

Before the
Administrative Hearing Commission
State of Missouri



MISSOURI BOARD OF PHARMACY,)	
)	
Petitioner,)	
)	
vs.)	No. 14-0197 PH
)	
CARE PHARMACY, LLC,)	
)	
Respondent.)	

DECISION

Care Pharmacy, LLC (“Care Pharmacy”) is subject to discipline for violating the drug laws, rules, and regulations of this state and of the United States.

Procedure

The Missouri Board of Pharmacy (“Board”) filed a complaint on February 6, 2014, seeking this Commission’s determination that Care Pharmacy’s permit is subject to discipline.

We authorized the Board to seek service by publication on July 29, 2014. On September 5, 2014, the Board filed its affidavit of publication, verifying the dissemination of notice of this action for four successive weeks from August 10 through August 31, 2014.

We convened a hearing on October 20, 2014. Care Pharmacy did not appear by counsel or any other person. The Board appeared by Joshua L. Hill of Newman, Comley & Ruth, PC. Care Pharmacy has failed to file an answer or other responsive pleading, and the Board moved

that we deem the facts in its complaint admitted as a sanction. We grant the motion. Regulation 1 CSR 15-3.380(1) and (7).¹ We also received evidence from the Board at the hearing. The matter became ready for our decision on October 23, 2014, when the transcript of the hearing was filed.

Commissioner Nicole Colbert-Bochway, having read the full record including all the evidence, renders the decision for the Commission. Section 536.080.2, RSMo 2000;² *Angelos v. State Bd. of Regis'n for the Healing Arts*, 90 S.W.3d 189 (Mo. App. S.D. 2002).

Findings of Fact

1. Care Pharmacy holds pharmacy permit number 2011012258, which is current and active and was so at all relevant times.
2. Care Pharmacy was owned and operated by Rehela Jamil and Wajid Ali.
3. Care Pharmacy was doing business in St. Louis County, Missouri, at all times relevant to this action.
4. Care Pharmacy employed multiple pharmacists during all relevant times, including Neil Gerstein, Imad Mohammad, Shabana Amir, Mike Elmore and Albert Zvibleman.
5. Prior to August 29, 2011, Pharmacist Albert Zvibleman notified Care Pharmacy ownership that the pharmacy was filling prescriptions without a pharmacist on duty and filling sSchedule II prescriptions prior to receiving the hard copy.

¹ All references to the CSR are to the Missouri Code of State Regulations as current with amendments included in the Missouri Register through the most recent update.

² Further statutory references are to RSMo Cum. Supp. 2013 unless otherwise noted.

Pharmacy Technician Violations

6. During the months of August 2011 through December 2011, Gulbahar Gurlekce was employed by Care Pharmacy, as a pharmacy technician, and her duties included entering prescription information into the computer, counting medications, affixing labels to drugs at Care Pharmacy, and assisting the pharmacists that worked at Care Pharmacy without being registered by the Board.

7. Gurlekce was not registered with the Board as a pharmacy technician until December 28, 2011.³

8. Gurlekce routinely filled prescriptions at Care Pharmacy without a pharmacist on duty and dispensed filled prescriptions to patrons in the absence of a licensed pharmacist on duty and present in the place of business.

9. Computer usernames and passwords assigned to pharmacists that worked at Care Pharmacy were used by non-pharmacists to process prescriptions, fill prescriptions and dispense medications when the pharmacists were not working.

Dispensing Schedule II controlled substances without a written prescription

10. Care Pharmacy did not possess original, hard copies of the following prescriptions when they were dispensed:

#400329 dated August 8, 2011 for Oxycodone/APAP 10/325⁴

#800002 dated September 16, 2011 for Oxycodone 5mg

#200013 dated October 13, 2011 for Morphine ER 100mg⁵

11. Prescriptions for Schedule II drugs were filled and delivered from physician orders sent to Care Pharmacy by facsimile. When those drugs were delivered to the physician's office,

³ The first application received from Gurlekce was denied on October 12, 2011 because it was not accompanied by the required fee.

⁴ Oxycodone is a Schedule II controlled substance under § 195.017.4(1)(a)n.

⁵ Morphine is a Schedule II controlled substance under § 195.017.4(1)(a)m.

the driver would retrieve the hard copy prescription with manual signature for the pharmacy records. However, these hard copy prescriptions were not available for the aforementioned prescriptions.

Prescription Error

12. On August 11, 2011, the drug Diltiazem⁶ CD 240 mg was dispensed by Care Pharmacy to a patient under prescription number 400382.

13. On August 16, 2011, the Diltiazem CD 240 mg was returned to Care Pharmacy and Diltiazem CD 120 mg was dispensed in its place to the same patient under prescription number 400382.

14. Zvibleman prepared the Diltiazem CD 240 mg, but suspected the dose was incorrect and thus set it aside to be verified with the prescribing physician. However, it was dispensed to the patient prior to verification, and the patient became ill as a result.

15. On Saturday, September 24, 2011, prescriptions 80014 and 400815 were processed in the Care Pharmacy computer under the initials M.E. for pharmacist Mike Elmore, despite the fact that he did not work on this date.

Conclusions of Law

Sections 338.055.2 and 621.045 give us jurisdiction over the Board's complaint. The Board has the burden of proof to show, by a preponderance of the evidence that Care Pharmacy's permit is subject to discipline. *See Kerwin v. Mo. Dental Bd.*, 375 S.W.3d 219, 229-30 (Mo. App., W.D. 2012) (dental licensing board demonstrates "cause" to discipline by showing preponderance of evidence). A preponderance of the evidence is evidence showing, as a whole, that "the fact to be proved [is] more probable than not." *Id.* at 230.

⁶ 21 USC Sec. 353(b) requires a prescription for the dispensing of certain drugs. Under this authority, the United States Food and Drug Administration requires a prescription for the dispensing of Diltiazem CD. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=SearchDrugDetails>

The Board correctly asserts that Care Pharmacy was responsible for compliance with applicable laws and regulations governing the lawful operation of a pharmacy, including the filling and dispensing of prescriptions for controlled substances. Care Pharmacy did not respond to the complaint; thus, all evidence submitted by the Board, including Exhibit 5, 6 and 7, is considered. Where no objection is made, hearsay evidence in the records can and must be considered in administrative hearings. *Clark v. FAG Bearings Corp.*, 134 S.W.3d 730, 736(Mo. App., S.D. 2004) (citing *Dorman v. State Bd. of Regis'n for the Healing Arts*, 62 S.W.3d 446 (Mo. App., W.D. 2001)).

Section 338.055.2 allows the Board to file a complaint against the holder of a pharmacy permit. Section 338.055.3 authorizes this Commission to find that grounds for disciplinary action are met as alleged in the complaint. Section 338.285 provides:

The board is hereby authorized and empowered, when examination or inspection of a pharmacy shall disclose to the board that the pharmacy is not being operated or conducted according to such legal rules and regulations [promulgated by the Board pursuant to § 338.280] and the laws of Missouri with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621 charging the holder of a permit to operate a pharmacy with conduct constituting grounds for discipline in accordance with section 338.055.

Section 338.140.1 and § 338.350.1, RSMo 2000, authorize the Board to promulgate regulations to enforce the provisions of Chapter 338, RSMo, as to pharmacists and pharmacies. Pursuant to that authority, the Board has promulgated the regulations appearing at Title 20 CSR Division 2220, Chapter 2.

20 CSR 2220-2.010(1)(O) provides:

When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws

or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

Section 338.010.1 provides:

The “practice of pharmacy” means . . . the compounding, dispensing and labeling of drugs and devices pursuant to . . . prescription orders . . . No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter.
. . .

Regulation 20 CSR 2220-2.010(1)(B) provides:

Whenever, in a pharmacy or other establishment holding a Missouri pharmacy permit, a person other than a licensed pharmacist does compound, dispense or sell any drug, medicine or poison pursuant to a lawful prescription, a licensed pharmacist must be physically present within the confines of the dispensing area[.]

Cause for Discipline

The Board asserts that Care Pharmacy’s permit is subject to discipline under § 338.055.2, which provides:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621 against the holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(13) Violation of any professional trust or confidence;

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government[.]

Pursuant to a determination that there is cause for discipline under any provision of § 338.055.2, the Board may take disciplinary action against a pharmacy permit holder under § 338.210.5, which states:

If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

Subdivision (5) - Incompetency, Misconduct,
Gross Negligence, Fraud, Misrepresentation or Dishonesty

Incompetency is a general lack of professional ability, or a lack of disposition to use an otherwise sufficient professional ability, to perform in an occupation. “Incompetent,” if used in a context relating to actual occupational ability, refers to “the actual ability of a person to perform in [the] occupation.” Section 1.020(9). We also look to the analysis of incompetency in a disciplinary case from the Supreme Court, *Albanna v. State Bd. of Regis’n for the Healing Arts*, 293 S.W.3d 423 (Mo. banc 2009). Incompetency is a “state of being” showing that a professional is unable or unwilling to function properly in the profession. *Id.* at 435. The repeated violation of state and federal pharmacy operating and dispensing requirements over the course of several months displays Care Pharmacy’s unwillingness to function properly as a pharmacy. Therefore, we find Care Pharmacy acted with incompetence.

Misconduct means “the willful doing of an act with a wrongful intention[.] intentional wrongdoing.” *Missouri Bd. for Arch'ts, Prof'l Eng'rs & Land Surveyors v. Duncan*, No. AR-84-0239 (Mo. Admin. Hearing Comm'n Nov. 15, 1985) at 125 *aff'd*, 744 S.W.2d 524 (Mo. App., E.D. 1988). Care Pharmacy allowed Gurlekce to work as a pharmacy technician at the pharmacy without a valid pharmacy technician registration in violation of 20 CSR 222.2.700 (1) (A). We find that this was an intentional wrongdoing; thus, Care Pharmacy committed misconduct.

Gross negligence is “an act or course of conduct which demonstrates a conscious indifference to a professional duty,” and that indifference constitutes “a gross deviation from the standard of care which a reasonable person would exercise in the situation.” *Duncan v. Missouri Bd. for Arch'ts, Prof'l Eng'rs & Land Surv'rs*, 744 S.W.2d 524, 533 and n.6 (Mo. App., E.D. 1988). This definition “imposes discipline for more than mere inadvertence and requires a finding that the conduct is so egregious as to warrant an inference of a mental state unacceptable in a professional[.]” *Id.* Although Care Pharmacy processed and dispensed prescriptions without a licensed pharmacist on duty, there was no evidence to support a finding that Care Pharmacy’s actions constitute a conscious indifference to a professional duty that rose to the level of a gross deviation of a reasonable standard of care. Therefore, we no find Care Pharmacy acted with gross negligence.

Fraud is an intentional perversion of truth to induce another, in reliance on it, to part with some valuable thing belonging to him. *State ex rel. Williams v. Purl*, 128 S.W. 196, 201 (Mo. 1910); *see also Ryann Spencer Group, Inc. v. Assurance Co. of America*, 275 S.W.3d 284, 287 (Mo. App., E.D. 2008) (elements of fraud include intent that another party act on the false representation). It necessarily includes dishonesty, which is a lack of integrity or a disposition to defraud or deceive. MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 359 (11th ed. 2004). Because fraud requires a perversion of truth intended to induce someone in particular to

part with something valuable, it necessarily requires an identifiable victim. No evidence was provided that Care Pharmacy posted a notice to customers that a pharmacist was on duty. We do not find that Care Pharmacy has perpetrated a fraud against any particular victim; thus, we find no cause for discipline for fraud. Misrepresentation is a falsehood or untruth made with the intent and purpose of deceit. *Id.* at 794. Care Pharmacy employees on at least one occasion, Saturday, September 24, 2011, processed prescriptions by using the initials M.E. of pharmacist Mike Elmore when he did not work. Although we have no direct evidence of the intent of Care Pharmacy's employees on this occasion, we may infer the requisite mental state from the conduct of the licensee "in light of all surrounding circumstances." *Duncan v. Missouri Bd. for Arch'ts, Prof'l Eng'rs & Land Surv'rs*, 744 S.W.2d 524, 533 (Mo. App., E.D. 1988). We infer that his action was taken with the intent to deceive and showed a lack of integrity and was thus dishonest. We find cause for discipline for misrepresentation and dishonesty.

We impute all of the actions of Care Pharmacy employees as set out above to Care Pharmacy under the principles set out in § 338.210.5 and 20 CSR 2220-2.010(1)(O). We conclude that Care Pharmacy knew that prescriptions were filled and dispensed by Care Pharmacy without a pharmacist on duty and the pharmacy filled Schedule II prescriptions prior to receiving the hard copy in violation of applicable law.

Care Pharmacy's permit is subject to discipline for incompetency, misconduct, dishonesty, and misrepresentation under § 338.055.2(5). It is not subject to discipline for gross negligence or fraud.

Subdivision (6) – Violation of Statutory and Regulatory Provisions

Section 338.013.1 governs the registration of personnel authorized to assist in the practice of pharmacy. The statutory requirements are as follows:

Any person desiring to assist a pharmacist in the practice of pharmacy as defined in this chapter shall apply to the board of

pharmacy for registration as a pharmacy technician. Such applicant shall be, at a minimum, legal working age and shall forward to the board the appropriate fee and written application on a form provided by the board. Such registration shall be the sole authorization permitted to allow persons to assist licensed pharmacists in the practice of pharmacy as defined in this chapter.

Regulation 20 CSR 2220-2.700 provides, in relevant part:

(1) A pharmacy technician is defined as any person who assumes a supportive role under the direct supervision and responsibility of a pharmacist and who is utilized according to written standards of the employer or pharmacist-in-charge to perform routine functions that do not require the use of professional judgment in connection with receiving, preparing, compounding, distribution, or dispensing of medications.

(A) No person shall assume the role of a pharmacy technician without first registering with the board in accordance with the requirements in section 338.013, RSMo and this rule. Nothing in this rule shall preclude the use of persons as pharmacy technicians on a temporary basis as long as the individual(s) is registered as or has applied to the board for registration as a technician in accordance with 338.013.1 and .2, RSMo.

We find that by allowing Gurlekce to work unsupervised by a licensed pharmacist and unregistered as a pharmacy technician, Care Pharmacy assisted her in violating the statutory requirement for technicians to be registered with Board. It is subject to discipline under § 338.055.2(6).

Further, Board regulations require that prescription medication be dispensed by a pharmacy permit holder only when there is a licensed pharmacist on the premises. Regulation 20 CSR 2220-2.010(1)(A), (B), and (O) provide:

(1) The word medicine or medicines is a word similar or of like import to the words pharmacist, pharmacy, apothecary shop, chemist shop, drug store, druggist and drugs, and no person shall carry on, conduct or transact a business under a name which contains, as part of the name, the word medicine or medicines, unless the place of business is supervised by a licensed pharmacist.

(A) At all times when prescriptions are compounded in a pharmacy or other establishments holding a Missouri pharmacy permit, there shall be on duty and present in the place of business a pharmacist licensed in Missouri as provided by law. ... When there is no pharmacist on duty, no prescription will be compounded, dispensed or otherwise provided and the public will be advised that no pharmacist is on duty by means of signs stating this fact. The signs will be displayed prominently on the doors of all entrances and the prescription counter of the pharmacy and the signs will be composed of letters of a minimum height of two inches (2”).

(B) Whenever, in a pharmacy or other establishment holding a Missouri pharmacy permit, a person other than a licensed pharmacist does compound, dispense or in any way provide any drug, medicine or poison pursuant to a lawful prescription, a licensed pharmacist must be physically present within the confines of the dispensing area, able to render immediate assistance and able to determine and correct any errors in the compounding, preparation or labeling of the drug, medicine or poison before the drug, medicine or poison is dispensed or sold. ... The pharmacist personally shall inspect and verify the accuracy of the contents of, and the label after it is affixed to, any prescribed drug, medicine or poison compounded or dispensed by a person other than a licensed pharmacist.

(O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

The "practice of pharmacy" means the interpretation, implementation, and evaluation of medical prescription orders under 21 U.S.C. Section 353. The Board has demonstrated that Care Pharmacy regularly conducted business and dispensed prescriptions in the absence of a licensed pharmacist in violation of the drug laws, rules, and regulations of this state and of the United States.

Disciplinary action can be taken against Care Pharmacy's permit under § 338.210.5. There is cause for disciplinary action under § 338.055.2(6).

Subdivision (13) – Violation of Professional Trust or Confidence

The phrase “professional trust or confidence” is not defined in Chapter 338. Nor has the phrase been defined in the case law. Therefore, we turn to the dictionary, which defines

“professional” as

of, relating to, or characteristic of a profession or calling...[;]...
engaged in one of the learned professions or in an occupation
requiring a high level of training and proficiency...[;
and]...characterized or conforming to the technical or ethical
standards of a profession or occupation....

WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY 1811 (unabr. 1986).

“Trust” is

assured reliance on some person or thing [;] a confident
dependence on the character, ability, strength, or truth of someone
or something...[.]

Id. at 2456. “Confidence” is a synonym for “trust.” *Id.* at 475 and 2456. Trust “implies an assured attitude toward another which may rest on blended evidence of experience and more subjective grounds such as knowledge, affection, admiration, respect, or reverence[.]” *Id.* at 2456. Confidence “may indicate a feeling of sureness about another that is based on experience and evidence without strong effect of the subjective[.]” *Id.*

Therefore, we define professional trust or confidence to mean reliance on the special knowledge and skills that professional licensure evidences.

Patients required to have their prescriptions filled at a pharmacy rely on that pharmacy to follow proper procedures regarding their prescriptions to protect them from the harm that might come from taking medicines in some manner other than as prescribed by a physician.

Additionally, to the extent that registered pharmacists provide an extra layer of skills and expertise in the process of safely and accurately dispensing medicines to the public, patients and doctors rely on the special knowledge required of pharmacy employees to review prescriptions

for errors to keep patients safe. By allowing prescriptions to be entered in a computer, filled, and dispensed to patients without being handled or checked by a licensed pharmacist, Care Pharmacy violated the professional trust and confidence of patients and physicians alike. Therefore, we find cause to discipline the pharmacy's permit under subdivision (13).

Subdivision (15) – Violation of State and Federal Drug Laws

Finally, the Board has alleged cause for discipline of Care Pharmacy's permit based on its violation of state and federal drug laws

Section 195.060.1 provides for the dispensing of controlled substances by prescription only and imposes additional verification requirements as follows:

Except as provided in subsection 4 of this section, a pharmacist, in good faith, may sell and dispense controlled substances to any person only upon a prescription of a practitioner as authorized by statute, provided that the controlled substances listed in Schedule V may be sold without a prescription in accordance with regulations of the department of health and senior services. All written prescriptions shall be signed by the person prescribing the same. All prescriptions shall be dated on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is prescribed, and the full name, address, and the registry number under the federal controlled substances laws of the person prescribing, if he is required by those laws to be registered. If the prescription is for an animal, it shall state the species of the animal for which the drug is prescribed. The person filling the prescription shall either write the date of filling and his own signature on the prescription or retain the date of filling and the identity of the dispenser as electronic prescription information. The prescription or electronic prescription information shall be retained on file by the proprietor of the pharmacy in which it is filled for two years, so as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this law. No prescription for a drug in Schedule I or II shall be filled more than six months after the date prescribed; no prescription for a drug in Schedule I or II shall be refilled; no prescription for a drug in Schedule III or IV shall be filled or refilled more than six months after the date if its original prescription or be refilled more than five times unless renewed by the practitioner.

Regulation 19 CSR 30-1.062(1) governs the handling of prescriptions for drugs in Schedule II as follows:

(1) Prescriptions in Schedule II. A pharmacist may dispense a controlled substance in Schedule II only under a written prescription signed by the practitioner, except as provided in section 195.060.3, RSMo. A prescription for a Schedule II controlled substance may be transmitted from the prescribing practitioner to a pharmacy by facsimile equipment or electronic computer transmission, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance[. ⁷]

In addition to state law requirements, federal regulation 21 CFR 1306.11(a) requires the presentation of the original, manually signed prescription for a Schedule II drug to a pharmacist for review prior to the dispensing of such drug after a written prescription is transmitted to a pharmacy by facsimile. It also provides that the original prescription be maintained in a prescription file at the pharmacy in accordance with 21 CFR 1304.04(h).

Based on the above statute along with the state and federal regulations governing the dispensing of Schedule II drugs, we find that Care Pharmacy's practice of first filling then delivering Schedule II drug orders while picking up the original, manually signed prescription from the provider constituted a violation of drug laws for which the law allows discipline. Further, the failure to retain and file such original prescriptions at the place of business is also cause for discipline pursuant to subdivision (15).

Actions Imputed to Care Pharmacy

Care Pharmacy knew the pharmacy was not operating lawfully because the owners were given notice by Pharmacist Albert Zvibleman.

⁷ Subsections (A) through (C) provide that the facsimile may serve, and shall be maintained, as the original prescription in cases where the Schedule II narcotic is for direct (non-oral) administration to the patient by the prescriber, when it is written for a resident of a long-term care facility, or when it is written for a hospice patient and so noted on the faxed prescription. We have no indication that any of these exceptions applied to the Schedule II prescriptions faxed to Care Pharmacy.

Disciplinary action can be taken against Care Pharmacy's permit under § 338.210.5,

which states:

If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

In this case, each of the illegal acts proven by the Board—allowing Gurlekce to work as a pharmacy technician without a license, allowing pharmacy personnel to fill and dispense prescriptions when a licensed pharmacist was not on the premises, failing to obtain an original, signed prescription from the prescribing physician before filling the prescription, dispensing the wrong dosage, and persons other than pharmacists entering pharmacists' initials in Care Pharmacy's computer records, were committed in connection with or adjunct to the preparation or dispensing of a prescription or drug order and in violation of the drug laws, rules, and regulations of this state and of the United States. Accordingly, Care Pharmacy, as the permit holder, is liable for those acts, and its permit is subject to discipline as a result.

Summary

There is cause to discipline Care Pharmacy, LLC's pharmacy permit under § 338.055.2 (5), (6), (13), and (15).

SO ORDERED on February 2, 2015.

\s\ Nicole Colbert-Botchway
NICOLE COLBERT-BOTCHWAY
Commissioner