

IN THE MATTER OF
VIVIAN K. BERINYUY
Respondent

License Number: 21252

*** BEFORE THE**
*** MARYLAND STATE**
*** BOARD OF PHARMACY**
*** Case Number: 24-001**

*** * * * ***
CONSENT ORDER

On December 20, 2023, the Maryland State Board of Pharmacy (the “Board”) charged **VIVIAN K. BERINYUY** (the “Respondent”), License Number: **21252**, under the Maryland Pharmacy Act (the “Act”), Md. Code Ann., Health Occ. (“Health Occ.”) §§ 12-101 *et seq.* (2021 Repl. Vol. and 2023 Supp.) and the Code of Maryland Regulations (“COMAR”).

The pertinent provisions of the Act and COMAR provide:

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:

.....

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

.....

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

The pertinent provisions of COMAR 10.34.10 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.

.....

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.

On February 14, 2024, a Case Resolution Conference ("CRC") was held before a committee of the Board. As a resolution of this matter, the Respondent 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:

BACKGROUND

1. At all times relevant hereto, the Respondent was and is licensed to practice pharmacy in the State of Maryland. The Respondent was originally licensed to practice pharmacy in Maryland on January 3, 2013, under License Number 21252. The Respondent's license is scheduled to expire on September 30, 2024, subject to renewal.

2. At all times relevant hereto, the Respondent was employed as a pharmacist to provide pharmacy services at a pharmacy (the "Pharmacy")¹ located in Hyattsville, Maryland.

3. At all times relevant hereto, the Pharmacy was owned by an individual (the "Owner"), who was not licensed as a pharmacist in Maryland.

THE COMPLAINT

4. On or about July 6, 2023, the Board received a referral from the Maryland Office of Controlled Substances Administration ("OCSA") regarding regulatory inspections it conducted of the Pharmacy on June 8, 2023, and July 5, 2023.

5. At the June 8, 2023, inspection, an OCSA inspector met with the Respondent and spoke with the Owner by telephone. During the inspection, the OCSA inspector discovered the following deficiencies: major discrepancy between the actual count of Schedule II Controlled Dangerous Substances ("CDS") compared to the Pharmacy's records; the Respondent could not produce Schedule II CDS invoices prior to October

¹ In order to maintain confidentiality, names of individuals and facilities involved in this matter will not be used in this document.

2021; and the Pharmacy's dispensing records indicated no dispensing of Schedule II CDS since May 23, 2019, even though the Pharmacy consistently ordered large quantities of Schedule II CDS after May 23, 2019. Moreover, the Owner stated that the Pharmacy had not ordered Schedule II CDS since October of 2021, even though records indicated that large quantities of oxycodone were ordered in January of 2022. Finally, the Owner stated that large quantities of Schedule II CDS were stolen during a break-in a couple of months ago, but he could not produce a police report nor a DEA 106 Form. The OCSA inspector gave the Respondent and the Pharmacy two weeks to produce documents to reconcile the significant discrepancies.

6. On or about July 5, 2023, OCSA inspectors conducted a follow-up inspection of the Pharmacy. During the inspection, OCSA inspectors noted the following deficiencies: even though the Respondent produced Schedule II CDS invoices from 2019 to 2022, many invoices were missing; the Respondent was unable to open the Schedule II CDS safe to perform a drug count due to battery problems; and the Owner reporting that he had transferred Schedule II CDS inventory from the Pharmacy to a new pharmacy ("Pharmacy 1") he planned to open in Takoma Park, Maryland, even though Pharmacy 1 did not have a CDS or DEA registration. OCSA inspectors then traveled to Pharmacy 1 in Takoma Park, Maryland with the Owner, intending to conduct an inspection of Pharmacy 1. The Owner, however, was unable to open the padlock to the door, stating that the "delivery person" had the key.

7. After receiving the referral from OCSA, the Board initiated an investigation of the Respondent and the Pharmacy.

BOARD INVESTIGATION

8. The Board's investigation included but was not limited to: subpoenaing pharmacy records from the Pharmacy; reviewing the Automation of Reports and Consolidated Orders System ("ARCOS") report regarding CDS purchased by the Respondent-Pharmacy; reviewing the Prescription Drug Monitoring Program ("PDMP") report regarding CDS the Pharmacy dispensed; onsite inspections and audits of the Pharmacy and Pharmacy 1 on or about July 7, 2023, and August 2, 2023.

9. On or about July 7, 2023, Board inspectors conducted an onsite inspection of the Pharmacy. Based on the ARCOS report, which detailed CDS the Pharmacy purchased, as reported by the drug wholesalers, and the PDMP report, which detailed all CDS the Pharmacy dispensed, the Respondent and the Pharmacy were unable to account for large quantities of CDS. The major discrepancies included but were not limited to the following number of CDS tablets being unaccounted for: 32,710 tablets of oxycodone 30 mg; 17,691 tablets of oxycodone 20 mg; 21,904 tablets of oxycodone 15 mg; 5,610 tablets of amphetamine salts 30 mg; and 3,500 tablets of hydrocodone/acetaminophen 10/325 mg.

10. On or about August 2, 2023, OCSA inspectors conducted a follow-up inspection and audit of the Pharmacy to determine if any of the unaccounted-for CDS could be reconciled. Present during the inspection were the Owner, another pharmacist ("Pharmacist 2"), and a pharmacy technician. At the August 2, 2023, follow-up inspection, OCSA inspectors and Pharmacist 2 engaged in a hand-count of tablets with respect to ten (10) different CDS drugs in the Pharmacy's inventory. An analysis of the results of the hand-count compared to the Pharmacy's records and reports again revealed major

shortages of CDS drugs. These shortages included but were not limited to the following: oxycodone 30 mg (shortage of between 24,300 to 26,910 tablets); oxycodone 20 mg (shortage of between 7,200 to 16,391 tablets); oxycodone 15 mg (shortage of between 786 to 10,548 tablets); and amphetamine salts 30 mg (shortage of between 1,600 to 4,110 tablets).

11. The Respondent was not the individual who ordered the CDS on behalf of the Pharmacy, nor was she involved in transporting the CDS from the Pharmacy to Pharmacy 1.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent's actions, as described above, constitute: being professionally incompetent, in violation of Health Occ. § 12-313(a)(21); and violating any rule or regulation adopted by the Board, *i.e.* COMAR 10.34.10.01(A)(1) and/or (B)(1)-(3), in violation of Health Occ. § 12-313(a)(25).

ORDER

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

ORDERED that the Respondent's license to practice pharmacy in Maryland, License Number: 21252, be and hereby is **REVOKED**, the revocation of which is **STAYED**; and it is further

ORDERED that the Respondent is placed on **PROBATION** for a minimum period of **THREE (3) YEARS**, subject to the following terms and conditions:

1. During the probationary period, the Respondent is prohibited from participating in any aspect of the dispensing process;
2. To the extent applicable, within thirty (30) days of the effective date of this Consent Order, the Respondent shall surrender her CDS registration with the Maryland Controlled Substances Administration and her DEA registration with the DEA;
3. To the extent applicable, the Respondent shall not apply for reinstatement of CDS registration with OCSA or DEA registration with the DEA;
4. The Respondent shall immediately provide whichever pharmacy she is currently employed or may be employed during the probationary period a copy of this Consent Order;
5. During the probationary period, the Board, at its discretion, may conduct random inspections of whichever pharmacy the Respondent is employed;
6. To the extent applicable, during the probationary period, the Respondent's employer shall submit quarterly reports of pharmacy supervisor on a Board approved form. The Respondent is responsible for ensuring that her employer submits the quarterly reports in a timely manner;
7. Within one (1) year of the effective date of this Consent Order, the Respondent shall successfully complete twelve (12) credit hours course(s) on the proper inventory and documentation of CDS at a pharmacy. This requirement is in addition to the continuing education credits necessary for license renewal;
8. Within three (3) years from the Effective Date of this Consent Order, the Respondent shall pay a monetary fine in the amount of **TWO THOUSAND FIVE HUNDRED DOLLARS (\$2,500)**, by certified check or money order payable to The Maryland Board of Pharmacy and sent to: Wells Fargo Bank, Attn: State of MD – Board of Pharmacy, Lockbox 2051, 401 Market Street, Philadelphia, PA 19106 with the reference "Case Number 24-001 – Vivian K. Berinyuy" on the certified check or money order; and
9. The Respondent shall practice in accordance with the laws and regulations governing the practice of pharmacy in Maryland; and

AND IT IS FURTHER ORDERED that at the conclusion of the entire **THREE (3) YEARS** from the effective date of this Consent Order, the Respondent may submit a

written petition to the Board requesting termination of probation, provided she has been fully compliant with this Consent Order and has no outstanding complaints; and it is further

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 has failed to comply with any terms or conditions of this Consent Order, the Board may lift the stay of the revocation; and it is further


ORDERED that the Respondent shall at all times cooperate with the Board in the monitoring, supervision, and investigation of her compliance with the terms and conditions of this Consent Order; and it is further

ORDERED that the Respondent 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.* (2019 Repl. Vol.).

4-15-24
Date



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

CONSENT

I, Vivian K. Berinyuy, acknowledges that I am represented by counsel and have 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, I agree 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 its own behalf, and to all other substantive and procedural protections provided by the law. I agree to forego any 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 might have followed after any such hearing.

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

04/4/24

Date

Berinyuy

Vivian K. Berinyuy
The Respondent

NOTARY

STATE OF MARYLAND

CITY/COUNTY OF Charles

I HEREBY CERTIFY that on this 4th day of April

 , 2024, before me, a Notary Public of the foregoing State and City/County personally appeared Vivian K. Berinyuy and made oath in due form of law that signing the foregoing Consent Order was her voluntary act and deed.

AS WITNESSETH my hand and notary seal.

Kelly L. Glascoe
Notary Public

My commission expires: June 02, 2025

