

WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES



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STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY
PROCEEDINGS AGAINST

ALLERGYCHOICES, INC., d/b/a
ALLERGYCHOICES PHARMACY,
RESPONDENT.

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FINAL DECISION AND ORDER

ORDER 0002288

Division of Legal Services and Compliance¹ Case No. 11 PHM 71

The parties to this action for the purpose of Wis. Stat. § 227.53 are:

Allergychoices, Inc.
2800 National Drive, Suite 100
Onalaska, WI 54650

Wisconsin Pharmacy Examining Board
P.O. Box 8935
Madison, WI 53708-8935

Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 8935
Madison, WI 53708-8935

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board (Board). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. Respondent Allergychoices, Inc., d/b/a Allergychoices Pharmacy, is licensed in the State of Wisconsin as a pharmacy, having license number 42-8984, first issued on December 14, 2009, and current through May 31, 2014. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is 2800 National Drive, Suite 100, Onalaska, WI 54650. Respondent's pharmacy is engaged exclusively in the compounding of liquid sublingual immunotherapy (SLIT) preparations.

¹ The Division of Legal Services and Compliance was formerly known as the Division of Enforcement.

2. The typical practice of the pharmacy has been that, upon receipt of a prescription for an individual patient, a 90 day supply of liquid medication is prepared with glycerin as a diluent/preservative, and dispensed in a bottle with a metered pump. The bottle is labeled for the patient, and shipped via Postal Service priority mail. In over 80% of cases, the initial medication is shipped to the prescriber's office, for the purpose of allowing the prescriber to observe the initial administration to the patient.

3. Respondent does not have a variance which would permit delivery of a prescription to a place other than the patient's residence.

4. In the majority of cases, the prescriber is billed for the medication by the pharmacy, with the expectation that the prescriber will pay the pharmacy directly, and then collect reimbursement from the patient.

5. In all other cases, the patient is billed by the pharmacy, and pays the pharmacy directly.

6. Respondent assures the Board that the practices described in paragraphs 3 and 4, above, will cease immediately.

7. In April 2007, Respondent caused to be prepared a piece of literature entitled "Answers to Common Questions about SLIT for Medical Staff" which is listed as "updated 4/07." Under a section entitled "Business Issues" was the following:

Q: Is it legal to re-sell the drops we have formulated by your pharmacy?

A: You should check your state regulations regarding re-selling of prescriptions. We are not aware of specific statutes that prohibit physicians from marking up a compounded prescription.

8. The Board finds that compounding for resale constitutes manufacturing under federal law, an activity for which Respondent was not licensed in Wisconsin, nor registered with the FDA. Respondent's position is that it was not functioning as a manufacturer. Rather, Respondent contends that it was dispensing patient-specific prescriptions to the patient via the physician, who functioned as an agent of the patient by accepting and paying for the prescription on the patient's behalf. The Board finds that all financial arrangements and transactions must be directly and exclusively between the patient and the pharmacy.

9. Respondent's managing pharmacist has represented to the Board that he was unaware of the existence of this piece of literature, which was prepared by persons not under his supervision. The Board finds that this constitutes failing to place the pharmacy under the control of a managing pharmacist, as required by Wis. Stat. § 450.09(1)(a).

10. Respondent does not have records of the number of pieces of literature, as described in paragraph 7, above, which were distributed to potential prescribers. Respondent represents to the Board that in January, 2008, Respondent revised the piece of literature referred to, above, and replaced it with a version stating the following:

Q: Is it legal to re-sell the drops we have formulated by your pharmacy?

A: No – a patient prescription cannot be marked up by a third party.

11. Presently, Respondent uses the following language in the successor to this particular piece of literature:

Q: Can I mark up the cost of the prescription?

A: No, Allergychoices is a retail pharmacy that prepares patient-named prescriptions, and like any other retail prescription, patient prescription charges must reflect actual retail pricing. Refer to your practice is standard pricing policy for any additional charges for staff time, office overhead and professional services that accompany, but are separate from, charges for prescriptions.

12. On rare occasion, a patient is thought to be intolerant to glycerin. On such occasions, Respondent's practice has been to compound the prescription using sterile water as a primary diluent, although some glycerin accompanies the active ingredient. Respondent does not have a protocol for assuring the safe delivery of such a prescription, nor is it given an appropriate expiration date (two weeks). Literature furnished by Respondent supporting glycerin as an effective preservative in lower concentrations did not, in fact, support Respondent's practice in all cases.

13. Respondent's labeling does not include the quantity or concentration of each active ingredient, in a manner which another health care practitioner could readily understand.

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10(1), and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).

2. By the conduct described in Finding of Fact 3, Respondent violated Wis. Admin. Code § Phar 7.01(1)(e), in that a prescription may be delivered only to a patient's residence unless the Board has granted a variance permitting delivery elsewhere.

3. By the conduct described in Findings of Fact 4 and 7, Respondent violated Wis. Admin. Code § Phar 10.03(1), in that the pharmacy's financial arrangements and transactions were not always directly and exclusively between the patient and the pharmacy.

4. By the conduct described in Finding of Fact 9, Respondent violated Wis. Stat. §§ 450.10(1)(a)2. and 450.09(1)(a), in that every pharmacy shall be under the control of the managing pharmacist, and the managing pharmacist shall be responsible for the professional operations of the pharmacy.

5. By the conduct described in Finding of Fact 12, Respondent violated Wis. Admin. Code § Phar 10.03(2).

6. By the conduct described in Finding of Fact 13, Respondent violated Wis. Admin. Code § Phar 10.03(16).

7. As a result of the above violation, Allergychoices, Inc., is subject to discipline pursuant to Wis. Stat. § 450.10(1).

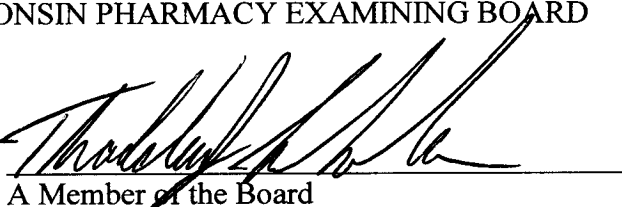
ORDER

1. The attached Stipulation is accepted.
2. Allergychoices, Inc., is REPRIMANDED.
3. Allergychoices, Inc., shall FORFEIT \$1,000, to be paid within 30 days of this Order.
4. Allergychoices, Inc., shall label all compounded prescriptions in compliance with USP 795.
5. Within 30 days from the date of this Order, Respondent shall pay the COSTS of this matter in the amount of \$3,500.
6. Payment of forfeiture and costs shall be made payable to the Wisconsin Department of Safety and Professional Services and sent to the Department Monitor at the address below:

Department Monitor
Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 8935, Madison, WI 53708-8935
Telephone (608) 267-3817; Fax (608) 266-2264
DSPSMonitoring@wisconsin.gov
7. Violation of any of the terms of this Order may be construed as conduct imperiling public health, safety and welfare and may result in a summary suspension of Respondent's license. The Board in its discretion may in the alternative impose additional conditions and limitations or other additional discipline for a violation of any of the terms of this Order. In the event Respondent fails to timely submit payment of the forfeiture or costs as ordered, Respondent's license (42-8984) may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with payment of the forfeiture and costs.
8. This Order is effective on the date of its signing.

WISCONSIN PHARMACY EXAMINING BOARD

by:


A Member of the Board

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February 13, 2013
Date