IN THE MATTER OF	*	**BEFORE THE**
DRUGGLOBE, INC.	*	**MARYLAND BOARD**
Respondent-Pharmacy	*	**OF PHARMACY**
PERMIT NO. PW0528	*	**Case No. 21-036**

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FINAL ORDER

On the 17th day of January, 2024, the Maryland Board of Pharmacy (the "Board") notified **DRUGGLOBE, INC.** ("the Respondent-Pharmacy"), Permit Number **PW0528**, of its intent to revoke its waiver permit pursuant to the Maryland Pharmacy Act, (the "Act") Md. Code Ann., Health Occ. §§ 12-101 *et seq.* (2021 Repl. Vol. and 2022 Supp.) and certain provisions of the Board's regulations found at Md. Code Regs. ("COMAR") 10.34 *et seq.*

Specifically, the Board based its action on the Respondent's violation of the following provisions of the Act:

Health Occ. § 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;

The pertinent statutes of the Board include:

Health Occ. § 12-413. Inspection of pharmacies

(a) *In general* - During business hours, the Secretary, the Board, or the agents of either may enter any permit holder's pharmacy and inspect for compliance with federal and State laws and regulations:

(1) Any drugs or devices, dentifrices, domestic remedies, and toilet articles that are in the pharmacy;

(2) Any records or publications that are required to be kept by a pharmacy under this title; and

(3) The facility.

Health Occ. § 12-513. Notice of closing

(a) Before the closing of a pharmacy for more than 7 consecutive days, at least 14 days before the anticipated closing of the pharmacy, the owner of the pharmacy shall provide notice of the closing by:

(1) Posting a notice:

(i) That is conspicuously positioned in the pharmacy and readable by pharmacy customers; and

(ii) If applicable, on the pharmacy's website; and

(2) Providing written and verbal notice to each customer who picks up a prescription or refill.

(b) Each notice shall indicate:

(1) The date of the anticipated closing of the pharmacy, if available;

(2) The name of the pharmacy to which the closing pharmacy will transfer pharmacy customers' prescriptions and records; and

(3) That a pharmacy customer may request the closing pharmacy to send the pharmacy customer's prescriptions and records to another pharmacy.

The pertinent grounds for Board action against a licensed pharmacist under § 12-313 of this title include:

Health Occ. § 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 . . . reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the licensee:

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

The pertinent provisions of Code Md. Regs ("COMAR"), 10.34.10 and COMAR 10.19.03 provide as follows:

COMAR 10.34.05.02 Prescription Area

A. The pharmacy permit holder shall:

(2) Provide a means of securing the prescription area;

(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[.]

COMAR 10.34.10.01. Patient Safety and Welfare.

A. A pharmacist shall:

(1) Abide by all federal and State laws relating to the practice of pharmacy and the dispensing, distribution, storage, and labeling of drugs and devices, including but not limited to:

(a) United States Code, Title 21,

(b) Health-General Article, Titles 21 and 22, Annotated Code of Maryland,

(c) Health Occupations Article, Title 12, Annotated Code

of Maryland,

(d) Criminal Law Article, Title 5, Annotated Code of Maryland, and

(e) COMAR 10.19.03;

(2) Verify the accuracy of the prescription before dispensing the drug or device if the pharmacist has reason to believe that the prescription contains an error[.]

B. A pharmacist may not:

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

COMAR 10.34.14.03. Information to be Included in Notification of Closing.

(A) At least 14 days before a location's anticipated date of ceasing to operate as a licensed pharmacy, the pharmacy permit holder shall:

(1) Notify the:

(a) Board in writing by certified mail, return receipt requested, or hand delivered to the Board's office of the day on which the licensed pharmacy will cease to operate as a pharmacy; and

(b) Division of Drug Control by certified mail, return receipt requested, of the day on which the licensed pharmacy will cease to operate as a pharmacy; and

(2) Request a closing inspection date.

COMAR 10.34.14.04. Required Information and Procedure.

A. At the closing inspection of a licensed pharmacy, the pharmacy permit holder shall provide to the Board, or the Board's agent, information and documentation required by Regulation .05 of this chapter.

B. The pharmacy permit holder shall remove or completely cover indications that the premises was a pharmacy within 30 days after the date the licensed pharmacy ceases to operate as a pharmacy.

C. The pharmacy permit holder shall notify prescription drug suppliers

to the pharmacy, before ceasing to operate as a pharmacy, of the date that the location will cease to operate as a pharmacy.

D. The pharmacy permit holder shall notify the public of the date that the pharmacy will cease to operate as a pharmacy by that date.

E. The pharmacy permit holder shall notify the public of the location to which the patients' records have been transferred, by the date the pharmacy ceases to operate.

F. If patient records are not transferred, the pharmacy permit holder shall notify the public of the:

(1) Location of the patient records;

(2) Method by which the patient records shall be maintained; and

(3) Procedure by which patients and other authorized individuals or entities may access the patient records.

G. The pharmacy permit holder shall comply with all federal and State laws and regulations.

H. If the Board's agent performs the closing inspection, the Board's agent shall obtain information and documentation required by Regulation .05 of this chapter.

COMAR 10.34.14.05. Documentation Due at Closing Inspection.

Information and documentation due at the closing inspection shall include:

A. The exact date on which the pharmacy ceased to operate as a pharmacy;

B. A copy of the inventory required by the Drug Enforcement Administration;

C. The pharmacy permit and Maryland Department of Health controlled dangerous substance registration for cancellation;

D. The names, address, telephone numbers, and Drug Enforcement Administration registration numbers of the persons or business entities to whom any prescription drugs in stock were returned or transferred under Regulation .05 of this chapter and for any prescription files or patient records transferred;

E. If prescription drugs are destroyed pursuant to Regulation .06 of this

chapter, and Regulation .07 of this chapter does not apply to the prescription drugs, the pharmacy permit holder shall provide the Board with a letter, signed under oath by the pharmacy permit holder, stating the:

(1) Date, place and manner in which the prescription drugs were destroyed;

(2) Names, addresses, and telephone numbers of the persons responsible for destroying the prescription drugs; and

(3) Name, dosage unit, and quantity of each type of prescription drug destroyed;

F. If any patient records which are not required to be maintained by law, or other documents containing patient information are destroyed, the pharmacy permit holder shall provide the Board with a letter, signed under oath by the pharmacy permit holder, stating:

(1) That the documents were destroyed;

(2) The date of the destruction of the documents;

(3) The name and address of the person who destroyed the documents;

(4) That the records or other documents were destroyed in a manner so as to avoid breaches of patients' confidentiality; and

(5) The identity of the records destroyed; and

G. If any patient records or other documents containing patient information are transferred, the pharmacy permit holder shall provide the Board with a letter, signed under oath by the pharmacy permit holder, stating:

(1) The date, time, place to which and manner in which the records or other documents were transferred;

(2) The names, addresses, and telephone numbers of the persons responsible for transferring the records or other documents;

(3) That the records or other documents were transferred in a manner so as to avoid breaches of patients' confidentiality; and

(4) The identity of the records transferred.

COMAR 10.34.14.06 Disposition of Prescription Drugs Other than Controlled Dangerous Substances.

With the exception of controlled dangerous substances, prescription drugs in stock shall be disposed of by one or more of the following means:

A. Returning them to a distributor or manufacturer; or

B. Transferring them to another licensed pharmacy, authorized prescriber, or other person or entity approved by the Board or the Division of Drug Control.

In its Notice, the Board informed the Respondent-Pharmacy that it had the opportunity to request a hearing before the Board by submitting a request in writing to the Board's Executive Director within thirty days of service of the Notice. More than thirty days have elapsed since the service of the Notice on the Respondent-Pharmacy, and the Respondent-Pharmacy has not requested a hearing.

FINDINGS OF FACT

The Board makes the following findings of fact:

1. At all times relevant hereto, the Respondent-Pharmacy had a permit to operate as a waiver pharmacy[1] in the State of Maryland.[2] The Respondent-Pharmacy was originally issued a waiver permit on or about May 19, 2020. The Respondent-Pharmacy's waiver permit was renewed on March 30, 2022, and expires on May 31, 2024.

[1] "Waiver pharmacy" means a pharmacy that has been issued a waiver permit by the Board in order to provide limited specialty pharmaceutical services. (*See* COMAR 10.34.17.01 *et.al*)

[2] The Respondent-Pharmacy described their specialty services on their May 12, 2020, Application for Pharmacy Waiver Permit as follows: "Mail Order Pharmacy only for the dispense of non[-]controlled prescription drugs. All the prescriptions will be received by [certified e-prescribe electronic system] to our HIPPA [*sic*] compliant pharmacy management system[.]"

2. At all times relevant, the Respondent-Pharmacy operated as a specialty, closed door, mail order only pharmacy located in Montgomery County, Maryland.

OPENING INSPECTION

3. On or about July 10, 2020, a virtual opening inspection was conducted at the Respondent-Pharmacy's premises by a board inspector.

4. Information provided by the Respondent-Pharmacy explained their e-prescription dispensing process as such:

    a. Online patients call or visit the website for treatment of symptoms.

    b. Online patients fill out a questionnaire and upload their drivers license into the system in order to verify their identity.

    c. The online patient's completed questionnaire is then reviewed by a licensed physician.

    d. The licensed physician initiates a video-based telehealth visit.

    e. If medication is warranted, the physician will issue an e-prescription.

    f. The e-prescriptions are received by the Respondent-Pharmacy.

    g. Licensed pharmacists may consult with the prescribing physician and/or patient through audio and video means if necessary.

    h. The Respondent-Pharmacy's licensed pharmacists review the e-prescription and check for drug interactions and oversee daily ordering.

    i. Prescriptions are then dispensed and sent via USPS to the online patient.

5. During the initial opening inspection, a dispensing report was provided from May 15, 2020, to July 10, 2020. The report revealed that the Respondent-Pharmacy

received a total of five (5) e-prescriptions from Doctor 1.[3] The e-prescriptions were for vitamins and were dispensed by the Respondent-Pharmacy to a single patient between June 22, 2020, and June 29, 2020.

6. A second dispensing report was requested and revealed that on July 17, 2020, the Respondent-Pharmacy received a total of two (2) additional e-prescriptions from Doctor 1. The e-prescriptions were for prescription-only vasodilators and were dispensed to a single patient on July 17, 2020.

BOARD INVESTIGATION

7. By subpoenas dated March 5, 2021, and April 9, 2021, the Board's investigator requested additional information regarding the Respondent-Pharmacy's operations and the relationship between the Respondent-Pharmacy and its prescribing physicians.

8. The Respondent-Pharmacy provided an updated dispensing report that revealed the following:

    a. From approximately June 22, 2020, to April 20, 2021, the Respondent-Pharmacy dispensed thirty prescriptions.

    b. Seven of the prescriptions were written by Doctor 1 for the time period of June 22, 2020, to July 17, 2020.

    c. The remaining twenty-three (23) prescriptions were written by Doctor 2 for the time period of February 10, 2021, to April 20, 2021.

    d. Out of the twenty-three (23) prescriptions written by Doctor 2, nine (9) were written and filled by the Respondent-Pharmacy for out-of-state patients. (IL, NJ, HI, OH, NY, IN, and FL)

[3] For confidentiality and privacy purposes, the names of individuals and facilities involved in this case are not disclosed in this document. Upon written request, the Administrative Prosecutor will provide the information to the Respondent-Pharmacy.

e. Out of the above listed states, Doctor 2 only had a license to practice medicine in New Jersey, and that license expired on or about June 30, 2011.

f. Both physicians have the same Maryland address listed on the dispensing report.

9. The Board's investigator discovered that:

a. Doctor 1 lives in California and does not work at the address listed on the Respondent-Pharmacy's dispensing report.

b. Doctor 1 is only licensed in California and Virginia – **NOT** in Maryland.

c. Doctor 2 lives in Maryland but does not work at the address listed on the Respondent-Pharmacy's dispensing report.

d. Doctor 2's Maryland medical license was summarily suspended by the Maryland Board of Physicians on March 24, 2020.

e. Doctor 2 surrendered his Maryland medical license in lieu of further disciplinary action on April 6, 2020.

f. Doctor 2's physician profile on the Board of Physicians' website shows his status as surrendered.

g. Doctor 2 submitted twenty-three (23) e-prescriptions to the Respondent-Pharmacy **AFTER** he surrendered his Maryland medical license.

2021 ANNUAL INSPECTION

10. On May 25, 2021, the Board conducted an Annual Inspection on the Respondent-Pharmacy.

11. The Board found the following issues:

a. Respondent-Pharmacy is located in an office within a suite of offices containing different businesses (mortgage company, staffing and personnel management company). Respondent-Pharmacy's licensed pharmacist does not possess a key to the pharmacy door and noted that the pharmacy is not locked or armed when the pharmacy closes – allowing unauthorized entry

after the pharmacy closes. (In violation of COMAR 10.34.05.02A(3))

b. Operating hours are not current with the Board

c. Personnel training is not current. (In violation of COMAR 10.34.21.03B(3) and (4))

d. Prescription labels missing expiration date. (In violation of Health Occ. § 12-505(b)(2))

e. Missing policies for informing patients of procedures to follow when reporting a suspected medication error (In violation of COMAR 10.34.26.02), removal of expired medications. (In violation of COMAR 10.34.12.01); and investigating discrepancies and reporting of theft or loss (In violation of COMAR10.19.03.12B(4))

f. Missing records of annual educational training for pharmacy staff. (In violation of COMAR 10.34.26.03B)

12. On or about June 11, 2021, the Respondent-Pharmacy provided evidence to support the completion of action items in the 2021 Annual Report – except those related to the Respondent-Pharmacy's security.

2022 ANNUAL INSPECTION

13. On May 27, 2022, at approximately 10:00 a.m., a Board inspector attempted to complete the Respondent-Pharmacy's Annual Inspection. Upon arrival, the inspector learned that the Respondent-Pharmacy's hours of operation had changed in March 2021 but were not updated with the Board.

14. The Respondent-Pharmacy's IT administrator arrived at approximately 11:00 a.m., with a key and opened the Respondent-Pharmacy. The inspector did not enter the Respondent-Pharmacy as there was no pharmacist on site.[4] At approximately

[4] COMAR 10.34.05.02B - The pharmacist shall: (2) Have sole possession of a means of access to the pharmacy, except in emergencies

12:30 p.m., a licensed pharmacist arrived on site and the Annual Inspection was conducted.

15. During the inspection, the Respondent-Pharmacy was unable to provide the inspector with a dispensing report or copy of a recent prescription.

RESPONDENT-PHARMACY CLOSING

16. By letter dated November 3, 2022, the Respondent-Pharmacy returned their waiver permit and stated "DrugGlobe, Inc. is hereby surrendering its pharmacy permit and has ceased operations."

17. The Board emailed the Respondent-Pharmacy regarding their November 3, 2022, letter and attempted to set-up a closing inspection as required by COMAR 10.34.14.01 *et.al.*

18. Receiving no response from the Respondent-Pharmacy, on December 13, 2022, Board inspectors went to the Respondent-Pharmacy's address of record and found the location empty.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent- Respondent-Pharmacy's actions, including those mentioned above, constitute violations of Health Occ. § 12-403(c)(1) and (9), § 12-413(a)(1)-(3), § 12-513(a) and (b), and § 12-313(b)(25), and COMAR 10.34.05.02(A)(2)-(5), COMAR 10.34.10.01(A)(1) and (A)(2) and (B)(1), and COMAR 10.34.14.03 through COMAR 10.34.14.06.

ORDER

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

ORDERED that the Respondent-Pharmacy, **DrugGlobe, Inc.**'s waiver permit to operate as a pharmacy in the State of Maryland under Permit Number **PW0528** be and hereby is **REVOKED**; and it is further

ORDERED that this Order is a **PUBLIC DOCUMENT** pursuant to Md. Code Ann., Gen. Prov. §§ 4-101 *et seq.* (2014).

1/17/2024
Date

Neil B Leikach, R.Ph., M.Sc.
President
Maryland Board of Pharmacy

NOTICE OF RIGHT TO APPEAL

Pursuant to Md. Code Ann., Health Occ. § 6-310(b) (2021 Repl. Vol. and 2022 Supp.), you have a right to take a direct judicial appeal. A Petition for Judicial Review must be filed within thirty (30) days of service of this Order and shall be made as provided for judicial review of a final decision in the Md. Code Ann., State Gov't §§ 10-201 *et seq.* (2021 Repl. Vol. and 2022 Supp.) and Title 7, Chapter 200 of the Maryland Rules.