IN THE MATTER OF * BEFORE THE

QUALITY CARE PHARMACY * MARYLAND STATE

* BOARD OF PHARMACY

PERMIT NO. P05148

Respondent

* Case No. 11-045

* * * * * * * * *

FINAL DECISION AND ORDER

Background

On July 20, 2011, the Maryland Board of Pharmacy (the "Board") issued charges against the pharmacy permit held by Quality Care Pharmacy, Permit No. P05148, (the "Respondent-Pharmacy") based on information received from the Maryland Division of Drug Control ("DDC"), specifically findings resulting from an inspection of Quality Care Pharmacy, which is owned and operated by the Uchenna P. Ekwunazu, a licensed pharmacist. The DDC findings indicated, among other things, that Mr. Ekwunazu dispensed large amounts of controlled dangerous substances based on false or invalid prescriptions from the Respondent-Pharmacy. Thereafter, on January 18, 2012, the Board issued Amended Charges against the Respondent-Pharmacy based on supplemental information received from DDC following a subsequent inspection of Quality Care 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 February 3, 2012 and March 16, 2012, for the purpose of adjudicating the charges. After the conclusion of the hearing, the same quorum 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.

SUMMARY OF THE EVIDENCE

A. Documents.

The following documents were admitted into evidence.

State's Exhibit No. 1	-	Investigative Summary, April 15, 2011
State's Exhibit No. 2	-	Complaint from Division of Drug Control, 11/1/10, with attachments 1-9
	A. B. C. D. E. F. G.	Attachment 1 – DDC Controlled Dangerous Substance ("CDS") Inspection Report Attachment 2 – Quality Care Pharmacy Customer log sheet Attachment 3 – 3 Prescriptions of Dentist I Attachment 4 – 6 Prescriptions of Doctor F Attachment 5 – Multiple prescriptions of Clinic Attachment 6 – 2 Prescriptions of Doctor B Attachment 7 – 2 Prescriptions of Doctor J Attachment 8 – 1 Prescription of Doctor A
	I.	Attachment 9 – 2 Prescriptions of Doctor G
State's Exhibit No. 3	-	Division of Drug Control CDS Inspection Report, 9/12/11
State's Exhibit No. 4	-	Division of Drug Control summary of CDS prescribed for Patient 35, 1/21/11 to 5/25/11
State's Exhibit No. 5	-	Quality Care Pharmacy "Custom Log" of Patient 35, 4/5/11 to 9/6/11
State's Exhibit No. 6	-	Quality Care Pharmacy "Custom Log" of Patient 36, 4/20/11 to 9/7/11
State's Exhibit No. 7	-	Quality Care Pharmacy "Custom Log" of Patient 37, 5/2/11 to 9/2/11
State's Exhibit No. 8	-	Copies of prescriptions for Patient 35
State's Exhibit No. 9	-	Copies of prescriptions for Patient 36

State's Exhibit No. 10	-	Copies of prescriptions for Patient 37
State's Exhibit No. 11	-	Copies of prescriptions for Patient 38
	A. B. C.	Not admitted 2 Prescriptions for Methadone 10 mg, dated 7/6/11 and 7/12/11 obtained from Quality Care Pharmacy Computer printout of labels for 2 above prescriptions
State's Exhibit No. 12	-	DEA ARCOS Repot, dated 7/13/11
State's Exhibit No. 13	-	DDC Confidential Report of Investigation, 9/15/11
State's Exhibit No. 14	-	License/Pemit Profiles
	A. B.	Uchenna Ekwunazu Quality Care Pharmacy
State's Exhibit No. 15	-	Wage history from DLLR, 6/8/11
State's Exhibit No. 16	-	Confidential Patient Identification List
State's Exhibit No. 17	-	Confidential Provider Identification List of Prescribers
State's Exhibit No. 18	-	Charges against U. Ekwunazu
	A. B.	Charges, 7/20/11 Amended Charges, 1/18/12
State's Exhibit No. 19	-	Charges against Quality Care Pharmacy
	A. B.	Charges, 7/20/11 Amended Charges, 1/18/12
Respondent's Ex. No. 1	-	Quality Care Pharmacy Opening Inventory
Respondent's Ex. No. 2	-	Prescription for M.B., dated 5/10/10
Respondent's Ex. No. 3	-	Prescription for M.P., dated 5/10/10
Respondent's Ex. No. 4	-	Prescriptions for N.M., dated 5/17/10 and Patient 38, dated 5/20/11
Respondent's Ex. No. 5	-	2 Prescriptions for T.L., dated 5/6/10
Respondent's Ex. No. 6	-	Prescription labels for A.W. (6/16/10), E.S. (5/7/10), R.E.

(6/8/10) and A.A. (6/9/10)

Respondent's Ex. No. 7 - Prescription label for D.T. (5/30/10)

Respondent's Ex. No. 8 - Quality Care Pharmacy Customer Log for Patient 38

Respondent's Ex. No. 9 - DEA Order form confirmation (#10XW00009), dated

6/21/2010

Respondent's Ex. No. 10 - DEA Order form confirmation (#10XW00019), dated

7/27/2010

Respondent's Ex. No. 11 - DEA Order form confirmation (#10XW00009). dated

6/21/2010 (duplicate of Respondent's Ex. No. 9)

B. Witnesses.

State: James Polek – Inspector, Maryland Division of Drug Control

Chandra Mouli - Deputy Chief, Maryland Division of Drug Control

Respondent: Uchenna P. Ekwunazu, P.D.

FINDINGS OF FACT

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

- The Respondent-Pharmacy was issued a permit to operate a pharmacy in Maryland on February 24, 2010 under Permit Number P05148. (State's Ex. 14) The Respondent-Pharmacy's permit is currently active.
- 2. At all times relevant herein, the Respondent-Pharmacy was owned and operated by Uchenna P. Ekwunazu, the sole dispensing pharmacist. Mr. Ekwunazu is licensed to practice pharmacy in Maryland under license number 18054.
- The Respondent-Pharmacy is a community pharmacy located at 1403B E. Cold Spring Lane, Baltimore, Maryland 21239.

- 4. The Board received the results of inspections of Quality Care Pharmacy conducted by the Maryland Division of Drug Control on August 4, 2010 and August 6, 2010. Quality Care Pharmacy had recently opened for business on March 24, 2010. (State's Ex. 2A)
- 5. The Division of Drug Control CDS Inspection Report ("DDC Report") resulting from the August 2010 inspections cited various deficiencies relating to CDS inventory, recordkeeping, and the validity of prescriptions. Mr. Polek reviewed the results of the inspection with the Respondent-Pharmacy's owner, Mr. Ekwunazu, and Mr. Ekwunazu signed the DDC Report on August 6, 2010. (State's Ex. 2A; T. 196, 199)
- 6. Although it is standard practice to provide a copy of a DDC Report to the pharmacy permit holder upon completion of a DDC inspection, Mr. Ekwunazu asserts that he did not receive a copy. (T. 199)
- 7. The DDC Report cited various CDS recordkeeping violations including: incorrect prescriber DEA numbers; missing prescription dates; incorrect prescriber names and DEA numbers in database: and changes made to strength, quantity, and directions without documentation of prescriber approval. (State's Ex. 2A)
- 8. During the August 4, 2010 DDC inspection, Mr. Polek also noticed several facially suspicious prescriptions for Schedule II drugs. Mr. Polek contacted the purported prescribers of all Schedule II prescriptions filled by the Respondent-Pharmacy between April 7, 2010 and July 6, 2010. Of the 60 Schedule II prescriptions filled by

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)

- the Respondent-Pharmacy during that period, approximately 40 prescriptions were confirmed to be false. (State's Exs. 2C-21; T. 143-44)
- 9. The false prescriptions contained certain indications that should have raised concern to any reasonable pharmacist and prompted an attempt by the Respondent-Pharmacy's owner and sole dispensing pharmacist to verify and document the legitimacy of the prescription. The majority of the false prescriptions were paid for in cash.² (State's Exs. 2B 2I)

10. A breakdown of the false prescriptions follows:

a. Dentist I – 3 false prescriptions

- Patient 32 received two (2) prescriptions, each for a quantity of 90 "Oxycodone-HCI 30 mg TAB 1 TAB po q 4th prn pain." Both prescriptions were dated 6/25/10 and had the same serial number. The prescriptions were filled on 6/28/10 and 7/5/10, one week apart. According to Mr. Polek, it is highly unusual for a dentist to write even one prescription for a quantity of 90 Oxycodone, much less two prescriptions on the same date. It is also not customary to write "q 4th prn pain"; the typical language would be "q 4th prn pain". Patient 32 paid cash for the prescription drugs totaling approximately \$385.84. (State's Exs. 2B and 2C; T. 24, 26-27)
- Patient 31 received one prescription for 90 Oxycodone 30 mg, written in the same uncustomary language. Patient 31 paid \$192.92, in cash, for the prescription drugs. (State's Exs. 2B and 2C)

b. Doctor F – 6 false prescriptions

² In this Final Decision and Order, the term "cash" is used to reference payment made directly by the patient for the drugs as opposed to having the pharmacy submit a claim to a third party payor.

³ The abbreviation "po" means *per os*, or by mouth.

The abbreviation "q 4h prn pain" means to take the medication every 4 hours for pain.

The Respondent-Pharmacy filled 6 prescriptions purportedly issued by Dr. F, although 2 prescriptions for Patient 23 were written on prescription blanks for a completely different physician and were written for Percocet and Oxycodone, both short-acting opioids on the same date (6/7/10). Furthermore, Dr. F's signature varied greatly, and two prescriptions used the word "pill", which, as Mr. Polek testified, is highly unusual. Lastly, the prescriptions contained an institutional DEA number without the necessary suffix assigned to the individual prescriber. All patients paid cash for the drugs totaling approximately \$ 906.46 (State's Exs. 2B and 2D; T. 31-34)

c. Clinic – 23 false prescriptions

The Respondent-Pharmacy filled 23 false prescriptions purportedly written by physicians at a Clinic primarily for Oxycodone 30 mg, despite the fact that the prescriptions contained uncustomary language stating "q 4th", the prescription blank itself was fraudulent, and most of the physicians were not even associated with the Clinic. Notably, on the same date, the Respondent filled 2 prescriptions for Patient 5 for Oxycodone 30 mg, each for a quantity of 90. In addition, the Respondent-Pharmacy filled 2 prescriptions for Patient 15, both for a quantity of 90 Oxycodone 30 mg, written 4 days apart by the same prescriber. Again, all of the patients paid cash for the drugs totaling approximately \$3,718.33. (State's Exs. 2B and 2E; T. 35-44)

d. Doctor B – 2 false prescriptions

The Respondent-Pharmacy filled 2 false prescriptions, both for Oxycodone 30 mg, which included the uncustomary word "pill". (State Ex. 2F; T. 44-45)

e. Doctor J – 2 false prescriptions

The Respondent-Pharmacy filled 2 false prescriptions written on the same date for the same patient for Percocet and Oxycodone 30 mg, both of which are short-acting opioids. The patient paid a total of \$372.19 in cash for 180 narcotic pills. (State's Exs. 2B and 2G)

f. Doctor A – 1 false prescription

The Respondent-Pharmacy filled a false prescription for Percocet containing the uncustomary, non-clinical verbage, "Take one every four to six hours as needed for pain." In addition, the prescription stated "ninety tablets", rather than the typical "#90". The patient paid \$75.00 cash for the drugs. (State's Ex. 2H; T. 46)

g. Doctor G – 2 false prescriptions

The Respondent-Pharmacy filled 2 false prescriptions written for the same patient on the same day for Percocet 10/325 mg and Oxycodone 30 mg, both of which are short-acting opioids. The prescription for Oxycodone also stated "pill", which is uncustomary. The patient paid a total of \$350.35 cash for 210 narcotic pills. (State's Ex. 2I; T. 47-48) 10. The Respondent-Pharmacy was inspected again by DDC on September 7 and 12, 2011. The DDC inspection again cited various deficiencies relating to the Respondent's dispensing of controlled dangerous substances. The Respondent-Pharmacy's owner again signed the inspection form. (State's Ex. 3)

11. The September 2011 inspections revealed further deficiencies in the Respondent-Pharmacy's CDS dispensing practice, including failure of the owner of the Respondent-Pharmacy to date the Schedule III-V invoices and discrepancies between the names and DEA numbers of prescribers on prescriptions versus those entered into the Respondent-Pharmacy's computer system. (State's Ex. 3; T. 73-74) In addition, the September 2011

inspection revealed the Respondent-Pharmacy filled prescriptions that had been visibly altered or lacked a prescriber's signature. The Respondent-Pharmacy also filled various prescriptions that suggested that patients were engaged in doctor-shopping, without verifying the prescriptions with the prescriber. ⁵

a. Patient 35

The Respondent-Pharmacy filled 4 prescriptions that had been illegally altered as set forth below:

- 4/14/11 prescription for Opana⁶, dosage altered from 10 mg to 40 mg.
- 5/2/11 prescription for Opana, dosage altered from 20 mg to 200 mg
- 5/25/11 prescription for Oxycodone 5 mg, date altered to 6/25/11
- 5/25/11 prescription for Oxycodone 5 mg, date altered to 7/25/11⁷

From 6/20/11 through 6/25/11, the Respondent-Pharmacy filled 4 prescriptions for Oxycodone written by 4 different prescribers, totaling 510 tablets. Although Patient 35 had insurance coverage, these prescriptions were paid for in cash in the amount of \$480.72.

On 7/5/11, Respondent-Pharmacy filled 2 prescriptions for Oxycodone written by 2 different prescribers, totaling 240 tablets. Patient 35 paid \$ 316.36 in cash despite having insurance coverage. (State's Exs. 4, 5, 9; T. 60-66)

b. Patient 36

_ 5

⁵ "Doctor-shopping" is a practice whereby a patient seeks prescriptions for the same or similar drug, typically an opioid, from multiple prescribers who are unaware that the patient is being prescribed the same or similar drug by other prescribers. (T. 68, 77, 100)

⁶ Opana contains oxymorphone, a Schedule II controlled substance, with an abuse potential similar to other opioid analgesics.

⁷ Patient 35 had three prescriptions for Oxycodone 5 mg, quantity 90, written by the same prescriber on 5/25/11, two with the dates altered as described above. In addition to having the two dates altered, the first two prescriptions filled by the Respondent-Pharmacy were filled within 4 days of one another, on 6/23/11 and 6/27/11. (State's Ex. 5)

On 6/6/11, the Respondent-Pharmacy dispensed 90 Oxycodone 15 mg, with directions to take one tablet 3 times a day. Although Patient 36 had insurance coverage, he paid \$ 73.21 in cash.

On 6/15/11 (8 days later), the Respondent-Pharmacy again dispensed Oxycodone 15 mg, quantity 180. Patient 36 again paid cash in the amount of \$141.42. On the same date, the Respondent-Pharmacy also dispensed Oxycodone 5 mg, quantity 180. In addition, the Respondent-Pharmacy had incorrect prescriber information for these prescriptions in its records. (State's Exs. 6 and 8)

c. Patient 37

Two prescriptions dated 5/2/11 for Oxycodone 10 mg and Duragesic transdermal film, both Schedule II drugs, do not have either a prescriber's signature or DEA number. (State's Ex. 10)

d. Patient 38

The Respondent-Pharmacy filled a 7/6/11 prescription for 240 Methadone 10 mg, a Schedule II drug, with directions to take 4 tablets twice a day. However, the prescription blank stated, "Prescription blank not valid for controlled substances". Patient 38 paid \$ 99.38 in cash. DDC confirmed the prescription to be false.

On 7/12/11 (6 days later), the Respondent-Pharmacy again filled a prescription for 240 Methadone 10 mg despite the prescription blank again stating, "Prescription blank not valid for controlled substances". Patient 38 paid \$99.38 in cash. DDC confirmed the prescription to be false. (State's Ex. 11B and 11C)

OPINION

Pharmacists and pharmacies play an integral part in the provision of quality healthcare services to patients. In addition to their expertise in pharmaceutical care, community pharmacists, through pharmacies, act as gatekeepers, allowing or prohibiting access to highly addictive drugs that may have significant street value. Thus, it is crucial that a pharmacist and pharmacy permit holders act in a completely ethical manner. Mr. Ekwunazu, as the owner and operator of the Respondent-Pharmacy, did not take his professional responsibilities seriously and his failure resulted in the provision of highly addictive and dangerous drugs to individuals for illegitimate purposes.

Mr. Ekwunazu concedes that he knew at least one of his patients had altered his prescriptions on two occasions, yet he continued to dispense controlled substances to this individual without verifying the prescriptions. Furthermore, Mr. Ekwunazu continues to fill controlled substance prescriptions for this patient notwithstanding the fact the most of the patient's prescribers have "dropped him" due to his doctor-shopping practices. The Board, as a body of pharmacists, is acutely aware of the "red flags" that should raise suspicions for any community pharmacist. One example of a "red flag" is a patient who has health insurance coverage yet elects to pay cash for a narcotics prescription. Another example is when a patient presents a subsequent prescription for the same narcotic early; i.e., before the prior prescription has (or should have) run out. A third example is if a patient presents numerous prescriptions for the same narcotic written by different prescribers in a short period of time. All of these "red flags" were evident in the prescriptions filled time and time again by Mr. Ekwunazu at the Respondent-Pharmacy.

In addition, Mr. Ekwunazu filled prescriptions that were facially questionable. Some contained uncustomary, non-clinical language such as "pill", "4th" or "as needed", or had been visibly altered. Other prescriptions had signatures for the same prescriber that varied greatly. In addition, two of the prescriptions did not even have a prescriber's signature, a basic legal requirement. And two others written for controlled substances contained template language that specifically indicated that the prescription blank was not valid for controlled substances. Mr. Ekwunazu filled all these prescriptions without documented verification from the prescriber, which resulted in large amounts of illegal narcotics being dispensed from the Respondent-Pharmacy. Mr. Ekwunazu incredibly argues that he did verify many of the false prescriptions with the prescribers but neglected to document that verification. However, if he did verify these prescriptions, he would have determined, as did DDC, that the prescriptions were false, and he would not, or should not, have filled them.

Although Mr. Ekwunazu has been a practicing community pharmacist at various chain pharmacies in Maryland since 2006, he only came to the Board's attention for deficient CDS dispensing practices immediately after he opened his own pharmacy, Quality Care Pharmacy. Mr. Ekwunazu was presented with a cadre of red flags yet he chose to ignore them in favor of financial gain for his fledgling pharmacy business at Quality Care Pharmacy. Indeed, Mr. Ekwunazu concedes that the Respondent-Pharmacy's computer system will alert him if a drug is being dispensed early, or if there is a therapeutic duplication. Particularly with respect to Patient 35, the Board is astounded that Mr. Ekwunazu could so blindly dispense 655 tablets of Oxycodone 15mg and 120 tablets of Oxycodone 30mg from six (6) different prescribers in June 2011 alone without contacting the prescribers. In doing so, Mr. Ekwunazu, through the Respondent-Pharmacy, dispensed highly addictive and dangerous narcotics in high dosages and

quantities, without any medical necessity. Although the suspicious prescriptions for Patients 35 and 36 were not confirmed false, the Board finds that professional standards required that Mr. Ekwunazu, at 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. Specifically, the regulations state:

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. COMAR 10.19.03.07C; 21 CFR § 13.06.04.

The ever-increasing health crisis involving prescription drug abuse renders this legal obligation all the more integral to community pharmacy practice. If a pharmacist willingly turns a blind eye to glaringly false narcotics prescriptions solely for his financial gain, there is little that differentiates that pharmacist from a common drug dealer. The Board finds that Mr. Ekwunazu failed to exercise even a minimum amount of professional judgment with respect to responsible dispensing of controlled substances through the Respondent-Pharmacy. Mr. Ekwunazu was abundantly aware of standard procedures for CDS verification and auditing based on his years of prior community pharmacy experience, yet failed to implement these practices at his own pharmacy, the Respondent-Pharmacy.

In addition, there were several instances in which the Respondent-Pharmacy's records did not have accurate information regarding the quantity, dosage, prescriber or DEA number. The

Board finds that a pharmacist and permit holder has the responsibility to maintain full and accurate records, particularly regarding dispensing of controlled substances.

At this juncture, Mr. Ekwunazu has testified that he no longer engage in the same cavalier CDS dispensing practices at the Respondent-Pharmacy. Mr. Ekwunazu asserts that he verifies all Schedule II prescriptions directly with the prescriber, and that he does not return those prescriptions that are confirmed to be false. However, based on the egregiousness of the misconduct by the Respondent-Pharmacy and the dire consequences that resulted, the Board finds that a fine against the permit is warranted. The Board feels that this sanction is necessary to address the violations committed by the Respondent-Pharmacy as well as to provide a deterrent to other pharmacy permit holders who may be tempted to engage in similar unethical and illegal acts.

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)(21) and (25); Code Md. Regs. tit.10 § 34.10.01A(1).

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 in lieu of a period of suspension, the Respondent-Pharmacy shall pay a FINE of \$5,000, payable to the Maryland Board of Pharmacy within ninety (90) days of the date of this Order; and be it further,

ORDERED that the Board, or its agents, shall inspect the Respondent-Pharmacy at least twice a year for the next three (3) years to ensure compliance with all laws governing the dispensing of controlled dangerous substances; 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 Art., §§10-611, et seq.

8 9 7 Z

LaVerne G. Naesea, Executive Director

for

Michael Souranis, P.D.

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. Art., § 12-412.