

IN THE MATTER OF	*	BEFORE THE
APOTHECURE, INC.	*	STATE BOARD OF
RESPONDENT-PHARMACY	*	PHARMACY
PERMIT NUMBER: P04701	*	CASE NO.: PI 13-104/13-504
* * * * *	*	* * * * *

FINAL OF ORDER OF REVOCATION OF NON-RESIDENT PHARMACY PERMIT

The State Board of Pharmacy ("the Board") notified Apothecure Inc., ("the Respondent-Pharmacy"), Permit Number: P04701 of the Board's intent to revoke the Respondent-Pharmacy's non-resident permit to operate a pharmacy in Maryland under the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") §§ 12-101 *et seq.* (2009 Repl. Vol.). The pertinent provisions state:

H.O. § 12-409. Suspensions and revocations - Grounds.

(a) In general - Subject to the hearing provisions of § 12-411 of this subtitle, the Board, may suspend or revoke any pharmacy permit, if the pharmacy:

- (1) Is conducted so as to endanger the public health or safety;
- (2) Violates any of the standards specified in § 12-403 of this title: or
- (3) Is otherwise not conducted in accordance with the law.

(b) Nonresident pharmacy - (1) A nonresident pharmacy is subject to the disciplinary actions stated in this subtitle.

- (2) The Board may fine a nonresident pharmacy in accordance with § 12-410 of this subtitle or deny, revoke, or suspend the permit of a nonresident pharmacy for any violation of § 12-403(d) through (g) of this subtitle.

H.O. § 12-403. Required standards.

(b) In general – Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:

(1) Shall be operated in compliance with the law and with the rules and regulations of the Board;

(9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under § 12–313 of this title or a registered pharmacy technician under § 12–6B–09 of this title;

(f) Notwithstanding subsection (a) of this section, a nonresident pharmacy shall:

(1) Comply with the requirements of subsection (b)(2), (7) through (12). and (19) of this section when:

(i) Dispensing prescription drugs or prescription devices to a patient in this State; or

(ii) Otherwise engaging in the practice of pharmacy in this State;

(4) Maintain at all times a valid, unexpired permit to conduct a pharmacy in compliance with the laws of the state in which it is located[.]

H.O. § 12-313. Denials, reprimands, suspensions, and revocations ---- Grounds.

(b) Subject to the hearing provisions of § 12–315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may deny a license to any applicant for a pharmacist's license, reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the applicant or licensee:

(24) Is disciplined by a licensing or disciplinary authority of any state or country or convicted or disciplined by a court of any state or country for an act that would be grounds for disciplinary action under the Board's disciplinary statutes;

FINDINGS OF FACT

The Board finds that:

1. On or about January 4, 2008, the Respondent-Pharmacy was originally issued a non-resident permit to operate a pharmacy. The Respondent-Pharmacy's non-resident permit expires on December 31, 2013
2. The Respondent-Pharmacy is located at 4001 McEwen Road, Dallas, Texas.
3. The Respondent-Pharmacy is a Texas based compounding pharmacy that specializes in custom compounded medications that are distributed to patients and physicians.
4. At all times relevant hereto, the Respondent-Pharmacy was owned and operated by Pharmacist A.
5. At all times relevant hereto, Pharmacist A acted as pharmacist-in-charge of Respondent-Pharmacy.
6. On or about November 9, 2010, the Respondent Pharmacy was disciplined by the Texas State Board of Pharmacy (the "Texas Board").
7. On or about November 10, 2010, Pharmacist A, president of the Respondent-Pharmacy, entered into a Consent Order with the Texas State Board of Pharmacy Texas Board.
8. Under the terms of the Consent Order, the Respondent-Pharmacy's license was suspended by the Texas Board for a period of one (1) year, with the suspension stayed. The Respondent-Pharmacy was placed on probation and required to abide by the terms and conditions set forth in the Consent Order. The Respondent-Pharmacy was

ordered to pay fines and administrative fees in the amount of one hundred and twenty-six thousand and seven hundred dollars (\$126,700) and comply with additional terms set forth in the Consent Order (A copy of the Consent Order is attached hereto and incorporated herein as Exhibit A).

9. The Texas Board found that the Pharmacist A, while acting as pharmacist-in-charge and corporate president of Respondent-Pharmacy, failed to prevent an error from occurring during the compounding of Colchicine²

10. In or around February 2007, the Respondent-Pharmacy shipped approximately seventy-two (72) vials of improperly compounded Colchicine to a medical center ("Medical Center A") in Portland, Oregon. The shipment consisted of seventy (70) 4-milliliter vials and two (2) ten-milliliter vials of injectable Colchicine.

11. Between March 2007 and April 2007, three patients died after receiving Colchicine injections from the February 2007 shipment that the Respondent-Pharmacy sent to Medical Center A. The patients were administered Colchicine that was more potent than the labels on the vials had indicated.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Respondent Pharmacy is in violation of H.O. § 12-403 (b) (1) and (9) and (f) (1) and (4) and: H.O. § 12-409 (a) (1), (2), and (3).

ORDER

¹ Pharmacist A is not identified in this document for privacy reasons, but this information will be provided upon request.

² Colchicine is a medication used to treat gout (a condition characterized by pain and swelling in the joints caused by a buildup of uric acid in the blood). Colchicine is also used to treat pain caused by a hereditary condition called Familial Mediterranean Fever (FMF).

Based on the foregoing Findings of Fact and Conclusions of Law, it is this
19th day of ~~September~~ ²⁰¹⁴ ~~2013~~, by a majority of the quorum of the Board, hereby

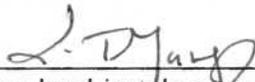
ORDERED that the Respondent-Pharmacy's non-resident pharmacy permit to operate a pharmacy is hereby **REVOKED** and the Board will not accept, from the Respondent-Pharmacy, any future application for a pharmacy permit; and it is further

ORDERED that for purposes of public disclosure and as permitted by Md. State Govt. Code Ann. §§ 10-601 *et seq.* (2009 Repl. Vol.), this document consists of the contents of the foregoing Findings of Fact, Conclusions of Law, and Order, and is reportable to any entity to whom the Board is obligated to report; and it is further

ORDERED that this Order is final and a public document pursuant to Md. State Govt. Code Ann. §§ 10-601 *et seq.* (2009 Repl. Vol.).

Date

9/19/2014


Lenna Israbian-Jamgochian, P.D., *Gen. D.*
President
State Board of Pharmacy