IN THE MATTER OF	*	**BEFORE THE**
HEALTH RITE PHARMACY & MEDICAL SUPPLY	*	**MARYLAND BOARD**
(FORMERLY HEALTH-WAY PHARMACY)	*	**OF PHARMACY**
Permit No: P06677	*	**Case No.: PI-15-140**
Respondent-Pharmacy	*	
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CONSENT ORDER

On June 17, 2015, the Maryland State Board of Pharmacy (the "Board") charged **HEATH RITE PHARMACY & MEDICAL SUPPLY (formerly HEALTH-WAY) (the "Respondent-Pharmacy") (Permit No: P06677)**, under the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") §§ 12-101 *et seq.* (2014 Repl. Vol.).

The pertinent provisions of the Act provide as follows:

§ 12-403. Required Standards.

(c) 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, a registered pharmacy technician under § 12-6B-09 of this title, or a registered pharmacy intern under § 12-6D-11 of this title;

(12) Shall store all prescription or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board;

The pertinent provisions of COMAR provide as follows:

COMAR 10.34.12.01 Manufacturer's Expiration Date.

B. A wholesale distributor, pharmacist, or pharmacy shall have adequate and credible provisions for return of outdated drugs, including but not limited to partials, through its wholesaler distributor or reverse distributor.

The pertinent provisions of Title 21 of the CFR provide as follows:

§201.66 Format and content requirements for over-the-counter (OTC) drug product labeling.

(c) *Content requirements.* The outside container or wrapper of the retail package, or the immediate container label if there is no outside container or wrapper, shall contain the title, headings, subheadings, and information set forth in paragraphs (c)(1) through (c)(8) of this section, and may contain the information under the heading in paragraph (c)(9) of this section, in the order listed.

(1) (Title) "Drug Facts". If the drug facts labeling appears on more than one panel, the title "Drug Facts (continued)" shall appear at the top of each subsequent panel containing such information.

(2) "Active ingredient" or "Active ingredients" "(in each [insert the dosage unit stated in the directions for use (e.g., tablet, 5 mL teaspoonful) or in each gram as stated in §§333.110 and 333.120 of this chapter])", followed by the established name of each active ingredient and the quantity of each active ingredient per dosage unit. Unless otherwise provided in an applicable OTC drug monograph or approved drug application, products marketed without discrete dosage units (e.g., topicals) shall state the proportion (rather than the quantity) of each active ingredient.

(3) "Purpose" or "Purposes", followed by the general pharmacological category(ies) or the principal intended action(s) of the drug or, where the drug consists of more than one ingredient, the general pharmacological categories or the principal intended actions of each active ingredient. When an OTC drug monograph contains a statement of identity, the pharmacological action described in the statement of identity shall also be stated as the purpose of the active ingredient.

(4) "Use" or "Uses", followed by the indication(s) for the specific drug product.

(5) "Warning" or "Warnings", followed by one or more of the following, if applicable:

> (i) "For external use only" [in bold type] for topical drug products not intended for ingestion, or "For" (select one of the following, as appropriate: "rectal" or "vaginal") "use only" [in bold type].

(ii) All applicable warnings listed in paragraphs (c)(5)(ii)(A) through (c)(5)(ii)(G) of this section with the appropriate subheadings highlighted in bold type:

(A) Reye's syndrome warning for drug products containing salicylates set forth in §201.314(h)(1). This warning shall follow the subheading "Reye's syndrome:"

(B) *Allergic reaction and asthma alert warnings.* Allergic reaction warnings set forth in any applicable OTC drug monograph or approved drug application for any product that requires a separate allergy warning. This warning shall follow the subheading "Allergy alert:" The asthma alert warning set forth in §§341.76(c)(5) and 341.76(c)(6) of this chapter. This warning shall follow the subheading "Asthma alert:"

(C) Flammability warning, with appropriate flammability signal word(s) (e.g., §§341.74(c)(5)(iii), 344.52(c), 358.150(c), and 358.550(c) of this chapter). This warning shall follow a subheading containing the appropriate flammability signal word(s) described in an applicable OTC drug monograph or approved drug application.

(D) Water soluble gums warning set forth in §201.319. This warning shall follow the subheading "Choking:"

(E) Liver warning set forth in §201.326(a)(1)(iii) and/or stomach bleeding warning set forth in §201.326(a)(2)(iii). The liver warning shall follow the subheading "Liver warning:" and the stomach bleeding warning shall follow the subheading "Stomach bleeding warning:"

(F) Sore throat warning set forth in §201.315. This warning shall follow the subheading "Sore throat warning:"

(G) Warning for drug products containing sodium phosphates set forth in §201.307(b)(2)(i) or (b)(2)(ii). This warning shall follow the subheading "Dosage warning:"

(H) Sexually transmitted diseases (STDs) warning for vaginal contraceptive and spermicide drug products containing nonoxynol 9 set forth in §201.325(b)(2). This warning shall follow the subheading "Sexually transmitted diseases (STDs) alert:"

(iii) "Do not use" [in bold type], followed by all contraindications for use with the product. These contraindications are absolute and are intended for situations in which consumers should not use the product unless a prior diagnosis has been established by a doctor or for situations in which

certain consumers should not use the product under any circumstances regardless of whether a doctor or health professional is consulted.

(iv) "Ask a doctor before use if you have" [in bold type] or, for products labeled only for use in children under 12 years of age, "Ask a doctor before use if the child has" [in bold type], followed by all warnings for persons with certain preexisting conditions (excluding pregnancy) and all warnings for persons experiencing certain symptoms. The warnings under this heading are those intended only for situations in which consumers should not use the product until a doctor is consulted.

(v) "Ask a doctor or pharmacist before use if you are" [in bold type] or, for products labeled only for use in children under 12 years of age, "Ask a doctor or pharmacist before use if the child is" [in bold type], followed by all drug-drug and drug-food interaction warnings.

(vi) "When using this product" [in bold type], followed by the side effects that the consumer may experience, and the substances (e.g., alcohol) or activities (e.g., operating machinery, driving a car, warnings set forth in §369.21 of this chapter for drugs in dispensers pressurized by gaseous propellants) to avoid while using the product.

(vii) "Stop use and ask a doctor if" [in bold type], followed by any signs of toxicity or other reactions that would necessitate immediately discontinuing use of the product. For all OTC drug products under an approved drug application whose packaging does not include a toll-free number through which consumers can report complaints to the manufacturer or distributor of the drug product, the following text shall immediately follow the subheading: "[Bullet] side effects occur. You may report side effects to FDA at 1-800-FDA-1088." The telephone number must appear in a minimum 6-point bold letter height or type size.

(viii) Any required warnings in an applicable OTC drug monograph, other OTC drug regulations, or approved drug application that do not fit within one of the categories listed in paragraphs (c)(5)(i) through (c)(5)(vii), (c)(5)(ix), and (c)(5)(x) of this section.

(ix) The pregnancy/breast-feeding warning set forth in §201.63(a); the third trimester warning set forth in §201.63(e) for products containing aspirin or carbaspirin calcium; the third trimester warning set forth in approved drug applications for products containing ketoprofen, naproxen sodium, and ibuprofen (not intended exclusively for use in children).

(x) The "Keep out of reach of children" warning and the accidental overdose/ingestion warning set forth in §330.1(g) of this chapter.

(6) "Directions", followed by the directions for use described in an applicable OTC drug monograph or approved drug application.

(7) "Other information", followed by additional information that is not included under paragraphs (c)(2) through (c)(6), (c)(8), and (c)(9) of this section, but which is required by or is made optional under an applicable OTC drug monograph, other OTC drug regulation, or is included in the labeling of an approved drug application.

(i) Required information about certain ingredients in OTC drug products (e.g., sodium in §201.64(b), calcium in §201.70(b), magnesium in §201.71(b), and potassium in §201.72(b)) shall appear as follows: "each (insert appropriate dosage unit) contains:" [in bold type (insert name(s) of ingredient(s) (in alphabetical order) and the quantity of each ingredient). This information shall be the first statement under this heading.

(ii) The phenylalanine/aspartame content required by §201.21(b), if applicable, shall appear as the next item of information.

(iii) Additional information that is authorized to appear under this heading shall appear as the next item(s) of information. There is no required order for this subsequent information.

(8) "Inactive ingredients", followed by a listing of the established name of each inactive ingredient. If the product is an OTC drug product that is not also a cosmetic product, then the inactive ingredients shall be listed in alphabetical order. If the product is an OTC drug product that is also a cosmetic product, then the inactive ingredients shall be listed as set forth in §701.3(a) or (f) of this chapter, the names of cosmetic ingredients shall be determined in accordance with §701.3(c) of this chapter, and the provisions in §701.3(e), (g), (h), (l), (m), (n), and (o) of this chapter and §720.8 of this chapter may also apply, as appropriate. If there is a difference in the labeling provisions in this §201.66 and §§701.3 and 720.8 of this chapter, the labeling provisions in this §201.66 shall be used.

§1305.04 Persons entitled to order Schedule I and II controlled substances.

(a) Only persons who are registered with DEA under section 303 of the Act (21 U.S.C. 823) to handle Schedule I or II controlled substances, and persons who are registered with DEA under section 1008 of the Act (21 U.S.C. 958) to export these substances may obtain and use DEA Form 222 (order forms) or issue electronic orders for these substances. Persons not registered to handle Schedule I or II controlled substances and persons registered only to import

controlled substances are not entitled to obtain Form 222 or issue electronic orders for these substances.

(b) An order for Schedule I or II controlled substances may be executed only on behalf of the registrant named on the order and only if his or her registration for the substances being purchased has not expired or been revoked or suspended.

§1305.05 Power of attorney.

(a) A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records.

On August 5, 2015, the Respondent-Pharmacy participated in a Case Resolution Conference (CRC) before a panel of Board members to discuss the potential resolution of the Charges by consent. At the conclusion of the CRC, the Respondent-Pharmacy agreed to enter into this Consent Order to resolve the pending charges and to avoid the expense and time of proceeding to an administrative hearing. 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 the following:

1. The Respondent-Pharmacy is a retail pharmacy located at 1116 Reisterstown Road, Pikesville, Maryland 21208.

2. A separate pharmacy, doing business as Health-Way Pharmacy ("Health-Way") at 1116 Reisterstown Road, Pikesville, Maryland 21208, was originally permitted to operate a retail pharmacy in the State of Maryland under Permit Number P01947.

Health-Way was owned by Timur Yusufov (T03304) and Salim Yusufov[1] (unlicensed). Each individual had a 50% ownership interest in Health Way.

3. On or about January 27, 2015, Health-Way sold substantially all of its pharmacy assets to the Respondent-Pharmacy. Respondent-Pharmacy was owned by Timur Yusufov (50% ownership) and Milana Mulgan (unlicensed) (50% ownership).

4. As a result of the change in ownership, Health-Way's permit (P01947) became inactive and the Board assigned a new permit (P06677) to the Respondent-Pharmacy.

5. The Respondent-Pharmacy employs many of the same individuals who were employed by Health-Way and is in the same location as Health-Way.

II. 2015 Inspection Violations

6. On January 16, 2015, the Board conducted an annual inspection of Health-Way.

7. During the inspection, the Board's inspector observed the following:

a. Over 50 outdated items in the compounding and refrigeration area;

b. The current pharmacist, Pharmacist A, was using Pharmacist B's Controlled Substance Power of Attorney to order from the DEA's Controlled Substance Ordering System. Pharmacist B was no longer employed at the Respondent-Pharmacy as of December 2014;

c. Prescription-only medical devices were found on the OTC shelves[2]; and

[1] On or about January 29, 2015, Salim Yusufov pleaded guilty to a conspiracy to traffic over $6.6 million in contraband cigarettes, health care fraud and the receipt and delivery of misbranded drugs. He was sentenced to 12 months home detention as part of four years probation.

d. Products with foreign packaging with non-compliant English labels affixed were located behind the counter.[3]

8. The Board's inspector reviewed the inspection report with Pharmacist A and Mr. Yusufov.

IV. Moral Turpitude Conviction

9. The Board received information that on February 5, 2015, Mr. Yusufov pleaded guilty in the United States District Court for the District of Maryland to one count of "knowingly aid[ing] and abet[ting] the receipt of, after removal, any tobacco products and cigarette papers and tubes upon which the federal tax had not been paid and determined in the manner and at the time prescribed by Chapter 52 of the United States Code, or regulations thereunder." 26 U.S.C. §§ 5751(1)(a) and 5762(b).

10. Mr. Yusufov entered into a plea agreement under which he agreed to plead guilty and pay a criminal monetary penalty of $50,000. Mr. Yusufov was also ordered to forfeit to the United States $200,000, which had been transferred by Mr. Yusufov to another defendant in the criminal enterprise.

11. According to the stipulated facts, on or about December 28, 2012, Mr. Yusufov accepted a delivery of contraband cigarettes on behalf of another individual. Mr. Yusufov provided a cash payment of $530,000 in exchange for the delivery. The contraband cigarettes were taxable pursuant to Chapter 52 of Title 26 of the United States Code, and the regulations thereunder. However, no such taxes were paid. Mr. Yusufov admitted to these facts.

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2 During the Board's annual inspection in 2013, similar violations were found by the inspector.
3 During the Board's annual inspection in 2013, similar violations were found by the inspector.

12. Mr. Yusufov and Respondent dispute that the plea agreement constitutes moral turpitude conviction under applicable regulations or that is related to the operation of the pharmacy.

13. On or about March 11, 2015, Mr. Yusufov was notified by the Maryland Department of Health and Mental Hygiene that effective April 11, 2015, he would be disqualified from future participation in the Maryland Medical Assistance Program, either as a provider or as a person providing services for which Medicaid payment will be claimed. Mr. Yusufov contested this disqualification and the matter is currently on appeal. No hearing has yet occurred and the Respondent-Pharmacy and Mr. Yusufov remain eligible to participate in the Maryland Medical Assistance Program.

V. Additional Facts

14. On or about August 7, 2015, the Board conducted an annual inspection of the Respondent-Pharmacy.

15. The annual inspection revealed that the Respondent-Pharmacy has cured the deficiencies cited during the Board's previous inspections.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent-Pharmacy violated the following provision of the Act: H.O. §§ 12-403(c)(1), (9) and (12).

ORDER

Based on agreement of the parties, it is therefore this 9th day of November 2015, 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 **SUSPENDED** for a period of thirty (30) days, with all thirty (30) days **STAYED**; and it is further;

ORDERED that within thirty (30) days, the Respondent-Pharmacy shall pay a fine in the amount of **$10,000**, payable to the Maryland Board of Pharmacy; and it is further

ORDERED that the Respondent-Pharmacy shall be placed on **PROBATION** for a period of three (3) years; and it is further

ORDERED that during the three (3) year probationary period, the Board, at its discretion, may conducted unannounced site visits; and it is further

ORDERED that at the conclusion of the three (3) year probationary period, and after the Respondent-Pharmacy has satisfied all of the required terms and conditions, including payment in full of the fine, the Respondent-Pharmacy may file a written petition for termination of its probationary status without further conditions or restrictions, but only if the Respondent-Pharmacy has satisfactorily complied with all conditions of the Consent Order and if there are no pending complaints before the Board regarding the Respondent-Pharmacy; and it is further

ORDERED that failure to comply with the terms and conditions of this Consent Order, including but not limited to failure to pay the required fine and/or failure to allow inspection by the Board and/or **a materially** unsatisfactory inspection, constitutes a violation of this Consent Order and the Board, in its discretion, after notice and an opportunity for a show cause hearing before the Board may impose any appropriate sanction under the Act; 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 its operation as 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.

Mitra Gavgani, President
State Board of Pharmacy

CONSENT

I, Timur Yusufov, Co-Owner of Health Rite Pharmacy & Medical Supply ("Health Rite"), for and on behalf of Health Rite acknowledge that Health Rite has had the opportunity to consult with legal counsel before signing this document. By this Consent, Health Rite agrees to be bound by this Consent Order and its conditions and restrictions. Health Rite waives any rights it may have had to contest the Findings of Fact and Conclusions of Law.

Health Rite acknowledges the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which Health Rite would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on its own behalf, and to all other substantive and procedural protections as provided by law. Health Rite acknowledges the legal authority and the jurisdiction of the Board to initiate

these proceedings and to issue and enforce this Consent Order. Health Rite waives any right to appeal any adverse ruling of the Board that might have followed any such hearing.

I sign this Consent Order on behalf of Health Rite 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.

I am a duly authorized representative of Health Rite and am legally authorized to sign this consent order on behalf of Health Rite.

10/30/15
Date

by: Timur Yusufov, Co-Owner
Health Rite Pharmacy & Medical Supply

Read and approved:

Kathleen McDermott, Esq., Attorney for Health Rite

NOTARY

STATE OF MARYLAND

CITY/COUNTY OF Baltimore :

I HEREBY CERTIFY that on this 30th day of Oct., 2015, before me, a Notary Public of the foregoing State personally appeared Timur Yusufov, Co-Owner of **Health Rite Pharmacy & Medical Supply**, 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.

Notary Public

My Commission Expires: 06/19/2019