

IN THE MATTER OF	*	BEFORE THE
Rx3 COMPOUNDING PHARMACY	*	MARYLAND STATE
Respondent	*	BOARD OF PHARMACY
Permit Number: P05099	*	Case Number: PI-13-106
* * * * *	* *	* * * * *

CONSENT ORDER

On October 16, 2013, the Maryland State Board of Pharmacy (the "Board") charged **Rx3 COMPOUNDING PHARMACY** (the "Respondent"), Permit Number P05099, a nonresident pharmacy, under the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") §§ 12-101 *et seq.* (2009 Repl.Vol. & 2012 Supp.).

The pertinent provisions of the Act are as follows:

12-313. Denials, reprimands, suspensions, and revocations – Grounds

...

(b) *In general.* – 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;

(25) Violates any rule or regulation adopted by the Board[.]

12-403. Required Standards.

...

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

...

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

...

(12) Shall store all prescription and nonprescription drugs or devices

properly and safely subject to the rules and regulations adopted by the Board;

- ...
- (d) *Nonresident pharmacy to hold permit and have licensed pharmacist on staff designated as responsible for in-State services.* – A nonresident pharmacy shall:
- (1) Hold a pharmacy permit issued by the Board; and
 - (2) Have a pharmacist on staff who is:
 - (i) Licensed by the Board; and
 - (ii) Designated as the pharmacist responsible for providing pharmaceutical services to patients in this State.
- (f) *Compliance by nonresident pharmacy.* – Notwithstanding subsection (a) of this section, a nonresident pharmacy shall:
- (1) Comply with the requirements of subsection (b)(2), (7) through (12) and (19) 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.

12-409. Suspensions and revocations – Grounds.

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

The Board's regulations provide in pertinent part:

Code Md. Regs. tit. 10, § 34.01.01

...

B. A pharmacist may not:

- (1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist[.]

On November 13, 2013, a conference with regard to this matter was held before the Board's Case Resolution Conference ("CRC") panel. As a result of the CRC, the Respondent agreed to enter into this Consent Order, consisting of Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. The Respondent is located at 12230 Ironbridge Road, Chester, Virginia.
2. The Board originally issued to the Respondent a permit to operate as a pharmacy on or December 21, 2009. The Respondent's permit is currently active and will expire on May 31, 2014.
3. At the time of the Board's investigation, the Respondent did not have a pharmacist on staff who is licensed in Maryland.¹
4. On November 5 and 9, 2012, the Virginia Department of Health Professions ("VDHP") conducted inspections of the Respondent.
5. On November 9, 2012, the VDHP inspector placed an embargo on several Schedule VI high-risk compounded sterile products ("CSPs")² that were found in the pharmacy labeled with beyond use dates ("BUDs") longer than those allowed by the United States Pharmacopoeia ("USP").
6. VDHP's review of additional records disclosed that in January, February, April, June, August and October 2012, a total of 114 CSPs were compounded.³ One hundred and ten of the 114 high-risk CSPs had no records indicating that sterility

¹ Effective December 20, 2013, the Respondent met licensure qualifications and was issued a license to practice pharmacy in Maryland.

² The CSPs included: prostaglandin 20mcg/ml; prostaglandin E-1 500 mcg/ml; papaverine 30mg/ml and two strengths of "Triple Mix," a combination of phentolamine, prostaglandin and papaverine.

³ None of the sterile products at issue were distributed or dispensed into Maryland.

testing had been performed or whether the product was batch-compounded or compounded for a specific patient. In addition, the high-risk CSPs were assigned BUDs longer than allowed by USP 797.⁴

7. Records also disclosed that between January 1 and October 31, 2012, Rx3 compounded and dispensed 9,889 30ml vials of "Medi-Bolic Booster," a Schedule VI product, and 14,386 30ml vials of pyridoxine/thiamine, also a Schedule VI product. When asked to produce compounding records for these products, Christopher K. Currin, the pharmacist in charge of Rx3 Compounding Pharmacy, was able to produce records that accounted for only 400 total doses. There was documentation of only eight in-house sterility tests and no endotoxin tests were documented. All of the compounded materials in this paragraph were labeled with BUDs longer than allowed by USP 797.⁵
8. On April 2, 2013, the Virginia Board notified the Respondent that it may have violated portions of the Virginia Board's statute and regulations. In addition to the allegations pertaining to the November 2012 inspections, the notice further alleged the following violations of the Board's regulations:
 - a. An individual performed the duties of a pharmacy technician at Rx3 Compounding Pharmacy in August 2012, although the individual was not registered as a pharmacy technician and had not been in an approved training program for over nine months;

⁴ USP 797 sets forth national standards governing the preparation of CSPs.

⁵ On January 17, 2013, the Virginia Board of Pharmacy ("Virginia Board") entered an Order of Summary Restriction ("Order") on the license of Mr. Currin. The Order stated that it was unlawful for Mr. Currin to perform sterile compounding and to supervise or allow sterile compounding to be performed. On February 28, 2013, subsequent to an inspection to determine compliance with the Order, the Virginia Board stayed the summary restriction on Mr. Currin's pharmacist license.

- b. Rx3 Compounding Pharmacy failed to maintain perpetual inventories of Schedule II controlled dangerous substances; and
 - c. Between January 1 and October 31, 2012, Rx3 Compounding Pharmacy compounded 24,275 vials of Medi-Bolic and pyridoxine/thiamine, constituting 19.4% of Rx3's total sales, without being licensed as a wholesale distributor.
9. Effective May 8, 2013, the Respondent entered into a Consent Order with the Virginia Board in which the Virginia Board concluded as a matter of law that the Respondent violated the Virginia Board's statutes and regulations as alleged.
 10. Under the terms of the Consent Order, the Respondent Pharmacy was assessed a monetary penalty of \$10,500 to be paid to the Virginia Board within 30 days and was ordered to maintain a course of conduct commensurate with the Virginia Board's statute.
 11. On May 8, 2013, the Virginia Board acknowledged the receipt of the monetary penalty and stated: "RX3 is now in compliance, this matter is closed."

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the imposition of terms and conditions on the Respondent pursuant to the Virginia Board's Consent Order constitutes disciplinary action by a licensing authority for acts that are grounds for disciplinary action under H.O. § 12-313(b)(24) with underlying grounds of H.O. § 403(b)(9) and (12), H.O. § 12-403(d) and H.O. § 12-403(f)(1) and Code Md. Regs. tit. 10, § 34.01.01B(1). In addition, the Respondent's failure to have a pharmacist on staff

who is licensed in Maryland constitutes grounds for disciplinary action under H.O. § 12-404(b).

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is by a majority of the quorum of the Board considering this case:

ORDERED that within 30 days from the effective date of the Consent Order, the Respondent-Distributor shall pay a monetary fine of \$2,000.00, to be paid in full to the Board by certified or bank guaranteed check made payable to the Maryland State Board of Pharmacy; and it is further

ORDERED that for a period of two (2) years from the effective date of the Consent Order, Rx3 Compounding Pharmacy shall immediately submit to the Board any action taken against it by any other state, including Virginia, and it is further

ORDERED that for a period of two (2) years from the effective date of the Consent Order, Rx3 Compounding Pharmacy shall immediately submit to the Board copies of reports of inspections conducted by the Virginia Board of Pharmacy; and it is further

ORDERED that the Respondent shall comply with the Maryland Pharmacy Act and all laws, statutes and regulations pertaining to the practice of pharmacy; and it is further

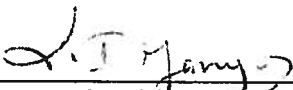
ORDERED that the Respondent's failure to comply with any of the conditions of this Consent Order shall be considered a violation of this Consent Order; and it is further

ORDERED that if the Respondent violates any of the conditions of this Consent Order, the Board, in its discretion, after notice and an opportunity for a show cause hearing before the Board, may impose any other disciplinary sanction for with the Board may have imposed, including an additional monetary fine; and it is further

ORDERED that the effective date of this Consent Order is that date that it is signed by the Board; and it is further

ORDERED that this document constitutes a formal disciplinary action of the Maryland State Board of Pharmacy and is therefore a public document for purposes of public disclosure, pursuant to Md. Code Ann. State Gov't §§ 10-611 *et seq.* (Repl.Vol. 2009 & Supp. 2012).

2/19/2014
Date



Lenna Israbian-Jamgochian, Pharm.D.
President
Maryland Board of Pharmacy

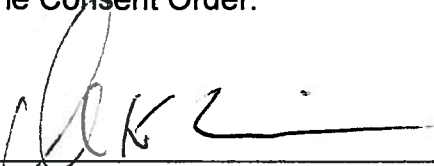
CONSENT OF CHRISTOPHER K CURRIN, PRESIDENT OF
X-GEN PHARMACEUTICALS Rx3 Compounding Pharmacy

I, Christopher Currin, R.Ph., Director of Pharmacy, Rx3 Compounding Pharmacy, acknowledge that I am represented by counsel and have consulted with counsel before entering this Consent Order. By this Consent and for the purpose of resolving the issues raised by the Board, I agree and accept to be bound by the foregoing Consent Order and its conditions.

I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other substantive and procedural protections provided by the law. I agree to forego my opportunity to challenge these allegations. I acknowledge the legal authority and jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. I affirm that I am waiving my right to appeal any adverse ruling of the Board that I might have filed after any such hearing.

I sign this Consent Order after having an opportunity to consult with counsel, voluntarily and without reservation, and I fully understand and comprehend the language, meaning and terms of the Consent Order.

2-3-14
Date



Christopher K. Currin, R.Ph.
Director of Pharmacy, Rx3 Compounding Pharmacy
Respondent

Reviewed by:

Attorney for Respondent

STATE OF Virginia

CITY/COUNTY OF Chesterfield

I HEREBY CERTIFY that on this 3 day of February 2014, before me, a Notary Public of the foregoing State and City/County, Christopher K. Currin, R.Ph. personally appeared, and made oath in due form of law that signing the foregoing Consent Order was his voluntary act and deed.

AS WITNESSETH my hand and notarial seal.

Sandra Mick
Notary Public

My Commission expires: April 30, 2015

