

CASE STUDY WITH RISK MANAGEMENT STRATEGIES

Presented by HPSO and CNA

Medical malpractice claims can be asserted against any healthcare provider, including pharmacists. Although there may be a perception that physicians are held responsible for the majority of lawsuits, the reality is that pharmacists are more frequently finding themselves defending the care they provide to patients.

Case Study: Alleged Failure to Require and Obtain Properly Completed Prescription Order Form; Failure to Inform Patient that Drug was Experimental in Oral Form; Failure to Adequately Inform Patient of Risks and Side Effects of Prescribed Experimental Medication

Settlement Payment: Mid-policy limits Legal Expenses: \$160,000

Note: There were multiple co-defendants in this claim who are not discussed in this scenario. While there may have been errors/negligent acts on the part of other defendants, the case, comments, and recommendations are limited to the actions of the defendant; the pharmacist.

The 25-year-old decedent/plaintiff had previously suffered severe leg injury and surgery resulting in severe chronic pain, restless leg syndrome and subsequent addiction to prescription pain medication. He was receiving Methadone for unremitting pain. His physician ordered Ketamine tablets to be compounded and dispensed by the co-defendant pharmacy that employed the defendant pharmacist. (This is an “off-label” experimental form of Ketamine, as only injectable Ketamine is FDA approved.)

The plaintiff was previously unknown to this pharmacy and had no prior records, so the defendant pharmacist was not aware of the plaintiff’s current medications. The defendant pharmacist filled the order and dispensed the prescription.

The Prescription Order Form required by the pharmacy for specially compounded drugs was not properly completed by the ordering physician, but the defendant pharmacist dispensed the medication. The defendant pharmacist provided the patient with an education sheet he had drafted for patients receiving oral Ketamine.

Five days after obtaining the oral Ketamine prescription, the plaintiff was found dead by his girlfriend. When the plaintiff’s body was found, there were open prescription bottles of Ketamine, Methadone and Oxycodone within the plaintiff’s reach as witnessed by police and ambulance personnel. The coroner gave the cause of death as Methadone overdose, but experts have opined that the coroner’s determination was inadequate absent autopsy, given the evidence of multiple drug use at the time of the plaintiff’s death. The plaintiff is survived by his girlfriend (domestic partner) and their biological minor child.

Resolution

Negative expert review determined that the defendant as the “pharmacist on duty” deviated from the standard of care when he failed to:

- Consult directly with the prescribing physician to obtain missing patient information required by the pharmacy’s Prescription Order Form for specially compounded drugs
- Query the plaintiff as to his routine medications and current pain medication usage
- Inform the plaintiff that oral Ketamine was an experimental form of the drug
- Counsel the plaintiff regarding the potential adverse effects and side effects of oral Ketamine, including respiratory depression, overdose and interaction with other drugs

Given the multiple departures from the standard of care, the case was settled on behalf of the defendant pharmacist for mid-policy limits with an additional \$160,000 in legal expenses.



Risk Management Comments

- While the defendant pharmacist believed it was the pharmacy's duty to obtain the required Prescription Order Form and to provide the written adverse and side effects of Ketamine he had previously drafted, defense experts determined that both the pharmacy's and the defendant pharmacist's actions were outside the standard of care.
- Regardless of administrative policy, the defendant pharmacist, as the "pharmacist on duty", was responsible for implementing the steps necessary to meet the standard of care in providing the prescription for the plaintiff.

Risk Management Recommendations

- **Contact the prescribing physician to obtain necessary patient information when receiving an incomplete prescription or medication order** or when medical, drug or other relevant patient history is not available.
- **Counsel the patient who is to receive an experimental form of an approved drug** to ensure the patient understands that the drug is experimental in the oral form ordered and the effects and adverse effects of the drug in that form are unknown. Further, ensure that the patient is aware of any known adverse reactions or side effects to the drug.
- **When dispensing a high-risk medication, query the patient to ensure that drugs or medications with known contraindication or adverse interaction** to the high risk medication dispensed are not being taken.
- **When dispensing powerful pain medication, counsel the patient regarding the risks of respiratory depression, overdose and drug interaction** if the drug is used with other prescribed or non-prescribed pain or sedating medication, or if the medication is taken in any manner other than in the dosage and frequency prescribed.
- **Counsel the patient to contact the physician or obtain immediate medical assistance if they experience difficulty breathing or swallowing, confusion, sedation or any other adverse reaction to the medication.**
- **In addition to counseling the patient, provide comprehensive, written Patient Education Information** for inventory medications, including:
 - **Indications for use**
 - **Known contraindications or drug interactions**
 - **Potential side effects, allergic reactions or complications**
 - **Proper dosage and frequency**
 - **Patient warnings, cautions and instructions in case of emergency**

Guide to Sample Risk Management Plan

Risk Management is an integral part of a healthcare professional's standard business practice. Risk management activities include identifying and evaluating risks, followed by implementing the most advantageous methods of reducing or eliminating these risks— A good Risk Management Plan will help you perform these steps quickly and easily!

Visit www.hpso.com/risktemplate to access the Risk Management plan created by HPSO and CNA. We encourage you to use this as a guide to develop your own risk management plan to meet the specific needs of your healthcare practice.



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