LEGAL RISK MANAGEMENT OPPORTUNITIES, PHARMACY PRACTICE, AND P&T COMMITTEES

Part 2: Risk Management Recommendations

James O’Donnell, PharmD; and F. Randy Vogenberg, RPh, PhD

INTRODUCTION

In the first installment of this two-part series, we presented the types and frequency of dispensing errors that result in malpractice claims, as reported in the CNA/Healthcare Providers Service Organization (HPSO) “2013 Pharmacist Liability” report.1 Wrong-drug and wrong-dose errors were the most common causes of monetary settlements or verdicts paid by this insurer.2 The findings in this report were similar to those of two separate CNA analyses of closed professional liability claims against nurses and nurse practitioners.3,4

RISK MANAGEMENT RECOMMENDATIONS

The CNA/HPSO pharmacist study also provides recommendations for avoiding errors, injuries, and claims. As the report warns, “Dispensing of any medication involves potential risk, and every possible safeguard must be undertaken to prevent errors.”5 Some of the strategies recommended by the authors are presented in Table 1.

These recommendations derive from legal or regulatory risks that have resulted in liability claims against health care professionals; they overlap with safe-medication practices and other best practices in patient safety. Additional risk management recommendations include pharmacist collaboration with pharmacies and colleagues at least annually to assess workplace safety practices. CNA/HPSO recommends the Institute for Safe Medication Practice’s Medication Safety Self-Assessment and the Agency for Healthcare Research and Quality’s Pharmacy Survey on Patient Safety Culture as useful tools for accomplishing this objective.6

SUGGESTIONS FOR PHARMACISTS AND ALLIED HEALTH PROFESSIONALS

William N. Kelly, PharmD, FISPE, a professional colleague and pharmacist, developed a “top 10” list of recommendations for pharmacist risk management. These recommendations are presented below, followed by the application of some of these suggestions to make them relevant to the pharmacist in the practice setting. Dr. Kelly’s recommendations are as follows:

2. Counsel every patient.
3. When in doubt, ask another pharmacist or call the prescriber.
4. Be careful when you have to open procedures.
5. Do not let technicians bypass any safety alerts. Never give the technician your bypass code. This is the pharmacist’s responsibility.
6. Read, know, and follow your employer’s pharmacy policies and procedures.
7. Document all errors.
8. Have someone else, even if he or she is a technician, check your calculations.
9. Always review the patient’s medication history before dispensing a prescription.
10. Always list the patient’s drug allergies, and document what happens when a patient takes a drug to which he or she is said to be allergic.

Based on personal expert-witness experience and Dr. Kelly’s suggestions, the following case examples illustrate risk-management situations that are common in health care settings. It is better to learn from the tragedies of others than to repeat the same flawed strategies yourself.


Besides demonstrating the need to think and ask questions, the following incident also addresses several other suggestions, such as calling the prescriber and reviewing the medication history. A 46-year-old man was treated for minor trauma in a local emergency department (ED). He was given a prescription for a fentanyl patch with a stated dose of 75 mcg/hour. His brother took the prescription to a local pharmacy. The prescription was legal on pharmacy. The prescription was legal on its face. However, the pharmacist failed to inquire about the patient’s opiate history, which is particularly vital with opiate-naïve patients. Transdermal patches (e.g., Duragesic) are contraindicated in patients who are not opioid tolerant. The pharmacist also ignored the caution that fentanyl patches are contraindicated for acute pain. The pharmacist did not call the prescriber, who had inadvertently written 75 mcg/hour on the prescription when she intended to write 25 mcg/hour, as she noted in the ED record. The patient died in his sleep the next day.

Either an inquiry about the patient’s opiate history or a call to the prescriber would have prevented the error. If the
prescriber had insisted that the dose was correct and if, perhaps, the patient had opiate tolerance, the overdose would probably have been avoided, and the patient might have survived.

**When in Doubt, Ask Another Pharmacist or Call the Prescriber**

The following example also encompasses multiple recommendations. A young hospital pharmacist who had recently finished her residency and doctorate in pharmacy was working alone in a pharmacy satellite. She received an order for colchicine 0.6 mg intravenous (IV) every six hours for an orthopedic patient who was to receive “nothing by mouth” (NPO). A “high dose” alert warning of the 2.4-mg upper cumulative dose limit appeared on the screen; she overrode the alert. No call was made to the prescriber. The patient received 4.8 mg over 48 hours; developed leukopenia and eventually pancytopenia, high fever, and sepsis; and died after a week in the intensive care unit (ICU).

The pharmacist testified that she was unfamiliar with IV colchicine and ignored the alert because she assumed that the prescriber was familiar with the risks. She did not call another pharmacist elsewhere in the hospital or her supervisor. After this incident, the Food and Drug Administration (FDA) removed IV colchicine from the market for safety reasons.

**Counsel Every Patient**

A few years ago, a 60-year-old patient’s primary care physician emailed a prescription for ciprofloxacin to a local pharmacy. The instructions were to take one 500-mg tablet every 12 hours. The prescription was filled after a pre-verification and then a verification process. The verifying pharmacist affixed auxiliary labels to allow pharmacist discretion in the selection of the computer-generated labels. One of the auxiliary labels, however, covered the “1” in the “12”-hour instruction. Subsequently, the patient interpreted the prescription as “1 tablet every 2 hours,” thereby increasing the intended dose sixfold—leading to the patient’s hospitalization.

The verifying pharmacist did not counsel the patient, missing an opportunity for one more inspection of the label during the counseling process. The prescription was picked up at the pharmacy by the patient’s spouse, who declined counseling. The technician testified that she always asks, “Do you have any questions for the pharmacist?”, and recorded that the spouse had no questions. The pharmacy company had a policy to counsel patients (or their designees) for all new prescriptions. The verifying pharmacist and the pharmacy manager both testified that if counseling had been performed, the labeling error would probably have been detected and the patient’s injury avoided.

Asking the patient or a patient’s family member if he or she “has any questions” is somewhat ludicrous, because the patient is, most likely, unfamiliar with the medication. In addition, why would there be an option to counsel when a policy requiring counseling was in place?

**Do Not Let Technicians Bypass Any Safety Alerts**

In a 2013 study (by the malpractice carrier Pharmacists Mutual) of closed

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**Table 1 Risk Management Recommendations Included in the CNA/HPSO Report**

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<thead>
<tr>
<th>Recommendation</th>
<th>Action</th>
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<td>Implement bar-coding technology, robotics, and other tools as appropriate to protect against human error and to ensure patient safety.</td>
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<td>Ensure that each pharmacy computer is programmed to provide comprehensive, current, and automatically updated drug research.</td>
<td>Stay within the pharmacist’s scope of practice.</td>
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<td>Consider any override of a computerized warning to be an incident, and regularly review all overrides to identify system errors, incomplete formulary information, inadequate or improper Sig (directions) codes, practitioner ordering issues, or pharmacist or technician competency issues. Review the pharmacist’s judgment in each incident, and provide coaching, counseling, and re-education as necessary. Incorporate disciplinary action if such efforts do not immediately lead to improved medication-safety practices.</td>
<td>Ensure that pharmacy policies, procedures, and protocols are consistent with that state’s regulations and standards related to pharmacist practice represents a substantial risk.”</td>
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<td>Never assume that similar-sounding names are equivalents. Sound-alike names are one of the major causes of pharmacy errors. Effective measures, such as the use of conspicuous warning labels, should be taken to separate and identify sound-alike drugs.</td>
<td>Provide written patient instructions and counsel the patient about medication regimens. Offer each patient the opportunity to ask questions during and after medication counseling, and document the patient’s response to this offer.</td>
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<td>Speak directly with the prescriber about any questions, including contraindications and potential interactions, related to the prescribed drug. Consult with the supervising pharmacist or pharmacy director as needed.</td>
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<td>Ensure that all prescriptions are checked prior to dispensing, preferably by a second pharmacist. In a single-pharmacist setting, the pharmacist must check each prescription against the original order; verify that the proper drug, dosage, and quantity are dispensed; and confirm that the label, patient instructions, and any warnings are correct.</td>
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<td>Treat pharmacy errors or “near misses” as teaching opportunities for pharmacy staff to prevent similar future events.</td>
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claims against pharmacists, antidepressants are listed as one of the drug classes most frequently involved in mechanical errors (i.e., dispensing errors or wrong-drug errors that reach the patient). A prime example is Elavil (amitriptyline), which is frequently prescribed in a 10-mg dose at bedtime for sedation at night or for urinary frequency in the elderly. A common mistake is to dispense 100 mg, either because of a prescriber error (writing 100 mg but intending to write 10 mg) or a dispensing error (selecting the 100-mg tablet instead of the 10-mg tablet). In a few cases, technicians have overridden the high-dose alerts covering elderly patients, presumably using the pharmacist’s override codes. A patient receiving such an elevated dose could develop severe central nervous system depression, manifest symptoms of toxicity (such as dysrhythmias, severe hypertension, and convulsions), lose balance, and/or fall and hit his or her head, requiring hospitalization. Sadly, some patients never fully recover.

Many factors are involved in medication mistakes, such as the example presented here. High-dose alerts need to be taken seriously, and the prescriber must be called when an alert is detected. A pharmacist should never give override codes to a technician. Consider the usage and the dosage: Amitriptyline is rarely used in 100-mg doses. It is almost always used for sedation in the lower dosage (10 mg). Counseling must occur with this product at least on the first fill. Simply asking, “What did your doctor tell you about this drug?” would likely be enough to confirm that the 100-mg dose was dispensed in error.

SUMMARY
The fields of patient safety and quality in health care continue to evolve in response to various drivers in the U.S. care-delivery system. The claim studies reviewed in part 1 of this series and the recommendations discussed in part 2 come from real-world experience—not an academic exercise or discussion. These studies show that liability problems have plagued health care providers for many years—a fact that should draw the attention of hospital, health-system, and group-practice leaders, as well as their P&T committees.

The problems of wrong-drug, wrong-dose, and other fundamental medication errors persist despite improvements in quality-review systems and technology. Clearly, gaps remain, and vigilance with regard to these issues is required in an era of tighter scrutiny of budgets and health care outcomes in the post-Affordable Care Act environment. The alternative is rapidly increasing litigation costs and loss of licensure and professional standing, not to mention the potential for greater oversight by regulatory bodies and the public.

This two-part insurance claims series serves as an opportunity to address the ongoing risk exposure related to medication use in organized care systems. It is now up to leaders in their respective professional communities and P&T committees to take action on this important issue in patient-care quality.

ACKNOWLEDGEMENTS
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REFERENCES