| IN THE MATTER OF | | | | | | | * | REE | ORE TI | | | |
|--|---|---|---|------|-------------------|-----------|------------|----------------------------|--------|---|---|----------|
| NEB 24 | | | | | | | * | | | | | 2 4 2012 |
| d/b/a MARYLAND RESPIRATORY GROUP | | | | | | | * | | | | | y y |
| | | | | | | | | OF PHARMACY | | | | |
| PERMIT No: PW0305 Respondent-Pharmacy | | | | | | | * | Case No.: PI-12-099/12-399 | | | | |
| _ | | | | macy | | | * | | | | | |
| * | * | * | * | * | * <u>CON</u> : | * SENT | * ORDEF | * { | * | * | * | * |

On May 18, 2012, the State Board of Pharmacy (the "Board") charged Maryland

Respiratory Group d/b/a Neb 24 ("Respondent-Pharmacy"), Permit No.: PW0305, the

Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") §§ 12-101 et seq.

(2009 Repl. Vol.).¹

Specifically, the Board charged the Respondent with the following provisions of the

Act under H. O. § 14-404:

The pertinent provisions of the Act provide as follows:

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;

(3) Shall ensure that a licensed pharmacist shall be immediately available on the premises to provide pharmacy services at all times the pharmacy is in operation; [and]

(4) Shall be supervised by a licensed pharmacist who is responsible for the operations of the pharmacy at all times the pharmacy is in operation[.]

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

¹ The Charges were reissued on June 13, 2012 due to a service issue.

(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:

(2) Violates any of the standards specified in §12-403 of this subtitle[.]

COMAR 10.34.05.02 Prescription Area

A. The Pharmacy Permit Holder shall:

(3) Prevent an individual from being in the prescription area unless a pharmacist is immediately available on the premises to provide pharmacy services;

(4) Monitor unauthorized or emergency entry after the prescription area has been secured by the pharmacist; and

(5) Prevent unauthorized entry when the prescription area is closed during a period that the rest of the establishment is open.

On Wednesday, August 15, 2012, the Respondent-Pharmacy appeared before

members of the Board and the Board's counsel for a Case Resolution Conference (CRC)

to discuss the potential resolution of the Charges by consent. The Respondent was not

represented by counsel. At the conclusion of the CRC, the Respondent-Pharmacy agreed

to enter into this Consent Order to resolve the pending charges. The Respondent-

Pharmacy and the Board agreed to the inclusion of Findings of Fact and Conclusions of

Law as required by the Board, and with the terms and conditions set forth herein.

FINDINGS OF FACT

The Board finds:

1. At all times relevant to the charges herein, the Respondent-Pharmacy was permitted to operate as a waiver pharmacy in the State of Maryland, having been issued permit number PW0305. The Respondent-Pharmacy was first issued a permit on April 11, 2007.

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2. At all times relevant to the charges herein, the Respondent-Pharmacy's permit was current and was scheduled to expire on December 31, 2013.

3. At all times relevant, the Respondent-Pharmacy was owned by Marilou Fritz and/or AI A. Balaa, RCP, Ph.D.

4. The Respondent-Pharmacy is currently located at 5711 Industry Lane, suite #33, Frederick, Maryland 21701.²

5. The Respondent-Pharmacy provides respiratory durable medical equipment and respiratory medications.

I. <u>Procedural History</u>

6. On July 15, 2011, the Board charged the Respondent-Pharmacy with violations of the Act after an annual inspection revealed that the Respondent-Pharmacy was operating without a pharmacist on duty. In addition, the Respondent-Pharmacy failed to notify the Board when it moved locations to schedule the appropriate inspections. Finally, the Respondent-Pharmacy failed an opening inspection on three occasions for various deficiencies.

7. On November 21, 2011, the Board and the Respondent-Pharmacy entered into a Consent Order ("2011 Consent Order") to resolve the charges against the Respondent-Pharmacy.

8. Pursuant to the 2011 Consent Order, the Respondent-Pharmacy agreed to pay a fine in the amount of \$1,000 within 30 days of the date of the Order.

9. The Respondent-Pharmacy paid the fine in full on January 6, 2012.

² Since becoming licensed by the Board, the Respondent-Pharmacy has relocated often, making it difficult to

10. The 2011 Consent Order further stated that the Respondent-Pharmacy "shall operate according to the Maryland Pharmacy Act and in accordance with all applicable laws, statutes and regulations pertaining to the practice of pharmacy[.]"

II. <u>Current Allegations</u>

11. On January 10, 2012 at 2:25 p.m., the Board's Inspector arrived at the Respondent-Pharmacy to perform an annual inspection. There was no pharmacist present.

12. The hours stated on the door are 8:30 a.m. to 9:00 a.m.

13. According to the Board's Inspector, there were three individuals (Witnesses A, B and C) in the pharmacy area and a woman behind the front desk in the clerical area. Witness A is a registered pharmacy technician, Witness B is an administrative assistant, and Witness C is in the process of renewing her technician license.

14. The Board's Inspector announced herself to the woman behind the front desk, who then walked into the pharmacy area and informed the Witnesses A, B and C of the Board Inspector's arrival.

15. Witnesses A, B and C "turn[ed] off the light and [left] the pharmacy" area.

16. Witness A had keys to the pharmacy.

17. Ms. Fritz was contacted and she informed the Board's Inspector that on January 6, 2012, she had submitted documentation to the Board changing the Respondent-Pharmacy's hours of operation.³ Ms. Fritz also stated that the pharmacist works on an as-needed basis.

determine its correct address at any given time. Suite numbers 28, 33 and 30 are used interchangeably. ³According to the documentation submitted by Ms. Fritz, the Respondent-Pharmacy's pharmacy hours are Monday through Friday 7:00 a.m. to 8:00 a.m. and the business hours are 8:00 a.m. to 5:00 p.m. A note on the document also states that "pharmacy hours may vary upon need of pharmacist. Please call prior to arrival."

18. The Board's Inspector did not conduct an annual inspection because there was no pharmacist present.

19. The Respondent-Pharmacy reports that it declared bankruptcy under Chapter7 and therefore ceased operations.

20. On or about May 13, 2012, the Respondent-Pharmacy notified the Board that it was planning to close. A closing inspection occurred on June 6, 2012.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent violated the following provision of the Act: under H.O. § 12-403(b)(1), (3) and/or (4), and/or H.O. § 12-409(a)(2) and/or COMAR 10.34.05.02A(3) and/or 10.34.05.02A(4) and/or 10.34.05.02A(5).

<u>ORDER</u>

Based on agreement of the parties, it is therefore this $\underline{19^{96}}$ day of September 2012, by an affirmative vote of the Board, hereby:

ORDERED that the Respondent-Pharmacy's permit to operate a pharmacy in the State of Maryland is hereby **SUSPENDED** for a period of **NINETY (90) DAYS**; and it is further

ORDERED that the suspension of the Respondent-Pharmacy's permit to operate a pharmacy in the State of Maryland is **IMMEDIATELY STAYED**; and it is further

ORDERED that the Respondent-Pharmacy shall pay a fine in the amount of \$2,000, payable to the Maryland Board of Pharmacy, within thirty (30) days of the date of this Order; and it is further

ORDERED that the Respondent-Pharmacy shall bear all expenses associated with this Order; and it is further **ORDERED** that the Respondent-Pharmacy shall operate according to the Maryland Pharmacy Act and in accordance with all applicable laws, statutes and regulations pertaining to the practice of pharmacy; and it is further

ORDERED that this document constitutes a formal disciplinary action of the State Board of Pharmacy and is therefore a public document for purposes of public disclosure, pursuant to the Public Information Act, State Gov't § 10-611 *et seq.* and COMAR 10.34.01.12.

Jobember 14,2012_

Souranis, Board President

State Board of Pharmacy

<u>CONSENT</u>

I, AI A. Balaa, RCP, Ph.D, owner and operator of Neb24, acknowledge that I opted not to consult with legal counsel before signing this document. By this Consent, I accept to be bound by this Consent Order and its conditions and restrictions. I waive any rights I may have had to contest the Findings of Fact and Conclusions of Law.

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 as provided by law. I acknowledge the legal authority and the jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. I also affirm that I am waiving my right to appeal any adverse

ruling of the Board that might have followed any such hearing.

I sign this Consent Order without reservation, and I fully understand and comprehend the language, meaning and terms of this Consent Order. I voluntarily sign this Order, and understand its meaning and effect.

Al A. Balaa, RCP, Ph.D., owner and operator Neb24, Respondent-Pharmacy

NOTARY

STATE OF MARYLAND

CITY/COUNTY OF Frederick

I HEREBY CERTIFY that on this ____ day of ______ day of ______, 2012, before

me, a Notary Public of the foregoing State personally appeared AI A. Balaa, RCP, Ph.D., owner and operator of Neb24, Permit Number PW0305, and made oath in due form of law that signing the foregoing Consent Order was his voluntary act and deed, and the statements made herein are true and correct.

AS WITNESSETH my hand and notarial seal.

SHANNON D. DOUGHTY NOTARY PUBLIC FREDERICK COUNTY MARYLAND MY COMMISSION EXPIRES FEB, 23, 2015

Notary Public

My Commission Expires 23,2015