IN THE MATTER OF	*	**BEFORE THE**
SOLEIL PHARMACY	*	**MARYLAND STATE**
Respondent	*	**BOARD OF PHARMACY**
Permit Number: P07732	*	**Case Number: 21-209**

* * * * * * * * * * * * *

CONSENT ORDER

On August 17, 2022, the Maryland State Board of Pharmacy (the "Board") charged **SOLEIL PHARMACY** (the "Respondent-Pharmacy"), Permit Number P07732, with violating the following provisions of the Maryland Pharmacy Act (the "Act"), Md. Code Ann., Health Occ. ("Health Occ.") §§ 12-101 *et seq.* (2021 Repl. Vol.) and/or the Code of Maryland Regulations ("COMAR").

The pertinent provisions of the Act provide:

§ 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[.]

§ 12-313. 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:

. . . .

(21) Is professionally... incompetent; [and]

. . . .

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

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

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;

(2) Practice pharmacy under circumstances or conditions which prevent the proper exercise of professional judgment; or

(3) Engage in unprofessional conduct.

COMAR 10.34.10.08. Refusing to Dispense a Controlled Substance.

A. If, based on generally accepted professional standards for the practice of pharmacy, a pharmacist has reason to believe, or should have reason to believe, that a prescription for a controlled dangerous substance was not issued for a legitimate medical purpose in the usual course of the prescriber's practice, the pharmacist may not dispense the controlled dangerous substance until the pharmacist:

(1) Consults with the prescriber; and

(2) Verifies the medical legitimacy of the prescription.

B. If, after consulting with the prescriber, and based on generally accepted professional standards for the practice of pharmacy, a pharmacist has reason to believe that the prescription for a controlled dangerous substance was not issued for a legitimate medical purpose in the usual course of the prescriber's practice, the pharmacist shall:

(1) Refuse to dispense the drug[.]

COMAR 10.34.20.02. Requirements for Prescription Validity.

A. A valid prescription shall be:

(1) Valid in the professional judgment of the pharmacist responsible for filling the prescription[.]

COMAR 10.19.03.07. Prescriptions.

. . . .

C. Purpose of Issue of Prescription (21 CFR § 1306.04).

> (1) A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the individual practitioner's professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Maryland Controlled Dangerous Substances Act Criminal Law Article, §§ 5-501-5-505, Annotated Code of Maryland, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled dangerous substances.

On November 16, 2022, a Case Resolution Conference ("CRC") was held before a committee of the Board. As a resolution of this matter, and to mutually resolve the pending charges and disputed claims against the Respondent-Pharmacy in lieu of an evidentiary hearing, the Respondent-Pharmacy and the Board agreed to enter into this public Consent Order consisting of Findings of Fact, Conclusions of Law, and an Order.

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 pharmacy in the State of Maryland. The Respondent-Pharmacy was originally issued a permit on or about May 18, 2018, under Permit Number P07732. The Respondent-Pharmacy's permit expires on May 31, 2024.

2. The Respondent-Pharmacy is co-owned and co-managed by a pharmacist ("Pharmacist-Owner") [1] and a pharmacy technician ("Pharmacy Technician-Owner").

3. At all times relevant hereto, the Pharmacist-Owner was licensed to practice pharmacy in the State of Maryland. The Pharmacist-Owner was originally licensed to practice pharmacy in Maryland on or about October 17, 2001. The Pharmacist's license expires on August 31, 2023.

4. At all times relevant hereto, the Pharmacy Technician-Owner was licensed to practice as a pharmacy technician in the State of Maryland. The Pharmacy Technician was originally licensed to practice as a pharmacy technician in Maryland on or about November 29, 2017. The Pharmacy Technician's license expires on November 30, 2023.

5. On or about April 15, 2021, the Maryland Office of Controlled Substances Administration ("OCSA") referred the Respondent-Pharmacy to the Board raising concerns about the Respondent-Pharmacy's controlled dangerous substance ("CDS") dispensing patterns.

6. After receiving the referral, the Board initiated an investigation.

7. As part of the Board's investigation, the Board obtained a dispensing report from the prescription drug monitoring program ("PDMP") regarding CDS prescriptions the Respondent-Pharmacy dispensed during a given time period and also obtained hard copies of prescriptions from the Respondent-Pharmacy.

[1] For confidentiality and privacy purposes, the names of individuals and facilities involved in this case are not disclosed in this document.

8. A review of the PDMP report revealed that out of 19,485 prescriptions of controlled (Schedule II to V) medications dispensed from the Respondent-Pharmacy from November 1, 2018 to August 5, 2021, 6,476 (33%) were Schedule II prescriptions, 4,879 (75%) of these Schedule II prescriptions were prescribed in quantities that were over a 30-day supply, 1,335 (20%) were prescribed in quantities that were over 120 tablets, and 3,124 (48%) of these Schedule II prescriptions were prescribed for patients under 40 years old.

9. A review of the PDMP report further revealed that out of 659 prescriptions for oxycodone 30mg dispensed by the Respondent-Pharmacy from November 1, 2018, to August 5, 2021, 369 (56%) were prescribed in quantities, greater than 120 tablets, and 427 (65%) were prescribed by five prescribers from two different health care facilities.

10. A review of the 24 hardcopy prescriptions obtained from the Respondent-Pharmacy from February 24, 2021, to March 23, 2021, found that there were red flags for many of the prescriptions. The red flags included the following:

a. 24 (100%) of the prescriptions were Schedule II prescriptions and were high dose opioids with 90 MME or higher daily dose;

b. 5 (20%) of the prescriptions were for long-distance patients from the same household;

c. 6 (25%) of the prescriptions were for patients under 40 years old; and

d. 3 (12%) of the prescriptions were prescribed by noted prescribers.

11. On or about November 5, 2018, during a routine inspection OSCA conducted at the Respondent-Pharmacy, the Pharmacist-Owner acknowledged a prescription of Oxycodone 30mg #475 (7 days of supply), 10-11 tablets every 4 hours written by a prescriber, but confirmed that the prescriber had provided the Pharmacist-Owner with a letter explaining the legitimacy of the prescription which was shown to inspectors and further noted that the prescription had been approved by Medicare.

12. On or about April 13, 2021, during a routine inspection OCSA conducted at the Respondent-Pharmacy, the Pharmacist-Owner acknowledged that some patients came to the Respondent-Pharmacy from great distances because they had trouble filling their prescriptions at other pharmacies.

13. After this interaction with OCSA, the Pharmacist-Owner promptly informed these patients that the Pharmacy would no longer fill their prescriptions. After affording these patients a short period of time to transfer their prescriptions to an alternate pharmacy, the Pharmacy stopped filling the prescriptions in question.

14. On or about July 14, 2022, Board staff conducted an inspection of a pharmacy located in Baltimore, Maryland ("Pharmacy 2"). During the inspection, Board staff observed the following: a will call bag with the Respondent-Pharmacy's label for a compound using CDS; a roll of labels from the Respondent-Pharmacy; a bag with the Respondent-Pharmacy's label; and a label from the Respondent-Pharmacy for a Schedule II CDS with a note stating, "Not due until 7/15/22."

15. On or about July 30, 2022, the Board received a complaint from an individual alleging that the Respondent-Pharmacy was using its CDS registration to purchase CDS

that was then transferred to Pharmacy 2, which was not authorized to receive CDS after June 30, 2022 (when its CDS Registration expired).

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent-Pharmacy's actions, as described above, constitute violations of the following provisions of the Act and COMAR: Heath Occ. § 12-403(c)(1) and (9), Health Occ. § 12-303(b)(21) and (25), and COMAR 10.34.10.01(A)(1) and (A)(2), and (B)(1), (2) and (3), COMAR 10.34.10.08(A)(1) and (2) and B(1), and COMAR 10.34.20.02(A)(1), and COMAR 10.19.03.07 (C)(1).

ORDER

It is, on the affirmative vote of a majority of the Board, hereby:

ORDERED that the permit held by the Respondent-Pharmacy (Permit No. P07732) is **SUSPENDED** for **ONE** (1) **YEAR**, all of which is **STAYED**, provided that the Respondent-Pharmacy complies with the following conditions:

1. Within six (6) months of the Effective Date of this Consent Order, the Respondent-Pharmacy shall require all pharmacy staff, including the Pharmacist-Owner and the Pharmacy Technician-Owner, to successfully complete an ACPE-accredited course in substance use disorder and provide proof of completion to the Board.
2. Within sixty (60) days of the Effective Date of this Consent Order, the Respondent-Pharmacy shall engage the services of a Board-approved peer consultant focusing on opioid dispensing practices, including prescription

verification, legitimate medical need, valid patient-prescriber relationships, and clinical documentation, subject to the following terms and conditions:[2]

a) The Respondent-Pharmacy shall submit the following documentation from the peer consultant to the Board for approval *prior to engaging any peer services*: curriculum vitae, outline of proposed consultation including goals/objectives, schedule and timeline, and curriculum content; and

b) The Respondent-Pharmacy shall ensure that the peer consultant submits to the Board a final report regarding the Respondent-Pharmacy.

3. Within one (1) year from the Effective Date of this Consent Order, the Respondent-Pharmacy shall pay a fine of **FIVE THOUSAND DOLLARS ($5,000),** payable to the Maryland Board of Pharmacy.

4. The Respondent-Pharmacy shall comply with the Maryland Pharmacy Act and all applicable laws and regulations pertaining to the practice of pharmacy.

AND IT IS FURTHER ORDERED that the Board, or its agents, may perform random inspections of the Respondent-Pharmacy to ensure compliance with all laws governing the dispensing of controlled dangerous substances; and it is further

[2] The Board-approved peer consultant may serve concurrently in compliance with the same conditions in the Consent Orders (Board Case Number 21-209) for the Pharmacist-Owner and the Pharmacy Technician-Owner, as well as the Pre-charge Consent Order in Voshell's Pharmacy.

ORDERED that if the Board determines, after notice and an opportunity for an evidentiary hearing before the Board if there is a genuine dispute as to a material fact or a show cause hearing before the Board if there is no genuine dispute as to a material fact, that the Respondent-Pharmacy has failed to comply with any terms or conditions of this Consent Order, the Board may take additional action; and it is further

ORDERED that the Respondent-Pharmacy is responsible for all costs incurred in fulfilling the terms and conditions of this Consent Order; and it is further

ORDERED that the Effective Date of this Consent Order is the date on which the Consent Order is executed by the Board President or a designee, and it is further

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

2-13-23
Date

Deena Speights-Napata, MA
Executive Director
Maryland State Board of Pharmacy

CONSENT

Soleil Pharmacy, through its co-owners Trieu Bao and Thuy Cao, acknowledges that it is represented by counsel and has consulted with counsel before entering into this Consent Order. By this Consent and for the purpose of resolving the issues, allegations, and disputed claims raised by the Board, Soleil Pharmacy agrees to be bound by the foregoing Consent Order and its conditions.

Soleil Pharmacy acknowledges the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which it 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 provided by the law. Soleil Pharmacy agrees to forego any opportunity to challenge these allegations. Soleil Pharmacy acknowledges the legal authority and jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. Soleil Pharmacy affirms that it is waiving my right to appeal any adverse ruling of the Board that might have followed after any such hearing.

Soleil Pharmacy voluntarily and without reservation signs this Consent Order after having an opportunity to consult with counsel, and it fully understands and comprehends the language, meaning and terms of this Consent Order.

1/9/2023 | 10:04 AM EST
Date

DocuSigned by:
Trieu Bao
354BE4A5A07E4E0...
Trieu Bao
Co-Owner of *Respondent-Pharmacy*

1/9/2023 | 10:04 AM EST
Date

DocuSigned by:
Thuy Cao
D94C9B02B5FD4EE...
Thuy Cao
Co-Owner of *Respondent-Pharmacy*

NOTARY

STATE OF MARYLAND
CITY/COUNTY OF _____

I HEREBY CERTIFY that on this _____ day of _____

_____, 2022, before me, a Notary Public of the foregoing State and City/County personally appeared Trieu Bao and Thuy Cao, and made oath in due form of law that signing the foregoing Consent Order was their voluntary act and deed.

AS WITNESSETH my hand and notary seal.

_____

Notary Public

My commission expires: