

BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of:

MEDISAVE INC. d/b/a KING'S
PHARMACY AND COMPOUNDING
LAB

(Permit No. 5304)

CONSENT ORDER

THIS MATTER came on to be considered at a prehearing conference (hereinafter, "Conference") before a member of the North Carolina Board of Pharmacy (hereinafter, "Board") pursuant to 21 N.C.A.C. 46 .2008. This Conference was scheduled for January 5, 2016 and, after appropriate notice, was heard on that day by Board Member Robert A. Graves at the office of the Board. Respondent Medisave Inc. d/b/a King's Pharmacy and Compounding Lab (hereinafter "Respondent" or "the Pharmacy") was present through its current pharmacist-manager, Roy P. Martin, and its former pharmacist-manager and current owner, Harold B. King. Counsel Clinton R. Pinyan represented the Board. Members of the Board's investigative staff were also present at the Conference.

Respondent has agreed to waive a formal hearing in the above-referenced matter. Both parties stipulate and agree to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order by its consent. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. The North Carolina Board of Pharmacy is a body duly organized under the laws of North Carolina and is the proper body for this proceeding under the authority granted it in Chapter 90 of the General Statutes of North Carolina, and the rules and regulations promulgated thereunder.

2. Respondent Medisave Inc. d/b/a King's Pharmacy and Compounding Lab, located at 2231 South College Road, Wilmington, North Carolina, is, and was at all relevant times referred to herein, the holder of Pharmacy Permit No. 5304. The Pharmacy and its employees are, and were at all relevant times, subject to the rules and regulations of the North Carolina Board of Pharmacy and the laws of the State of North Carolina.

3. In February, May and August 2014, the Pharmacy's then-pharmacist-manager, R. Ph. King, declined to fill prescriptions for 90-day supplies of trazodone 100 mg for a patient, instead filling only 30-day supplies. R. Ph. King incorrectly represented to the patient that the Pharmacy was not permitted by the insurer to fill 90-day prescriptions. Instead, it was the Pharmacy's policy not to fill prescriptions for longer than a 30-day period, so that it could instead receive multiple co-pays in order to increase profits (or, in some cases, reduce losses) on its dispensing. R. Ph. King testified that he often varied from this policy if patients complained, however he did not do so with respect to this patient. During the investigation of this complaint, the Pharmacy cooperated with the Board investigator and disclosed both its representations to the patient, as well as the true state of affairs.

4. Between June 2014 and April 2015, on at least nine (9) occasions, the Pharmacy engaged in wholesale shipments into the states of Arizona, Arkansas, Kentucky, New Jersey, Texas and Virginia, without having the required non-resident permits. In addition, the Pharmacy

shipped some of these drugs in opened, partial packages, which was not permitted by some or all of these states. The Pharmacy made these shipments by using services provided by MatchRx to pair interested buying and selling pharmacies for overstocked prescription drugs. Similar services are provided by other companies, including RxCherryPick, RxTrade and ExchangeMeds. In using the MatchRx service, the Pharmacy relied upon representations that the Pharmacy could lawfully ship to other states using the service. The Pharmacy's representatives acknowledged that they should have researched permitting requirements in other states before shipping there, rather than relying upon MatchRx's representations. Although the Board finds that it was not reasonable for the Pharmacy to rely on the representations of a third-party with a profit motive to cause the Pharmacy to use the service, rather than researching legal requirements on its own, the Board finds that the Pharmacy acted in good faith in its reliance.

5. On April 16, 2015, the Arizona Board of Pharmacy sent a cease and desist letter to the Pharmacy, requesting that the Pharmacy cease shipments into Arizona without a permit. The Arizona Board of Pharmacy sent similar letters to a number of other North Carolina pharmacies. The other states into which the Pharmacy had shipped (Arkansas, Kentucky, New Jersey, Texas and Virginia) had similar permitting requirements with which the Pharmacy had not complied. Upon receipt of this letter, the Pharmacy immediately stopped using the MatchRx service and fully cooperated with the Board's investigation of MatchRx shipments.

6. Although the Pharmacy cooperated completely with the Board's investigation of its shipments through MatchRx, the Board is unable to accurately find the full scope of shipments made to other states because MatchRx refused to cooperate fully with the Board's investigation.

7. When an inspection was conducted on April 16, 2015, the Pharmacy was engaged in the following acts:

- a. The Pharmacy, on occasion, failed to maintain the required documentation of photo identification presented by all of the individuals seeking the dispensation of schedule II and III controlled substances;
- b. The Pharmacy failed to keep a compounding log containing all information required to be documented;
- c. The Pharmacy failed to comply with required compounding standards, including but not limited to, proper beyond use dating, master formulation records, garbing, facility design, installing a powder containment hood and quality controls; and
- d. The Pharmacy was unlawfully compounding for office use on occasion, rather than only compounding patient-specific drugs pursuant to valid prescriptions.

8. The Board has received no evidence of any contamination in the Pharmacy's compounded products or injury to any patient. No patient or prescriber has complained to the Board or otherwise reported any issues with any of the Pharmacy's compounded products.

9. Since the inspection, the Pharmacy has cooperated with the Board's efforts to ensure compliance with all applicable laws governing compounding and documentation. Between April 2015 and the present, inspections showed that the Pharmacy has come into substantial compliance with respect to the previously identified violations.

10. As an aggravating factor in this case, the Board has considered prior letters of warning to the Pharmacy on April 7, 2006 and February 16, 2011, which addressed previous violations of the Pharmacy Practice Act and its regulations by the Pharmacy.

11. As substantial mitigating factors in this case, the Board has considered the Pharmacy's cooperation with the investigation, its immediate compliance with its obligations not to ship without wholesale permits (once it was alerted to those requirements), and its efforts to promptly remedy compounding and documentation deficiencies. In addition, the Pharmacy has changed pharmacist-managers since the events in question, and the new pharmacist-manager (who is personally responsible for ongoing legal compliance by the Pharmacy) has assured future compliance with respect to the issues raised during these investigations.

CONCLUSIONS OF LAW

1. All parties are properly before the Board, and the Board has jurisdiction over Respondent and the subject matter of this proceeding.

2. Respondent's conduct, as set out in the findings of fact and conclusions of law above, constitutes grounds for discipline pursuant to North Carolina General Statutes § 90-85.38(b) because Respondent's acts were in violation of North Carolina General Statutes §§ 90-85.40(f), 90-85.47, 90-106.1 and 106-122; 21 N.C.A.C. 46 .1601, 46 .1804, 46 .1810 (former rule), and 46. 2801, 21 U.S.C. §§ 351, 353(e) and 353a; 21 C.F.R. 201.17, 201.18, and Part 205; Ark. Code § 20-64-505; Ark. Code R. §§ 08-00-0003 and 08-00-0008, Ariz. Rev. Stat. §§ 32-1929 and 32-1982; Ariz. Admin. Code § R4-23-607; Ky. Rev. Stat. Ann. § 315.402; 201 Ky. Admin. Regs. 2:105; N.J. Stat. Ann. § 24:6B-1; N.J. Admin. Code §§8:21-3A.4,

8:21-3A.5 and 8:21-3A.12; Tex. Health & Safety Code §§ 431.402, 431.406; 25 Tex. Admin. Code § 229.424; Va. Code Ann. § 54.1-3435.01; and 18 Va. Admin. Code § 110-50-110.

3. Respondent admits that the conduct in this matter constitutes sufficient grounds for disciplinary action on its permit under North Carolina General Statutes § 90-85.38(b).

CONCLUSIONS REGARDING DISCIPLINE

Based upon the foregoing Findings of Fact and Conclusions of Law, and with the consent of the Respondent, IT IS THEREFORE ORDERED that the permit of Respondent Medisave Inc. d/b/a King's Pharmacy and Compounding Lab (Permit No. 5304) is hereby REPRIMANDED.

This the 16th day of February, 2016.

NORTH CAROLINA BOARD OF PHARMACY

By: 

Jack W. Campbell, IV
Executive Director

Medisave Inc. d/b/a King's Pharmacy and Compounding Lab, the holder of permit number 5304, has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. The undersigned freely, knowingly and voluntarily waives such right by entering into this Consent Order.

The undersigned understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions which may be taken concerning this matter.

The undersigned further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional disciplinary action.

The undersigned understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

The undersigned understands that it has the right to have counsel of its choice review and advise it with respect to its rights and this Consent Order, and represents that it enters this Consent Order after consultation with its counsel or after knowingly and voluntarily choosing not to consult with counsel. The undersigned certifies that its agent executing this Consent Order is duly authorized to accept the Consent Order on behalf of Medisave Inc. and to bind the permit holder.

ACCEPTED AND CONSENTED TO BY:

MEDISAVE INC. D/B/A KING'S PHARMACY AND
COMPOUNDING LAB (Permit No. 5304)

Roy P. Martin Date 2-5-16

By: Roy P. Martin

Title: Pharmacist-Manager

STATE OF NORTH CAROLINA

NH COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the following person personally appeared before me this day and acknowledged the due execution of the foregoing document: Roy P. Martin.

Date: 2-5-2016

Calvin Barnes
Notary Public
CALVIN BARNES

My commission expires: 12-07-2019



REJECTED BY:

MEDISAVE INC. D/B/A KING'S PHARMACY AND
COMPOUNDING LAB (Permit No. 5304)

_____ Date _____

By: Roy P. Martin

Title: Pharmacist-Manager