

**IN THE MATTER OF  
ALLERGYCHOICES, INC.**

**Respondent**

**Permit No. P04854**

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**BEFORE THE  
MARYLAND STATE  
BOARD OF PHARMACY  
Case No. PI-14-063/14-563**

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**PRE-CHARGE CONSENT ORDER**

**Background**

On February 13, 2013, Allergychoices, Inc. (the “Respondent”), Permit No. P04854, entered into a stipulation with the Wisconsin Pharmacy Examining Board concerning the Respondent’s practice of sending patient-specific compounded prescriptions to a physician’s office for resale to the patient. The Wisconsin Pharmacy Examining Board reprimanded the Respondent’s permit and imposed a \$1,000 fine and \$3,500 in costs. The Respondent informed the Maryland Board of Pharmacy (the “Board”) of the action taken by the Wisconsin Board and subsequently informed the Board of further reciprocal actions taken by the Boards of Pharmacy in Utah, Michigan, South Carolina, and Alabama based on the conduct at issue in the Wisconsin stipulation. On May 16, 2016, the Respondent notified the Board that the Louisiana Board of Pharmacy imposed a fine on the Respondent based on the Respondent’s failure to disclose the Alabama action on a renewal application.

In lieu of instituting formal proceedings against the Respondent, in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq.*, the Board proposed, and the Respondent agreed, to resolve this matter as set forth in this Consent Order.

## FINDINGS OF FACT

1. At all times relevant hereto, the Respondent possessed a Maryland non-resident pharmacy permit, Permit No. P04854, and operated as a non-resident pharmacy in Onalaska, Wisconsin. The Respondent's permit was initially issued on November 26, 2008. The Respondent's permit is active and is set to expire on May 31, 2018.
2. On February 13, 2013, the Respondent entered into a stipulation with the Wisconsin Pharmacy Examining Board related to its compounding and dispensing of liquid sublingual immunotherapy ("SLIT") preparations. Specifically, the Wisconsin Pharmacy Examining Board found the following facts:
  - a. The Respondent compounded patient-specific prescriptions which it then, in over 80% of cases, shipped directly to the prescriber's office to allow the prescriber to observe the initial administration to the patient;
  - b. In the majority of cases, the Respondent billed the physician for the medication, and the physician sought reimbursement from the patient;
  - c. In April 2007, the Respondent prepared a document titled "Answers to Common Questions about SLIT for Medical Staff" in which it stated it was "not aware of specific statutes that prohibit physicians from marking up a compounded prescription";<sup>1</sup>
  - d. In rare cases, with a patient thought to be intolerant to glycerin, the Respondent compounded its prescriptions using sterile water as a primary diluent, but it did not have protocols for assuring the safe delivery of such

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<sup>1</sup> The Respondent later updated the document to state that its products could not be marked up for resale by a third-party physician.

prescriptions and it did not give them appropriate two-week expirations dates;  
and

- e. The Respondent's labeling did not include the quantity or concentration of the active ingredients in a manner easily understandable by other health care practitioners.
3. The Wisconsin Board based its action against the Respondent on a finding that the practice of compounding drugs for resale constituted manufacturing, which the Respondent was neither licensed to do in Wisconsin nor registered to do with the FDA. The Respondent argued that it was simply dispensing the drugs to the patients through the physicians who were acting as agents for the patients, which the Wisconsin Board found to be improper in and of itself.
  4. The Wisconsin Board reprimanded the Respondent's license, fined the Respondent \$1,000, and imposed costs of \$3,500. The Respondent also agreed to label all compounded prescriptions in accordance with USP 795.
  5. On September 4, 2013, the Board received notification from the Respondent that the Utah Board of Pharmacy had taken reciprocal action against the Respondent based on the Respondent's stipulation with the Wisconsin Board. The Utah Board reprimanded the Respondent's license and fined the Respondent \$1,000, half (\$500) of which was stayed.
  6. On or about October 21, 2015, the Respondent applied to the Board for relocation. On its application, the Respondent disclosed that the Boards of Pharmacy in Michigan, South Carolina, and Alabama also took the following reciprocal actions against the Respondent based on the Respondent's stipulation with the Wisconsin Board:

- a. On or about February 12, 2014, the Michigan Board of Pharmacy issued a reprimand against the Respondent and imposed a \$500 fine;
  - b. On or about June 19, 2014, the State Board of Pharmacy of South Carolina issued a reprimand against the Respondent; and
  - c. On or about March 20, 2015, the Alabama State Board of Pharmacy imposed a \$1,000 fine against the Respondent.
7. Finally, on May 16, 2016, the Respondent informed the Board that on March 15, 2016, the Louisiana Board of Pharmacy imposed a \$5,000 fine and \$250 in costs against the Respondent for the Respondent's failure to report the disciplinary action in Alabama on its Louisiana renewal application.

#### **CONCLUSION OF LAW**

Based on the foregoing Findings of Fact, the Board concludes that the Respondent is subject to disciplinary action in accordance with Md. Code Ann., Health Occ. §§ 12-409(b), 12-403(c)(9), (g), and 12-313(b)(24), (25), and COMAR 10.34.19.

#### **ORDER**

Based on the agreement of the parties and an affirmative vote of a majority of the Board, it is this 5<sup>th</sup> day of August, 2016, hereby:

**ORDERED** that within 30 days of the effective date of this Consent Order, the Respondent shall pay a fine in the amount of \$1,000, payable to the Maryland Board of Pharmacy; and be it further,

**ORDERED** that the Respondent shall practice in Maryland at all times in accordance with the Maryland Pharmacy Act; and be it further,

**ORDERED** that failure to comply with the terms and conditions of this Consent Order, including failure to pay the required fine, constitutes a violation of this Consent Order, and the Board, in its discretion, after notice and an opportunity for a hearing before the Board, may impose any appropriate sanction under the Maryland Pharmacy act; and be it further

**ORDERED** that the Respondent shall bear all expenses associated with this order; and be it further

**ORDERED** that this is a formal order of the Maryland Board of Pharmacy and as such is a public document pursuant to Md. Code Ann., General Provisions § 4-333(b)(6).

8/5/16  
Date


*Mitra Gavvani*  
Mitra Gavvani, President  
Maryland Board of Pharmacy

CONSENT

1. By signing this Consent, the Respondent, Allergychoices, Inc., submits to the foregoing Consent Order as a resolution of this matter in lieu of formal charges, which process would have afforded the Respondent the right to a full evidentiary hearing. The Respondent consents and submits to the foregoing Findings of Fact, Conclusions of Law, and Order as if made after a full evidentiary hearing in which the Respondent would have the right to counsel, to confront witnesses, to give testimony, to call witnesses on its behalf, and to all other substantive and procedural protections provided by law.
2. By signing this Consent, the Respondent waives any rights it may have had to contest the findings and determinations contained in this Consent Order.
3. The Respondent acknowledges that this is a formal order of the Board and as such is a public document.
4. The Respondent acknowledges the legal authority and the jurisdiction of the Board to enter into and enforce this Consent Order.
5. The Respondent signs this Consent Order freely and voluntarily and after having had the opportunity to consult with counsel. The Respondent fully understands the language, meaning, and effect of this Consent Order.

ALLERGYCHOICES, INC.  
Permit No. P04854

8-2-16  
Date

  
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Michael B. Kachel, RPh  
Director of Pharmacy  
Allergychoices, Inc.

STATE OF Wisconsin  
COUNTY/CITY OF LaCrosse :

I hereby certify that on this 2<sup>nd</sup> day of August, 2016,  
before me, a Notary Public of the State of Wisconsin and County/city aforesaid,  
personally appeared Michael B. Kachel, on behalf of ALLERGYCHOICES, INC., and made  
an oath in due form that the foregoing Consent was his voluntary act and deed.

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Notary Public

My commission expires: 02/21/20