions had not been gainfully employed for five years due to medical disability. The patient was taking more than 20 medications for COPD, type 2 diabetes, hypertension and pain associated with lower back and hip joint problems. Despite shortness of breath and multiple cessation attempts, his 30-year pack per day smoking habit continued.

During the two weeks prior to his death, the patient received multiple medication orders from the defendant pharmacist, including refills for a calcium channel blocker (verapamil) as well as citalopram, prescribed for generalized anxiety disorder. He also received a new prescription for tamsulosin to treat urinary hesitancy. Several days after receiving the medications, he collapsed at home and his spouse found him unresponsive. She called 911 and after transport to the hospital emergency department, efforts to resuscitate the patient were not successful.

Eighteen months later, the patient's spouse filed suit against the pharmacy for wrongful death from myocardial infarction, alleging a failure to counsel the patient about a potential drug interaction. The Complaint asserted that tamsulosin created a significant risk (primarily related to verapamil and citalopram), leading to the patient's death.

The pharmacy's procedures for filling prescriptions included confirming that medication counseling is offered, provided (or declined) *and documented*. Moreover, the pharmacist informed his attorney that he performed a medication review prior to dispensing and found no clinically significant drug-drug interactions. The attorney and pharmacist agreed that the patient's death involved a complex medical history and multiple cardiovascular risk factors. The attorney believed that the baseless allegations may have represented an attempt by the plaintiff or plaintiff counsel to obtain a pre-trial settlement.

The pharmacologist defense expert supported the pharmacist's actions and testified that, in his opinion, the standard of care had been met. The pharmacy records also documented that medication counseling had been offered and provided. The pharmacist found no clinically significant drug-drug interaction with the addition of tamsulosin. The counseling documentation was consistent with the defense position that the drug interaction allegation was baseless.

The patient's spouse testified that she pursued the lawsuit based upon medical test results before her husband's death. A few months prior to his death, his complaint of chest pain was investigated by a cardiologist, and coronary artery catheterization findings were negative. Plaintiff counsel also identified a medical expert who opined that the patient's medications contributed to his death. However, the expert was unable to provide convincing supporting evidence.

The defense built a strong case with a high probability of success. Important factors included:

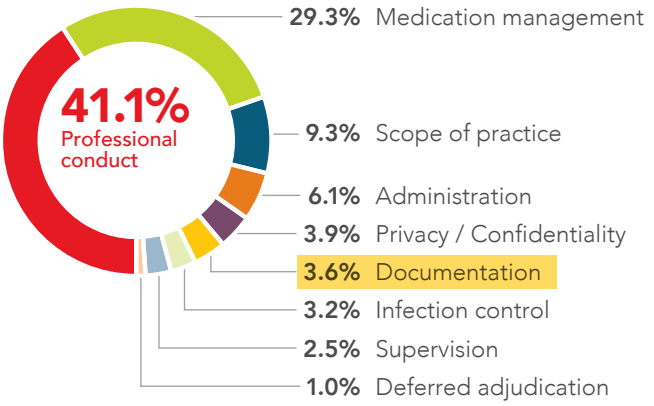
- A defendant pharmacist whose medication counseling procedures, patient communication, careful prescription review and associated recordkeeping met or exceeded the standard of care.
- Appropriate experts to strengthen the defense and identify plaintiff case gaps and weaknesses.
- Full engagement of the insured pharmacist with claim professionals and legal counsel.

Defense counsel submitted a Motion for Summary Judgment. Soon after, the plaintiff voluntarily withdrew the action prior to the court's decision on the Motion.

As with professional liability matters, the primary allegation may involve documentation issues. Or, documentation lapses may be considered as contributory to the primary allegation. Although documentation deficiencies are often identified during licensing board investigations, claims involving documentation as a primary allegation against pharmacists are relatively uncommon, as displayed in **Figure 1**.

Claims in which documentation issues are the primary allegation comprise 3.6 percent of all license defense matters in the *Pharmacist Professional Liability Exposure Claim Report: 3rd Edition* dataset. Examples of documentation-related allegations may include failure to document care/treatment as required by law, regulation or agency/facility procedures, as well as fraudulent or falsified patient care or billing records.

1 **License Defense Matters by Primary Allegation Class**



As a contributory allegation, inadequate, erroneous or fraudulent documentation may often be associated with allegations involving medication management, privacy issues, infection control matters and other allegation classes. Whether primary or contributory, documentation issues may have severe legal and patient safety consequences and should not be discounted or minimized based solely upon the primary allegation class.

The following license defense matter describes a case of alleged documentation fraud, leading to sanctions against an insured pharmacist.

Alleged Fraudulent Documentation for Medication Therapy Management

An administrative complaint was filed against the insured pharmacist employed as a community pharmacy medication therapy manager. The investigation revealed that documented medication therapy management (MTM) services for certain individuals did not, in fact, occur. In one case, the documented telephone consultation was documented to have occurred several weeks after the patient's death.

The insured pharmacist testified that his practice is to plan medication therapy management encounters in advance, documenting the information on paper forms. The information was then entered into the online software later. He explained that the incidents were simply unintentional errors and that the uncompleted encounter forms were inadvertently placed among completed consultation forms.

The pharmacist agreed that his documentation process was flawed and upon completion of the investigation process, the Disciplinary Subcommittee's proposed consent order was accepted and signed by all parties. The consent order delineated several counts of negligence, as well as "fraud or deceit" by attempting to obtain reimbursement for services not rendered. The case resulted in sanctions against the insured pharmacist (two years' probation, continuing education and a $2,000 fine) and defense payments of more than $10,000.

Community/Ambulatory Care Pharmacy Documentation

There may be barriers to completing comprehensive documentation in any busy healthcare environment, including pharmacy practice. However, as pharmacy practice continues to evolve, it is anticipated that documentation will remain paramount to patient safety, or increase in importance. Refer to Page 6 for information about a newly developed tool or "rubric" that may be used to evaluate community-based pharmacy patient record systems. In addition, the following documentation considerations may aid community-based pharmacists, such as those practicing in community pharmacies and ambulatory care clinics, in risk mitigation related to documentation practices.

- Obtain complete patient information and update this during each encounter. The information should include the patient's full name, address, telephone (home/cell), email address, date of birth and any known allergies. Obtain and maintain a current medication list (prescription and over-the-counter medications) with drug name, strength, frequency, route of administration, and its indication.

- Obtain and update essential information about the patient's health conditions including chronic disease states such as hypertension, diabetes, coronary artery disease, heart failure, etc.
- In compliance with pharmacy and regulatory requirements, *document in patient/pharmacy records all discussions with patients, parents/guardians, caregivers, and prescribing practitioners.* Document discussions with pharmacy team members and other health care professionals that are relevant to medication therapy, dispensing activities and decisions, and recommendations and patient counseling that are provided. Examples include:
  - Questions posed to and responses from prescribing practitioners regarding prescription details, the patient's medical history, medication indication for use, or medication therapy options.
  - For those drugs where it is clinically required, review and document relevant laboratory test results. If indicated based on test results, consult with the prescribing practitioner to modify the patient's prescription, and document those actions.
  - With respect to education and medication counseling activities, document that patients are able to describe and that they understand proper use of the medication, potential adverse effects, and signs of important adverse effects or an allergic reaction. In addition, require patients to sign a form attesting that they have received—or have refused—counseling. The refusal attestation should include an acknowledgment that the patient medications may present risks.
  - If a medication has been prescribed for an off-label use, advise the patient to discuss the reason for taking the medication with the prescribing practitioner, potential adverse effects and the rationale for its use over other medication options.
  - If the prescription is unclear or an error is suspected, and the prescribing practitioner is not available, inform the patient and explain that in order to ensure safety, the prescription cannot be dispensed until you are able to consult with the prescriber. The patient may wish to contact the practitioner to facilitate this communication. If the delay in initiating drug therapy may pose a patient hazard, consider recommending that the patient seek emergency medical care.
- *Examine and review every medication with the patient before placing it into the patient's bag, in order to ensure that the correct medications have been prepared and dispensed.* Document this discussion and review. The patient must be aware of both the medication brand and generic names (when applicable), as well as their correct appearance. At this juncture, advise the patient of a change in the medication appearance (shape or color) from that which was previously dispensed and document this discussion. These changes may be due to a change in the drug's supplier, or perhaps the prescriber ordered a different medication strength.
- *Document any patient requests for non-childproof packaging* and require the patient to sign for any non-safety bottle caps dispensed.

If appropriate for their practice, pharmacists may wish to access extensive information available on the Centers for Medicare & Medicaid Services Pharmacy Toolkits web page. Specifically related to documentation, consider reviewing the Pharmacy Self-Auditing Toolkit on the toolkit page, and the associated Checklist. This toolkit offers many documentation recommendations related to prescribing practices, controlled substance management, invoice management and billing practices.

Immediately **contact your professional liability insurer** if you become aware of a filed or potential **professional liability matter against you**.

Health-System and Facility Documentation

Pharmacists should understand and comply with documentation related policies and procedures specific to the health system/facility in which they practice. Ideally, the pharmacy department should establish pharmaceutical care policies and procedures, and/or be directly involved in the development of relevant health system/facility policies and procedures, especially those related to the medication-use process.

In addition, pharmacists may wish to access long-standing guidelines issued by the American Society of Health-System Pharmacists (ASHP) regarding the documentation of pharmaceutical care in patient medical records to ensure that the organization's practices meet the needs of pharmacy practice and patient care services. Key points from the guidelines include but are not limited to:

- If necessary, work with appropriate internal personnel, committees or others to obtain authorization for entry of pharmaceutical care documentation in the patient medical record (PMR).
- Comply with established criteria for PMR for completeness, clarity and non-judgmental language.
- Follow the preferred documentation format when appropriate, such as "SOAP" (subjective, objective, assessment and plan), or "TITRS" (title, introduction, text, recommendation and signature).
- Pharmaceutical care documentation may include, but is not limited to:
  - Medication history, allergies, or other adverse reactions
  - Documentation of consultations provided regarding drug therapy and management
  - Prescriber medication orders received by the pharmacist
  - Drug order clarifications, dose/frequency/dosage form/administration route changes or adjustments
  - Medications administered.
  - Actual/suspected medication-related problems that require monitoring and follow-up
  - Drug therapy monitoring findings and related recommendations
  - Patient medication education and counseling
- Develop/implement quality indicators and include pharmaceutical care documentation within the organization's continuous quality improvement processes.

Additional information regarding the documentation of patient encounters and general health record documentation practices may be accessed on the Centers for Medicare & Medicaid Services Documentation Matters Toolkit web page.

Conclusion

Across all healthcare disciplines, risk managers and patient safety officers often advise and remind practitioners of the mantra, "not documented, not done". As pharmacy practice continues to change and evolve, in all practice settings, documentation plays a key role in the provision of safe pharmacy services, transparent interprofessional communication, and accurate billing. Finally, when pharmacy patient care services allegedly result in a professional liability claim, lawsuit or license defense matter, comprehensive documentation is essential to case defense.

PHARMACIST SPOTLIGHTS ON RISK MANAGEMENT

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

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

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Pharmacists' Patient Care Plan and the Pharmacist eCare Plan (PeCP) Initiative: Enhancing Collaboration, Documentation and Communication for Consistent Pharmacy Services.

Access to patient information and documentation of pharmacy services are critical to safe care. The 2014 Publication of the Pharmacists' Patient Care Process (PPCP) by the Joint Commission of Pharmacy Practitioners (JCPP) provided a consistent patient care process applicable to pharmacists in all practice settings (**Figure 2**). With *collaboration, documentation and communication* at its core, the PPCP aligns with the processes of other healthcare professionals, while addressing the unique medication-related aspects of pharmacy. The PPCP became the cornerstone for development of an electronic clinical workflow within pharmacy systems: the Pharmacist eCare Plan (PeCP) Initiative. Implementation of the PeCP will facilitate consistent documentation of pharmacy services, electronic exchange of critical patient information, and collaboration among healthcare professionals. Additional background and status of the initiative follows.

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Image used with permission. Joint Commission of Pharmacy Practitioners. Pharmacists' Patient Care Process. May 29, 2014. Available at: https://jcpp.net/wp-content/uploads/2016/03/PatientCareProcess-with-supporting-organizations.pdf.

- JCPP* was established in 1977 as a forum for addressing common issues among national pharmacy organizations.
- The PPCP describes use of evidence-based practice principles to guide pharmacists as they:
  - Collect and assess information about the patient and their medication history.
  - Collaborate with the patient and other healthcare professionals to plan and implement an individualized patient-centered medication-related care plan.
  - Follow-up, monitor and evaluate the effectiveness of the care plan, and collaboratively implement appropriate plan modifications.
- The PPCP is enhanced by the use of a standard, interoperable pharmacy system technology that will support and facilitate communication and collaboration described in the process.
- Although the details of PeCP research, and the collaboration/development process resulting in the interoperable standard, are beyond the scope of this Spotlight, further information may be found on the Pharmacy Health Information Technology Collaborative (PHIT) website, including this February 20121 press release and on the Collaborative Outreach page of the PHIT website.

*JCCP member organizations are listed here.

Essential Elements and Functionalities for a Community Pharmacy Patient Record System

McDonough and co-authors (2023, see **Additional Resources**) describe the development of a tool designed to facilitate the assessment of pharmacy software. The tool applies key elements and functionalities determined to be necessary for pharmacy patient care encounters and records. Compliant systems will facilitate effective documentation and improved patient, provider and payer communication. In community pharmacy, patient care activities require a robust patient record system with multiple functionalities to meet the demands of an evolving profession (e.g., the PeCP standard).

The Community-based Pharmacy Patient Record Clinical Rubric:

- Development of the tool was accomplished using an online Delphi method. The expert panel consisted of 26 individuals, including pharmacy practitioners, PeCP vendors, pharmacy payers, government personnel and health information technology experts.
- The panel considered and reached consensus on 46 key elements of pharmacy patient record systems. The elements involve three areas:
  - Longitudinal pharmacy patient record (including patient demographics, therapy goals and past medical history)
  - Single patient encounter (such as encounter date/time and history of present illness)
  - Functionalities of a pharmacy patient record system (including filtering/sorting capabilities, a "dashboard" view to aid metric analysis, efficient documentation processes, and secure transmission features).
- In closing the article, the authors note that, "Pharmacists, organizations and vendors are encouraged to utilize the rubric in evaluating their documentation software to ensure that it meets the needs of pharmacy practitioners who are providing patient care services."

Additional Resources

Although hyperlinked website pages and documents in the Spotlight text are freely accessible, the following documents in the professional literature require APhA membership or a subscription to the *Journal of the American Pharmacists Association* for full text access. Abstracts are accessible at the URLs provided.

- McDonough RP, Fish H, Satterfield J, Roberts K, Clifton CL, Doucette WR, Determining Essential Elements and Functionalities for a Patient Record System in Community Pharmacy, *Journal of the American Pharmacists Association* (11/2023), DOI: https://doi.org/10.1016/j.japh.2023.10.033. Accessed November 10, 2023.
- Baggett AC, Dorval E, Balou JM, Dalton E, Rhodes LA, Barriers and Best Practices Related to Documentation of Electronic Care Plans: A Survey of Community-based Pharmacies in 4 States, *Journal of the American Pharmacists Association* (11/2021), DOI: https://doi.org/10.1016/j.japh.2021.11.016. Accessed November 10, 2023.
- Jindal N, Clifton C, Trahms K, Roberts K, Rhodes LA, Marciniak W, Community-based pharmacy Use of the Pharmacist eCare Plan: A Retrospective Review, *Journal of the American Pharmacists Association* (12/2020). DOI: https://doi.org/10.1016/j.japh.2020.12.023. Accessed November 10, 2023.
- Spiro S, Digital Transformation of Pharmacists' Clinical Services, *Journal of the American Pharmacists Association* (10/2018), DOI: https://doi.org/10.1016/j.japh.2018.10.016. Accessed November 10, 2023.

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In addition to this publication, CNA and Healthcare Providers Service Organization (HPSO) have produced numerous studies and articles that provide useful risk control information on topics relevant to pharmacists, as well as information relating to pharmacist insurance, at www.hpso.com. These publications are also available by contacting CNA at 1-866-262-0540 or at www.cna.com.

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