

IN THE MATTER OF * **BEFORE THE**
SHAYONA PHARMACY * **STATE BOARD**
Permit No. P05005 * **OF**
Respondent-Pharmacy * **PHARMACY**
* **Case No. 14-008**

* * * * *

FINAL CONSENT ORDER

Based on information received and a subsequent investigation by the State Board of Pharmacy (the "Board"), and subject to Md. Health Occ. Ann. § 12-101, *et seq.*, (2014 Repl. Vol. II) (the "Act"), the Board charged **SHAYONA PHARMACY** (the "Respondent-Pharmacy"), under the Maryland Pharmacy Act on October 21, 2015. On March 30, 2016, a Case Resolution Conference was held with the Respondent-Pharmacy, which was represented by Counsel, members of the Board, along with Board Counsel, and the Administrative Prosecutor in order to determine whether the matter could be resolved. As a result, the following settlement was reached.

BACKGROUND

The Board based its Charges on the following facts that the Board had cause to believe are true:

1. Based on information received and a subsequent investigation by the Board, and subject to the Act, on or about December 9, 2011, the Board issued Charges against the Respondent-Pharmacy due to the Board's receipt of a report following an inspection by the Division of Drug Control (DDC) of the Respondent-Pharmacy, which Mr. P¹ owns and is the primary dispensing pharmacist. The DDC found that the Respondent-

Pharmacy dispensed large amounts of oxycodone, a Controlled Dangerous Substance (CDS), based on false or invalid prescriptions.

2. As a result of an evidentiary hearing held on March 28, 2012 and February 6, 2013, the Board issued a Final Decision and Order dated August 12, 2013.

3. The Board opined that “pharmacists and pharmacies play an integral role in the provision of quality healthcare services to patients. In addition to their expertise in pharmaceutical care, community pharmacists, through their pharmacies, act as gatekeepers who allow or prohibit access to highly addictive drugs that may have significant street value. Thus, it is crucial, both to individual patients and to the community at large to act in an ethical manner . . . his lapse of judgment resulted in the provision of highly addictive and dangerous drugs to individuals for illegitimate purposes.” The Board found that the Respondent-Pharmacy filled 119 false prescriptions. The Board opined that “the Respondent-Pharmacy failed to appropriately exercise professional judgment with respect to responsible dispensing of controlled substances. . . .filled all 119 prescriptions at issue in the case over a seven month period. . . .prescriptions were facially suspicious. . . .the Respondent-Pharmacy dispensed highly addictive and dangerous narcotics in high dosages and quantities, without any medical necessity.”

4. As a result of the above findings, the Board fined the Respondent-Pharmacy \$2500, payable within 90 days from the date of the Order.

¹The owner’s name is confidential.

FINDINGS OF FACT

1. At all times relevant hereto, the Respondent-Pharmacy was permitted to operate as a pharmacy in Maryland. The Respondent-pharmacy was first permitted on June 3, 2009. The Respondent-Pharmacy's permit expires on May 31, 2016.

2. At all times relevant hereto, the Respondent-Pharmacy was owned by Mr. P, a pharmacist who was the primary dispensing pharmacist at the Respondent-Pharmacy in Salisbury, Maryland.

3. On or about August 21, 2013, the Board received a complaint from Provider A (the "Complainant") regarding Patient A² as follows:

...patient was seen last in our office for regular f/u (follow-up) on 6/24/11, and is on Hyzaar³ daily. He called for refill medication 10/30/12 and a 30 day supply was sent to [Respondent-Pharmacy] and pt. was informed of need for f/u office visit. We did not here (*sic*) from patient again until patient came in to office today 8/21/13 to be seen for f/u/office visit. He had been getting his Hyzaar each month from [Respondent-Pharmacy A] since October 2012 through August 2013 with only one prescription of medication being sent to Respondent-Pharmacy for a 30 day supply back on 10/30/12. We contacted the Respondent-Pharmacy to see if another provider was prescribing his medication and were told that "they" (*sic*) were filling it for patent (*sic*) since he "was a regular customer and was out of his meds." They (*sic*) stated "we were the only prescribers."

4. As a result of this complaint, the Board's Pharmacy Compliance Officer undertook an investigation, which caused her to visit the Respondent-Pharmacy on

²The names of individuals or facilities are confidential.

³Hyzaar contains a combination of hydrochlorothiazide and losartan. Hydrochlorothiazide is a thiazide diuretic (water pill) that helps prevent the body from absorbing too much salt, which can cause fluid retention. Losartan is an angiotensin II receptor antagonist. Losartan keeps blood vessels from narrowing, which lowers blood pressure and improves blood flow. In rare cases, Hyzaar is used to treat high blood pressure (hypertension). It is also used to lower the risk of stroke in certain people with heart disease.

September 21, 2013. The visit disclosed the following:

A. When she arrived, she was informed by the store next door that the Respondent-Pharmacy would not be open until 9:00 A.M. Upon returning at 9:35 A.M., she found a male adult behind the counter, who identified himself as a Pharmacy Technician (“Pharm Tech”);

B. The Pharm Tech informed the Board’s Officer that Mr. P was purchasing something “next door”. However, after the Pharm Tech spoke on the phone with a caller in a language not understood by the Board’s Officer, Mr. P arrived in the Respondent-Pharmacy at approximately 9:43 A.M.;

C. A person traveling with the Board’s Officer had waited in the parking lot in his car and later informed the Board’s Officer that the driver of the other car in the parking lot was the one who entered the Respondent-Pharmacy at 9:43 A.M.--Mr. P;

D. While at the Respondent-Pharmacy, the Board’s Officer requested a dispensing report for Patient A. She then requested the hard copies of the prescriptions dispensed on November 29, 2012, January 12, 2013, February 21, 2013, April 1, 2013, May 3, 2013, June 6, 2013, July 12, 2013 and August 21, 2013, as per the dispensing report. The Respondent-Pharmacy could not provide the prescriptions for January 12, 2013, April 1, 2013 and July 12, 2013;4

E. The dispensing report ran monthly from June 2012-September

Hyzaar can cause a condition that results in the breakdown of skeletal muscle tissue, leading to kidney failure.

⁴The Respondent-Respondent-Pharmacy claimed that he later provided the Board’s Officer with the

2013. The report showed medication purportedly prescribed for Patient A by five different providers, including the Complainant;

F. All of the hard copies provided to the Board's Officer were "Telephoned Prescriptions;"

G. After obtaining the hard copies of the prescriptions, the Board's Officer sent them to the providers listed therein as authorizing the prescriptions and asked whether these, in fact, were authorized by them. The providers responded as follows:

(1) The Board's Officer faxed to the Complainant, who worked with Provider B, the dispensing report she had obtained from the Respondent-Pharmacy a few days earlier regarding Patient A's prescription copies for Hyzaar;

(2) The Complainant, on behalf of Provider B, stated "Our office did not authorize Hyzaar refills for [Patient A] on February 21, 2013, May 3, 2013, and June 6, 2013. We did not authorize refills on January 12, 2013, April 1, 2013 or July 12, 2013. We do not have any record in his chart of filling Hyzaar from January 12, 2013, April 1, 2013 or July 12, 2013."

H. Thereafter, on November 20, 2013, the Board's Officer requested, via subpoena to Patient A's insurer, the billing submitted by the Respondent-Pharmacy for Patient A. The insurer submitted billing information as follows:

(1) For Provider C, who works with Provider B:

4/20/12, Losartan, 100/25 mg; and

5/23/12, Losartan 100/25 mg.

(2) There is no evidence that Provider C authorized these two prescriptions.

5. Mr. P disputes that he failed to call the Complainant's office each time he filled/refilled Patient A's medication and asserts that Provider B (who employed the Complainant [Provider A], as well as Provider C) no longer maintains an office in the Salisbury area.

6. Mr. P asserts that he was in the parking lot of the store located adjacent to the Respondent-Pharmacy at the commencement of the Board's inspection, although not physically in the pharmacy.

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact, the Board finds that Respondent-Pharmacy violated §§12-313(16) and (25) as well as § 12-403 (c) (1) and (3) of the Act and COMAR 10.34.10.01 A. (1) (a) through (c).

ORDER


Based on the foregoing Findings of Fact, Conclusions of Law and agreement of the parties, it is this 18th day of May 2016, by a majority the Board,

ORDERED that the Respondent-Pharmacy be placed on Probation until the signing of this Consent Order.⁵

ORDERED that the Consent Order is effective as of the date of its signing by the Board; and be it

ORDERED that the Respondent-Pharmacy shall operate in accordance with the laws and regulations governing the operation of pharmacies in Maryland; and be it further

ORDERED, that for purposes of public disclosure, as permitted by Md. General Provisions. Code Ann. §§ 4-101, *et seq.* (Repl. Vol. 2014), this document consists of the contents of the foregoing Findings of Fact, Conclusions of Law and Order, and that the Board may also disclose same to any national reporting data bank that it is mandated to report to.



Mitra Gavvani, Pharm.D. President
Maryland Board of Pharmacy

⁵The Respondent-Pharmacy has satisfied the terms of the Board's Order of August 12, 2013.

CONSENT OF DIPAL PATEL, P.D., OWNER ON BEHALF OF SHAYONA PHARMACY

I, Dipal Patel, P.D., on behalf of Shayona Pharmacy, acknowledge that I am represented by counsel, Dirk Widdowson, Esquire 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, on behalf of Shayona Pharmacy, do not admit to violating any provisions of the Pharmacy Act or COMAR regulations regarding Pharmacist and Pharmacy Technician Code of Conduct but expressly deny any wrongdoing in Case No. P1-11-029.

I, on behalf of Shayona Pharmacy, submit to the foregoing Consent Order, however, as a resolution of this matter in lieu of formal charges, which process would afforded it the right to a full evidentiary hearing.

I, on behalf of Shayona Pharmacy, 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, on behalf of Shayona Pharmacy, agree to forego my opportunity to challenge these allegations. I, on behalf of Shayona Pharmacy acknowledge the legal authority and jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. I, on behalf of Shayona Pharmacy, affirm that the Pharmacy is waiving its right to appeal any adverse ruling of the Board that might have followed after any such hearing.

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

May 17, 2016
Date


Dipal Patel, P.D., on behalf of Shayona Pharmacy

STATE OF Maryland :

CITY/COUNTY OF Wicomico :

I HEREBY CERTIFY that on this 17th day of May 2016, before me, Irene Aubain, a Notary Public of the foregoing State and (City/County),
(Print Name)
personally appeared Dipal Patel, P.D. on behalf of Shayona Pharmacy, Permit No. 05005, 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: 9-10-2019

