IN THE MATTER OF	*	**BEFORE THE**
HOSSEIN ZAMANI, R.Ph.	*	**STATE BOARD OF**
RESPONDENT	*	**PHARMACY**
LICENSE NO.: 18128	*	**CASE NO.: 18-243**

* *

CONSENT ORDER

On or about May 15, 2019, the State Board of Pharmacy ("the Board") charged Hossein Zamani, R.Ph., license number: 18128 (the "Respondent"), with violating certain provisions of the Maryland Pharmacy Act, (the "Act") Md. Code Ann., Health Occ ("Health Occ.") §§12-101 *et seq*. (2014 Repl. Vol. 2018 Supp.).

The pertinent provisions state:

Health Occ. §12–313. Denials, reprimands, suspensions, and revocations – Grounds.

(b) 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 deny a license to any applicant for a pharmacist's license, reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the applicant or licensee:

(1) Fraudulently or deceptively obtains or attempts to obtain a license for the applicant or licensee or for another;

(15) Dispenses any drug, device, or diagnostic for which a prescription is required without a written, oral, or electronically transmitted prescription from an authorized prescriber;

(24) Is disciplined by a licensing or disciplinary authority of any state or country or convicted or disciplined by a court of any state or country for an act that would be grounds for disciplinary action under the Board's disciplinary statutes;

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

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;

(3) Maintain proper sanitation, hygiene, biohazard precautions, and infection control when performing tasks in the prescription process.

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.

FINDINGS OF FACT

1. On or about September 22, 2006, the Respondent was originally issued a license to practice pharmacy in the State of Maryland.

2. The Respondent's license expires on July 31, 2020.

3. At all times relevant hereto, the Respondent was the owner and managing

pharmacist of a pharmacy ("Pharmacy A") located in Montgomery County, Maryland[1].

Background

4. On December 7, 2017, Pharmacy A entered into a Consent Order ("2017 Consent Order") with the Board.[2]

5. The Board concluded in the 2017 Consent Order that Pharmacy A violated Health. Occ. § 12- 403(c)(1), (5), (9), (11), (12), (13), (19), and (21); § 12- 409 (a) (1), (2), and (3); § 12- 313(b) (3), (15), and (25); 409 and COMAR 10. 34.22.03A (1)(a) and (b), and (2).

6. The Board's findings in the 2017 Consent Order were based upon Pharmacy A's engagement in the inappropriate compounding of the Federal Food and Drug Administration ("FDA") approved, commercially available Enstilar Foam, and dispensing it in a smaller, clear plastic container that was not the FDA approved 60-gram pressurized aluminum spray can.[3]

7. The Board's investigation confirmed allegations that Pharmacy A had been compounding Enstilar Foam despite its commercial availability.

8. The Board's findings in the 2017 Consent were also based upon deficiencies found during inspections of Pharmacy A that occurred on July 22, 2016 and August 11, 2016. The following deficiencies were found during the inspections:

July 22, 2016 inspection

[1] The name of Pharmacy A has been omitted to protect confidentiality. The Respondent is the permit holder of Pharmacy A.
[2] As owner of Pharmacy A, the Respondent was a signatory to the 2017 October Consent Order.
[3] Enstilar Foam was not approved by the FDA until October 2015. Enstilar Foam did not become commercially available in Maryland until January 18, 2016. This medication is a topical solution used to treat certain types of psoriasis.

A. An unregistered pharmacy technician entering orders and pulling medications;

B. No technician registrations posted in Pharmacy A;

C. Pharmacists were not vaccination certified, but vaccines were found stored in Pharmacy A's refrigerator;

D. A prescription for Zostavax filled for a patient on March 15, 2016 was stored in Pharmacy A's refrigerator instead of the freezer;

E. The refrigerator used for storage of vaccines and medication pick- ups did not have a thermometer;

F. Multiple expired compounded medications that were incorrectly labeled were stored in non-sterile compounding room;

G. Expired bulk drug products;

H. Excessive stock of compounded medications (including ointments and capsules) that were not being used as anticipatory compounding, including ointments and capsules compounded for patients' prescriptions. The labels on the prescription had the patient name crossed out. Several ointments did not have sufficient closures;

I. Unlabeled and illegibly labeled compounded medication;

J. Pharmacy A was acting as repository and was accepting several patient medications for disposal but was not registered to act as a repository;

K. The compounding area of Pharmacy A was disorganized with poor segregation of different compounded preparations. For example, two baskets filled with unlabeled tubes next to one another contained different strengths of Tretinoin;

L. An expired box of Oral Transmucosal Fentanyl Citrate was stored outside the controlled substance cabinet in an unlocked cabinet alongside miscellaneous storage;

M. A bottle of simple syrup without an expiration date or other information was stored in a Deer Park water bottle, beside compounding ingredients;

N. No compounding logs;

O. Expired eye drop products in the over the counter area;

P. A bottle labeled with prescription information found on shelf with compounded medication contained the kidney stones of the managing pharmacist;

Q. A bottle containing an unknown powder with a patient prescription labeled for Viagra tablets was stored with the compounding stock;

R. A bottle of an herbal sleep aid contained an assortment of unknown partially broken tablets.

August 11, 2016 inspection

A. An unregistered pharmacy technician was entering orders and pulling medications;

B. The Zostavax that was found in the refrigerator during the July 22, 2016 was not disposed. It was observed in the freezer.

9. Under the terms sets forth in 2017 Consent Order, Pharmacy A was placed on probation for a period of two (2) years, agreed to submit to follow-up inspections conducted by the Board, and agreed to operate in accordance with the Act including all applicable laws and regulations.

Inspections Pertaining to the Current Charges

10. Pursuant to the 2017 Consent Order, Board inspectors conducted four inspections at Pharmacy A between February 2018 and September 2018. During these inspections, Board inspectors found numerous deficiencies.

February 15, 2018 Inspection

11. On February 15, 2018, Board inspectors conducted an inspection of Pharmacy A and reviewed the computerized compounding log and the manual compounding record book from September 1, 2017 to February 23, 2018. The Board inspectors found the following in the inspection report:

A. A Pharmacy A technician with an inactive registration was working at the pharmacy as a clerk;

B. Pharmacy A did not maintain a minimum of two continuous years of records clearly demonstrating the content of annual educational training provided to each member of the pharmacy staff involved in the medication delivery system regarding the roles and responsibilities of pharmacy staff in preventing medication errors; and

C. Pharmacy A could not locate its biennial inventory of Schedule II - V controlled substances.

February 23, 2018 Inspection

12. On February 23, 2018, the Board inspectors returned to Pharmacy A to conduct a follow-up inspection. The Board's inspectors found the following deficiencies:

A. There was no documentation explaining the reason(s) why commercially available medications were being compounded; and

B. Compounded medications were not marked on the prescription label to indicate it had been compounded.

13. During the February 23, 2018, follow-up inspection, Board inspectors also obtained a copy of the dispensing report for compounded prescriptions for September 1, 2017- February 23, 2018 and copies of a sampling of the prescriptions from that period.

14. The February 23, 2018, inspection report raised questions as to whether FDA-approved, commercially available products were still being compounded by Pharmacy A, an additional inspection was therefore conducted on April 20, 2018.

April 20, 2018 Inspection

15. The inspectors found the following deficiencies during the April 20, 2018 inspection:

A. Numerous examples of Pharmacy A's compounding of FDA-approved, commercially available products that were not documented properly for doctor authorization;

B. Prescriptions for lidocaine 4% nasal spray which were compounded and had two prescription labels attached to the prescriptions. One of the labels for both prescriptions had an NDC which matched olopatadine hydrochloride, but the drug name listed on the label was Lidocaine 4% NS;

C. Sterile procedures were not being used when compounding formula for the product required it to be sterilely compounded;

D. Naltrexone was compounded without documentation of the formula or proof of bioavailability;

E. Compounding logs were incomplete, and several prescriptions lacked completed worksheets;

F. There were many CDS Schedule II prescriptions that were filled for patients whose addresses or addresses for the prescriber were over 20 miles away;

G. Rx 60967 was written for hydrocodone/APAP 7.5/300mg solution to be taken 7.5/300mg po q6h for 10 days but dispensed as hydrocodone/APAP tab 7.5-300mg #120 "Compound liquid 7.5/300g/5ml" was handwritten in a different pen/hand;

H. There were large gaps in prescription files. These gaps coincided with prescriptions that were billed for costly brand-name medications;

I. At least six prescription bags waiting in a bin had copays that were crossed off and replaced with a lower, handwritten price. One prescription bag waiting in the same bin had a UHC code and a zero copay that was crossed out and replace with a handwritten price of $15.00;

J. Pharmacy A has an agreement with a hospital ("Hospital A") to fill prenatal prescriptions for its patients. The preprinted Pharmacy A Referral Form states that: Hospital A "will pay $3.00 per prescription" to Pharmacy A. Many of these prescriptions had a back tag with a higher cash price;

K. Prenatal prescriptions had only a back tag on a blank prescription pad with no other information;

L. Expired medication was observed on windowsills and in file cabinets, including a container with a prescription label identifying it as Epiduo with no other identifying labels or markings from the manufacturer;

M. Expired medications were observed in the CII safe and in the prescription refrigerator;

N. Return to stock vials were on the prescription shelves with no NDC, lot, or expiration date;

O. A prescription vial was found in a bag in the will-call bin that had at least two desiccant packs in with the tablets;

P. CII prescriptions were dispensed under a nurse practitioner instead of the prescribing physician.

The Respondent denies the facts set forth in paragraphs B, C, F, G, H, I, and J.

September 11, 2018 Inspection

16. On September 11, 2018, Board Inspectors conducted a follow-up inspection Pharmacy A. During the inspection, the Board Inspectors requested and obtained computer

records and signature logs for a sampling of the prescription numbers which were noted on the April 20, 2018, inspection as missing from the physical file.

17. The Respondent signed the list of prescription numbers attesting that there were no prescriptions or signature logs for patient pick-ups for the prescriptions. For several prescription numbers listed on the request, the Respondent indicated that Pharmacy A did not have prescriptions or signature logs for the prescription numbers that appeared on Pharmacy A's dispensing records.

18. The prescriptions listed on Pharmacy A's dispensing records were billed to insurance companies and/or manufacturer's coupon cards. Several of these prescriptions requested also appeared on the Respondent-Pharmacy's dispensing records more than once. The Respondent denies the facts set forth in this paragraph.

District of Columbia Board of Pharmacy Disciplinary Action

19. On or about March 2, 2012, the Respondent was disciplined by the District of Columbia Board of Pharmacy (the "District of Columbia Board."). According to the Order issued by the District of Columbia Boars, on several occasions between March 2009 and October 2009, the Respondent dispensed medication to patients using another pharmacist's initials.

20. The District of Columba Board reprimanded the Respondent's license and ordered the Respondent to pay a fine in the amount of One Thousand Dollars ($1,000).

21. An investigation conducted by Board staff revealed that the Respondent filed an Application for Renewal of his license, for three renewal periods, from 2014 through 2018, with the Board.

22. Despite having been disciplined by the District of Columbia Board, Pharmacist A answered "no" to the following questions on his 2014, 2016, and 2018 renewal applications

1. "Has any state licensing or disciplinary board (including Maryland) or similar agency in the Armed Forces, filed any complaints or charges against you or investigated you for any reason?

2. "Has any state licensing or disciplinary board (including Maryland) or similar agency in the Armed Forces, denied your application for registration, reinstatement or renewal, or taken any action against any registration or license held by you? Such actions include, but are not limited to, limitations on the registration, additional education, admonishment, reprimand, suspension or revocation. file any complained or charges against you or investigated you for any reason?"

23. The Respondent's conduct as set forth above is a violation of § 12- 313(b) (1), (3), (15), (21), (24), and (25) and COMAR 10. 34.22.05.04 A (3) (a) and (b); COMAR 10.34.08 .01 (A) and (B)(1) and (2); COMAR 10.34.19.04 and COMAR 10.34.19.07A (1), (2), and (3).

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Respondent violated § 12- 313(b) (1), (3), (15), (21), (24), and (25) and COMAR 10. 34.22.05.04 A (3) (a) and (b); COMAR 10.34.08 .01 (A) and (B)(1) and (2); COMAR 10.34.19.04 and COMAR 10.34.19.07A (1), (2), and (3).

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, on this 16 day of October 2019, a majority of a quorum of the Board, hereby

ORDERED that the Respondent license shall be **SUSPENDED** for a period of **one (1) year**; and it is further

ORDERED that following the suspension, the Respondent's license shall be placed on **PROBATION for a minimum period of three (3) years;** and it is further

ORDERED that Respondent shall pay a fine in the amount of seven thousand five hundred dollars ($7500), payable to the Maryland Board of Pharmacy, no later than 60 (sixty) days from the date that this Order is signed by the Board; and it is further

ORDERED that the Respondent shall ensure that if he is employed as a pharmacist, his pharmacy employer submits quarterly report to the Board; and is it further

ORDERED that the Respondent shall take a minimum two (2) credit hour ethics course; a minimum six (6) credit hour pharmacy law course; and a minimum four (4) credit hour Board-approved course in pharmacy practice within one (1) year. All courses shall be pre-approved by the Board and the credit hours earned shall not be used to satisfy the continuing education credit requirements for renewal; and it is further

ORDERED that the Respondent shall cooperate with the Board in the monitoring, supervision, and investigation of the Respondent's compliance with the terms and conditions of this Consent Order; and be it further,

ORDERED that the Respondent shall not hold any type of new ownership in a

pharmacy in the Maryland for a period of period of five (5) years; and it is further

ORDERED that the Respondent may petition the Board for modification of the terms and conditions of his probation no earlier than two (2) year from the date of this Consent Order and provided the Respondent has been fully compliant with the terms and conditions set forth in this Consent Order; and it is further

ORDERED that at the end of the Respondent's probationary period, the Respondent may file a written petition to the Board for termination of the probationary status and the removal of any conditions or restrictions that resulted from this disciplinary action, provided that Respondent has fulfilled all the terms and conditions set forth herein, is not in violation of this Consent Order, and there are no outstanding complaints against the Respondent; and it is further

ORDERED that failure to comply with the terms and conditions of the Consent Order, constitutes a violation of the 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 shall bear all costs associated with this Consent Order; and it is further,

ORDERED that the Respondent shall practice pharmacy in accordance with the Maryland Pharmacy Act and all applicable laws and regulations; and it is further

ORDERED that the effective date of this Consent Order is the date that it is signed by the Board; and it is further

ORDERED that for purposes of public disclosure, the Consent Order is considered a **PUBLIC DOCUMENT** pursuant to Md. Code Ann., Gen. Prov. §§ 4-101 *et seq.* (2014 & 2018 Supp.) and is reportable to any entity to whom the Board is obligated to report.

10/16/19
Date

Kevin M. Morgan, Pharm.D.
President
State Board of Pharmacy

CONSENT OF HOSSEIN ZAMANI, R.Ph.

I, Hossein Zamani, R.Ph, acknowledge that I am represented by Courtney B. Schaefer and Hong Suk Chung, and have consulted with counsel before entering into this Consent Order. By this Consent and for the purpose of resolving the issues raised by the Board, I agree and accept to be bound by the foregoing Consent Order and its conditions. I waive any rights I may have to contest the Findings of Fact and the 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 provided by the law. 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 sign this Consent Order, voluntarily and without reservation, after having an opportunity to consult with counsel, and I fully understand and comprehend the language, meaning and terms of this Consent Order.

10/11/19
Date

Hossein Zamani
Hossein Zamani,R.Ph.

STATE OF Maryland

CITY/COUNTY OF Montgomery

I HEREBY CERTIFY that on this 11th day of October 2019, before me, Jenny Choi, a Notary Public of the foregoing State and (City/County),
(Print Name)

Personally, appeared Hossein Zamani, R.Ph. License Number: 18128, 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: May 31, 2022

JENNY J. CHOI NOTARY PUBLIC MONTGOMERY COUNTY, MD

Jenny J. Choi
NOTARY PUBLIC
Montgomery County
State of Maryland
My Commission Expires
May 31, 2022