

IN THE MATTER OF
SHAYONA PHARMACY
PERMIT NO. P05005

* BEFORE THE
* MARYLAND STATE
* BOARD OF PHARMACY
* Case No. PI-11-029

Respondent

* * * * *

FINAL DECISION AND ORDER

Background

On December 9, 2011, the Maryland Board of Pharmacy (the “Board”) issued charges against the pharmacy permit held by Shayona Pharmacy, Permit No. P05005 (the “Respondent-Pharmacy”), based on information received from the Maryland Division of Drug Control (“DDC”) following an inspection of the Respondent-Pharmacy, which is owned and operated by Dipal Patel, a licensed pharmacist. The DDC findings indicated, among other things, that Mr. Patel dispensed large amounts of oxycodone, a controlled dangerous substance, based on false or invalid prescriptions from the Respondent-Pharmacy.

A contested case hearing was held under the Administrative Procedure Act, Md. Code Ann., State Gov’t §10-201 *et seq.*, and COMAR 10.34.01, before a quorum of the Board on March 28, 2012 and February 6, 2013, for the purpose of adjudicating the charges. After the conclusion of the hearing, the same quorum¹ of the Board convened to deliberate and voted unanimously to sanction the permit held by the Respondent-Pharmacy for the reasons set forth in this Final Decision and Order.

¹ One of the Board members present for the first day of the hearing was not present for the second day of the hearing. Because there was still a quorum present, however, the hearing continued in the Board member’s absence. That Board member did not participate in the deliberation in this case. (Tr. at 168)

SUMMARY OF THE EVIDENCE

A. Documents.

The following documents were admitted into evidence.

- State's Exhibit No. 1 - License/Permit Profiles
 - A. Dipal Patel
 - B. Shayona Pharmacy
- State's Exhibit No. 2 - Email from Chandra Mouli to James Polek, dated 10/25/09
- State's Exhibit No. 3 - DDC Controlled Dangerous Substances ("CDS") Inspection
 - A. DDC CDS Inspection Report, 5/12/10
 - B. Memo from James Polek to Peninsula Orthopaedic Associates, dated 5/14/10, with prescriptions
 - C. Letter from Peninsula Orthopaedic Associates to James Polek, dated 5/25/10, with letters from physicians and prescriptions; Fax from Peninsula Orthopaedic Associates to James Polek, dated 5/14/10, with prescriptions
 - D. Note regarding 5/12/10 DDC CDS Inspection
 - E. Fax from Chandra Mouli to Linda Bethman, dated 11/18/10
- State's Exhibit No. 4 - Salisbury Police Department Incident Report
 - A. Letter from Pfc. Brian Whitman, received 12/16/10, with Incident Reports and Arrest Reports
 - B. DVD of interrogation of Rameez Asif – NOT ADMITTED
- State's Exhibit No. 5 - Requests for records to Peninsula Orthopaedic Associates
 - A. Fax from Vanessa Thomas-Gray to Peninsula Orthopaedic Associates, dated 1/24/11, with prescriptions
 - B. Subpoena Duces Tecum issued to Peninsula Orthopaedic Associates, 4/8/2011, with response
 - C. Board of Pharmacy Investigative Report, 6/7/11
- State's Exhibit No. 6 - Charges against Dipal Patel and Shayona Pharmacy
 - A. Letters of Procedure to Dipal Patel and Shayona Pharmacy, dated 12/9/11
 - B. Charges against Dipal Patel and Shayona Pharmacy, 12/9/11

- C. Summons and Notice of Hearing, 12/9/11
 - D. Entry of Appearance, Dirk W. Widdowson, 12/21/11
- Respondent's Ex. No. 1 - Board of Pharmacy Inspection Report, 10/29/10
- Respondent's Ex. No. 2 - Fax from Dipal Patel to Jeanelle McKnight, dated 4/3/10
- Respondent's Ex. No. 3 - Certified copy of Case Judicial Search for criminal records for Rameez Asif, Accomack County Circuit Court, Virginia
- Respondent's Ex. No. 4 - Certified Criminal Records for Rameez Asif, Maryland
- A. Case No. 5H00054983, Wicomico County District Court
 - B. Case No. 4H00055115, Wicomico County District Court
 - C. Case No. 6H00054774, Wicomico County District Court
 - D. Case No. 2H00053986, Wicomico County District Court
 - E. Case No. 2H00053307, Wicomico County District Court
 - F. Case No. 22-K-07-000912, Wicomico County Circuit Court
 - G. Case No. 22-K-05-001015, Wicomico County Circuit Court
 - H. Case No. 0I00083846, Worcester County District Court (Asif Rameez)
- Respondent's Ex. No. 5 - Fax from Linda Bethman to Dirk Widdowson, dated 3/16/12, with Order
- Respondent's Ex. No. 6 - Subpoena Duces Tecum issued to Rameez Asif, 2/29/12
- Respondent's Ex. No. 7 - Subpoena Duces Tecum issued to Shayona Pharmacy, 4/8/11

B. Witnesses.

State: Brian Whitman – Corporal, Salisbury Police Department
 James Polek – Inspector, Division of Drug Control
 YuZon Wu – Pharmacist Compliance Officer, Board of Pharmacy

Respondent: None

FINDINGS OF FACT

Based upon the testimony and documentary evidence presented at the evidentiary hearing, the Board finds that the following facts are true:

1. The Respondent-Pharmacy was issued a permit to operate a pharmacy in Maryland on June 3, 2009, under Permit Number P05005. The Respondent-Pharmacy's license is due to expire on May 31, 2014. (State's Ex. 1B)
2. At all times relevant herein, the Respondent-Pharmacy was owned and operated by Dipal Patel, the sole dispensing pharmacist at the Respondent-Pharmacy. Mr. Patel is licensed to practice pharmacy in Maryland under license number 18393.
3. The Respondent-Pharmacy is a community pharmacy located at 910 West Road, Salisbury, Maryland 21801.
4. On October 13, 2009, Corporal Brian Whitman, an undercover narcotics detective with the Salisbury Police Department, received a call from a doctor's office in Ocean City, Maryland, indicating that an individual had been in Kinko's making photocopies of fraudulent prescriptions purportedly written by a doctor at the Ocean City practice. Corporal Whitman called Kinko's and asked them to call him if the individual returned to the store. (State's Ex. 4A; Tr. at 70-71)
5. Later that day, a Kinko's employee called Corporal Whitman and informed him that the individual had returned. Corporal Whitman went to the store and observed the individual making copies of valid-looking prescriptions onto blue prescription paper, purportedly from Peninsula Regional Medical Center ("PRMC"). The prescriptions turned out to be fraudulent, and the individual was later arrested and identified as Rameez Asif. (Tr. at 71-76, 100)

6. During an interrogation with Corporal Whitman, Mr. Asif, who appeared to be under the influence of prescription opiates, indicated that he got the prescriptions he was copying “from a pharmacist on West Road.” Mr. Asif did not give Corporal Whitman the name of the pharmacist involved. (Tr. at 78-80, 97-99)
7. On October 19, 2009, Corporal Whitman sent an email to DDC Deputy Chief Chandra Mouli, providing him information on Mr. Asif’s arrest. Corporal Whitman also spoke to Mr. Mouli on the phone “a few times” regarding the situation. (State’s Ex. 2; Tr. at 81)
8. On May 12, 2010, DDC inspector James Polek performed a CDS Inspection at the Respondent-Pharmacy. Mr. Mouli instructed Mr. Polek to be on the lookout for fraudulent prescriptions on blue paper from PRMC. (State’s Ex. 3A; Tr. at 110-11)
9. The DDC CDS Inspection Report resulting from the May 12, 2010 inspection at the Respondent-Pharmacy cited various deficiencies relating to CDS inventory, electronic recordkeeping, and validity of prescriptions. Mr. Polek reviewed the results of the inspection with Mr. Patel, who signed the DDC CDS Inspection Report. (State’s Ex. 3A)
10. During the May 12, 2010 DDC CDS inspection at the Respondent-Pharmacy, Mr. Polek noticed several facially suspicious prescriptions, each for 100 tablets of oxycodone 30mg, a Schedule II drug,² from Peninsula Orthopaedic Associates (“POA”). Mr. Polek did not find any prescriptions on blue paper from PRMC. (State’s Exs. 3A-3C; T. at 113-14, 128)

² Controlled dangerous substances under the Controlled Substances Act are divided into five schedules (I-V). Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in treatment. Substances in Schedule II have a high potential for abuse which may lead to severe psychological or physical dependence. (DEA Pharmacist’s Manual)

11. During the May 12, 2010 DDC CDS inspection, at the Respondent-Pharmacy, Mr. Polek spoke to POA, and the practice confirmed that the prescriptions were not legitimate. In order to get written confirmation, Mr. Polek faxed copies of 21 prescriptions to POA while he was still at the Respondent-Pharmacy. On May 14, 2010, Mr. Polek faxed an additional 99 prescriptions to POA from his office for written confirmation. (State's Ex. 3B; Tr. at 115-16)
12. On May 14, 2010, POA provided written confirmation that all 21 of the prescriptions faxed on May 12 were not legitimate, noting either "no current [patient] on file with this name" or "no [prescriptions] given" on the majority of the prescriptions. On May 25, 2010, POA provided written confirmation that 98 of the 99 prescriptions faxed on May 14 were not legitimate, noting "no current [patient] with this name" or "no [prescriptions] given" on the majority of the prescriptions. In total, 119 of 120 POA prescriptions found at the Respondent-Pharmacy were not valid.³ (State's Ex. 3C; Tr. at 118-20)
13. Attached to the May 25, 2010 letter from POA were individual letters signed by five of the practice's physicians or physician's assistants, each of which states, "I have reviewed these prescriptions and can assure you that I did not and would not write prescriptions for oxycodone with a quantity of 100. The signature on the noted prescriptions is not mine." (State's Ex. 3C, Bates stamp 000081-000085; Tr. at 120-22)
14. The 119 false prescriptions contained certain indications that should have raised concern to any reasonable pharmacist and prompted an attempt by the Respondent-

³ The one valid prescription was for 60 tablets of Dilaudid 2mg. Dilaudid is a brand name of generic hydromorphone, a Schedule II opioid. (State's Ex. 3C, Bates stamp 000085-4)

Pharmacy's owner and sole dispensing pharmacist to verify and document the legitimacy of the prescription. All 119 false prescriptions are for 100 tablets of oxycodone 30mg, a large quantity; in addition, all 119 false prescriptions include identical instructions, "1 poq 12hrs for pain PRN,"⁴ despite the fact that "prn pain" is much more common in prescription writing than "pain prn." Despite these red flags, none of the prescriptions bear any indication that the Respondent-Pharmacy's owner and sole dispensing pharmacist attempted to verify their legitimacy. (State's Ex. 3C; Tr. at 114, 125-26, 129-30)

15. On the May 12, 2010 DDC CDS Inspection Report, under "Actions required by this report," it is noted that pharmacists have a "corresponding responsibility to ensure all CDs prescriptions are valid and written for a legitimate medical use," and it is suggested that the Respondent-Pharmacy's owner and sole dispensing pharmacist document, on the prescription, any attempts made to verify the prescription. On July 26, 2010, DDC inspectors returned to the Respondent-Pharmacy and did not find any additional fraudulent prescriptions from POA; the Board also performed an annual inspection of the Respondent-Pharmacy on October 29, 2010, and did not note any fraudulent prescriptions from POA. (State's Exs. 3A, 3E; Respondent's Ex. 1: Tr. at 123-24, 128)

OPINION

Prior to the hearing in this matter, counsel for the Respondent-Pharmacy filed a *motion in limine* requesting that the Board exclude, among other things, the testimony of Corporal Whitman and a DVD of Corporal Whitman's interrogation of Mr. Asif. Counsel for the

⁴ The abbreviation "po" means *per os*, or "orally"; "q" means *quaque*, or "every"; "PRN" means *pro re nata*, or "as needed." Taken together, the instructions mean "1 tablet orally every 12 hours for pain as needed."

Respondent-Pharmacy argued that because Mr. Asif would not be present at the hearing,⁵ admitting any statements made by Mr. Asif would violate the Respondent-Pharmacy's owner's constitutional right to confrontation. The Board denied the motion.⁶ Counsel for the Respondent-Pharmacy objected to the evidence when it was presented at the hearing; the Board overruled the objection in relation to Corporal Whitman's testimony but excluded the DVD because it was redundant of evidence already presented.⁷ In any event, these rulings are not relevant to this Final Decision and Order, because the Board is dismissing all charges related to an alleged relationship between the Respondent-Pharmacy's owner and sole dispensing pharmacist and Mr. Asif. The Board does not believe there is a preponderance of evidence in the record to demonstrate any connection between the Respondent-Pharmacy, Mr. Patel, Mr. Asif, and fraudulent prescriptions from PRMC.

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, that pharmacists and pharmacy permit holders act in an

⁵ Although Mr. Asif was subpoenaed to appear at the hearing, the subpoena was returned undeliverable and he did not appear. Mr. Asif apparently fled Maryland in the face of criminal charges against him, and there are multiple warrants out against him for fleeing both Maryland and Virginia. (Respondent's Exs. 3-4; Tr. at 8, 14)

⁶ After the Board ruled on the initial motion, counsel for the Respondent-Pharmacy filed an Amended Witness List seeking the testimony of Board Counsel, the Administrative Prosecutor, and the Board President regarding the role of Board Counsel and the relationship between Board Counsel and the Administrative Prosecutor. The Board denied the request and both the Board President and Board Counsel put a statement on the record concerning Board Counsel's role in this case. As noted *infra*, the ruling on the initial motion is irrelevant to this Final Decision and Order, so it is not necessary to belabor the point; however, the Board believes Board Counsel and the Administrative Prosecutor acted in accordance with the Office of the Attorney General's "Guidelines for Administrative Adjudicatory Proceedings" in this case. The Guidelines were provided to Respondent-Pharmacy's counsel separately at the time of the issuance of this Final Decision and Order.

⁷ During the hearing, the Administrative Prosecutor asked Corporal Whitman if the DVD "summarize[d] the information you gave today," to which he responded, "Yes, it does." (Tr. at 84-85)

ethical manner. Mr. Patel, as the owner and operator of the Respondent-Pharmacy, did not give his professional responsibilities the weight they demand, and his lapse in judgment resulted in the provision by the Respondent-Pharmacy of highly addictive and dangerous drugs to individuals for illegitimate purposes.

Mr. Patel, through counsel, concedes that he filled 119 fraudulent prescriptions purportedly written by prescribers at POA. These prescriptions were facially questionable. All 119 prescriptions were for 100 tablets of oxycodone 30 mg, a high amount of a powerful and dangerous opiate. In addition, all 119 prescriptions used the uncustomary language “pain PRN” instead of the much more common “prn pain.” Further, all 119 prescriptions were confirmed to be fraudulent by POA, and Mr. Patel filled all these prescriptions without documented verification from POA, which resulted in hundreds of illegal narcotics being dispensed from the Respondent-Pharmacy. If Mr. Patel did verify these prescriptions, he would have determined, as DDC did, that the prescriptions were false, and he would not, or should not, have filled them.

Mr. Patel has been a licensed pharmacist in Maryland since 2007, but he only came to the Board’s attention for deficient CDS dispensing practices after he opened the Respondent-Pharmacy in the summer of 2009. Mr. Patel filled all 119 fraudulent prescriptions at issue in the case over a seven month period shortly after he opened the Respondent-Pharmacy, between October 2009 and May 2010. The prescriptions were facially suspicious, yet Mr. Patel apparently turned a blind eye to build business at the Respondent-Pharmacy. In doing so, Mr. Patel, through the Respondent-Pharmacy, dispensed highly addictive and dangerous narcotics in high dosages and quantities, without any medical necessity. The Board finds that the standard of care required that Mr. Patel, at a minimum, verify the prescriptions with the various prescribers and document that verification.

Both State and federal regulations provide that a pharmacist bears corresponding liability for insuring that prescriptions for controlled substances are valid. The ever-increasing health crisis involving prescription drug abuse renders this legal obligation all the more integral to community pharmacy practice. The Board finds that Mr. Patel failed to appropriately exercise his professional judgment with respect to responsible dispensing of controlled substances through the Respondent-Pharmacy.

The Board recognizes that the 119 fraudulent prescriptions from POA filled by Mr. Patel represent a small percentage of the prescriptions he filled at the Respondent-Pharmacy over that time period. The Board also recognizes that it would appear Mr. Patel took the suggestion from the May 10, 2010 DDC CDS Inspection Report that he verify prescriptions in accordance with his corresponding responsibility seriously – follow up inspections of the Respondent-Pharmacy by both DDC and the Board identified no further fraudulent prescriptions from POA. Based on the large quantity of dangerous and highly addictive narcotics dispensed from the Respondent-Pharmacy shortly after it opened, however, the Board believes that a fine against the Respondent-Pharmacy's permit is warranted. The Board feels that this sanction, in addition to random follow-up inspections, will address the violations committed through the Respondent-Pharmacy while allowing the Respondent-Pharmacy to continue serving the community.

CONCLUSION

Based upon the foregoing summary of evidence, findings of fact, and opinion, the Board concludes that the Respondent-Pharmacy is subject to discipline in accordance with Md. Code Ann., Health Occ. § 12-403(b)(1) and (9), *to wit*: Md. Code Ann., Health Occ. § 12-313(b)(25); Code Md. Regs. tit.10 § 34.10.01A(1)(e) and B(1). The Board dismisses the remaining charges.

ORDER

Based on the foregoing Findings of Fact, Opinion, and Conclusion, by a unanimous decision of a quorum of the Board, it is hereby:

ORDERED that the Respondent-Pharmacy shall pay a FINE of \$2,500, payable to the Maryland Board of Pharmacy, within ninety (90) days of the date of this Order; and be it further,

ORDERED that the Respondent-Pharmacy shall be subject to random inspections by the Board; and be it further,

ORDERED that this is a final order of the State Board of Pharmacy and as such is a **PUBLIC DOCUMENT** pursuant to Md. Code Ann., State Gov't § 10-617(h).

8/13/13
Date



LaVerne G. Naesea, Executive Director
for
Lenna Israbian-Jamgochian, PharmD.
President, Board of Pharmacy

NOTICE OF RIGHT TO APPEAL

You have the right to appeal this Final Decision and Order. A petition for appeal shall be filed within thirty days of this Final Decision and Order and shall be made pursuant to Md. Code Ann., Health Occ. § 12-412.