

IN THE MATTER OF

* **BEFORE THE**

EASTERN SHORE PHARMACY

* **MARYLAND BOARD**

Respondent

* **OF PHARMACY**

PERMIT No: P02267

* **Case No.: PI-11-065**

* * * * * * * * * * *

CONSENT ORDER

On June 15, 2011, the State Board of Pharmacy (the "Board") charged **EASTERN SHORE PHARMACY ("the Respondent-Pharmacy")**, Permit No.: **P02267**, the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") §§ 12-101 *et seq.* (2009 Repl. Vol.). The Board issued Amended Charges on May 18, 2012.

Specifically, the Board charged the Respondent-Pharmacy with the following provisions of the Act under H. O. § 14-404:

H.O. §12-403 Required Standards.

(b) *In general.* – Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:

- (1) Shall be operated in compliance with the law and with the rules and regulations of the Board; [and]
- (9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under 12-313 or a registered pharmacy technician under 12-6B-09 of this title[.]

H.O. §12-409. Suspensions and revocations – Grounds.

(a) *In general.* – Subject to the hearing provision of §12-411 of this subtitle, the Board may suspend or revoke any pharmacy permit, if the pharmacy:

- (1) Is conducted so as to endanger the public health or safety;

- (2) Violates any of the standards specified in §12-403 of this subtitle; or
- (3) Otherwise is not conducted in accordance with the law.

The pertinent provisions of Code Md. Regs ("COMAR"), tit. 10, § 34.10 provide as follows:

.01 Patient Safety and Welfare.

B. A pharmacist may not:

- (1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist[.]

COMAR 10.19.03.07C:

Purpose of Issue of Prescription

- (1) 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. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Maryland Controlled Dangerous Substances Act Criminal Law Article, §§ 5-501 – 5-505, Annotated Code of Maryland, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violation of the provisions of the law relating to controlled dangerous substances.

COMAR 10.19.03.09A:

- (1) A pharmacist may dispense directly a controlled dangerous substance listed in Schedules III, IV, or V, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, or State Law, only pursuant to either a written prescription signed by a prescribing individual practitioner or a facsimile received by facsimile equipment of a written, signed prescription

transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by a prescribing individual practitioner and immediately reduced to writing by the pharmacist containing all information required in Regulation .07 of this chapter, except the signature of the prescribing individual practitioner.

FINDINGS OF FACT

1. The Respondent-Pharmacy is licensed to operate a retail pharmacy in the State of Maryland under permit number P02267. The Respondent-Pharmacy was first licensed on October 17, 2000. The Respondent-Pharmacy's permit is currently active and will expire on December 31, 2011.
2. At all times relevant, Eastern Shore Pharmacy ("Eastern") was owned/or operated by William R. Elliott. Mr. Elliott is licensed to operate a pharmacy in the State of Maryland under license number 06640, which is current and scheduled to expire on May 31, 2012.
3. At all times relevant, the Respondent-Pharmacy was operating a retail pharmacy at 400 Eastern Shore Drive, Salisbury, Maryland 21804.
4. On or about November 5, 2010, the Washington State Department of Health ("WSDH") received a complaint from a Federal Express delivery person in Washington State (the "complainant") alleging that he believed that the Respondent-Pharmacy was engaging in the practice of Internet pharmacy. The complainant stated that he "noticed a large number of prescriptions being delivered under many different names to a Federal Express customer". The prescriptions were from the Respondent-Pharmacy, as well as pharmacies in Texas, Wisconsin and Pennsylvania.
5. WSDH forwarded the complaint information to the Board, which subsequently opened an investigation.

6. On or about December 8, 2010, a Board inspector inspected the Respondent-Pharmacy. Mr. Elliott was the pharmacist on duty.

7. In response to questioning by the Board's inspector, Mr. Elliott stated that the Respondent-Pharmacy fills original prescriptions received through the Internet and had been doing so since December 2009.

8. Pursuant to the Board inspector's request, Mr. Elliott provided a list of all prescriptions that the Respondent-Pharmacy had filled through the Internet.

9. According to the Board's investigation, the Respondent-Pharmacy fills approximately 300 internet prescriptions per day. Most of the prescriptions filled are for Ultram, Soma and Fioricet.¹ Of these drugs being dispensed by the Respondent-Pharmacy's Internet pharmacy, only Fioricet is a controlled drug (Schedule III) on the Maryland Drug Schedule. Fioricet is not a DEA scheduled drug.

10. According to the investigation, the Respondent-Pharmacy obtained prescriptions via the Internet from three different websites or intermediaries, which were designated by the Respondent as "blue", "red" and "green".

11. The physicians prescribing the medications were not located in Maryland and the patients were located all over the United States.² Prescriptions were mailed by Federal Express to patients in at least 41 states.

12. The prescriptions observed by the Board's investigator contained the prescribing physician's electronic signature.

¹ Ultram (Tramadol) is an opioid analgesic used to treat moderate to severe pain. Fioricet (Butalbital/APAP/Caffeine) is a combination drug product used to treat tension headaches. Fioricet is habit-forming and has the potential for abuse.

² A review of the Internet prescriptions filled by the Respondent-Pharmacy revealed that most prescriptions were written by the same four physicians. One physician was located in Delaware, two physicians were located in Pennsylvania, and one physician was located in California.

13. Prescriptions for controlled substances require either a written prescription signed by a prescribing practitioner, or a facsimile received by facsimile equipment of a written signed prescription transmitted to the pharmacy. All of the prescriptions being filled by the Respondent-Pharmacy's Internet pharmacy operation were generated using a computer with attached printer. The Internet intermediaries generated the labels, which were then printed by Mr. Elliott.

14. The Board charged the Respondent-Pharmacy with allegedly filling invalid prescriptions via the Internet. Mr. Elliott attended a Case Resolution Conference on August 29, 2012. Thereafter, his attorneys, Board counsel, and the Administrative Prosecutor exchanged numerous drafts of a proposed consent order that would have allowed the Respondent-Pharmacy to continue to fill prescriptions received via the Internet, but only through a pharmacy that met VIPPS (Verified Internet Pharmacy Practice Site) criteria.

15. On or about December 5, 2011, the Maryland Board of Physicians ("MBP") received a telephone call from a physician ("Dr. A") in Reno, Nevada to report that a patient ("Patient A") in his hospital had overdosed on Tramadol, which had been allegedly prescribed by a Maryland physician ("Dr. B"), who allegedly practiced in Salisbury, Maryland.

16. Dr. A contacted the MBP to report Dr. B; however the MBP could not locate Dr. B in its licensing system and contacted Dr. A for more information.

17. Dr. A provided Dr. B's address as it appeared on Patient A's prescription bottle. The address was 400 Eastern Shore Drive, Suite 103, Salisbury, Maryland 21804. The telephone number on the prescription bottle was 866-343-2288.

18. The MBP called the telephone number on the prescription bottle and a recording indicated that it was for Village Meds, an online pharmacy.

19. The MBP also determined that the address on the prescription bottle matched the address of the Respondent-Pharmacy's retail pharmacy.

20. On December 6, 2011, the MBP provided this information to the Maryland Division of Drug Control ("DDC").

21. On December 6, 2011, the DDC contacted Dr. A and requested a serum level of Tramadol on Patient A.

22. According to Dr. A, Patient A's serum level of Tramadol (1000 ng/ml at the time of admission³) indicated a life-threatening overdose. Dr. A stated that Patient A was "completely obtunded and had a large aspiration pneumonia. [Patient A] was critically ill with Severe Sepsis and almost intubated due to his severe respiratory compromise, all of this due to overdosing on a prescription medication that he has been addicted to for a number of years and had also recently been through a drug rehab program for."

23. On March 5, 2012, two DDC inspectors visited the Respondent-Pharmacy for an inspection and interviewed Mr. Elliott, who stated that he has never heard of Village Meds. Village Meds was not the name of the Internet intermediary for the prescription and was not a name that appeared on the label.

24. Mr. Elliott also stated that he could not locate any prescriptions for Patient A at that time.

25. The DDC inspectors reviewed the Respondent-Pharmacy's purchase invoices and determined that the Respondent-Pharmacy's purchase of generic Fioricet

³ The reporting limit for Tramadol is 100 ng/ml

substantially increased from 1600 tablets in all of 2011 to 69,500 tablets in the first two months of 2012.

26. The DDC inspectors observed five large stock bottles of Tramadol, which were not accounted for on the invoices.

27. The DDC inspectors asked Mr. Elliott to conduct an inventory of generic Fioricet, Carisoprodol and Tramadol, but Mr. Elliott stated that he couldn't get all the stock together immediately and would conduct the inventory at a later time.

28. On March 8, 2012, a DDC inspector visited the Respondent-Pharmacy to resolve questions from the March 5 inspection. Mr. Elliott was not available to meet with the inspector, but had left a single, unsigned page of a multiple-page document reflecting an agreement his counsel was negotiating with the Board that he believed would authorize him to conduct business with Internet intermediaries.

29. Mr. Elliott provided an inventory as requested at the March 5 inspection. His inventory as of March 8, 2012 upon start of business was:

Butalbital/APAP/Caffeine (Fioricet) – 25, 350 tablets
Carisoprodol (Soma) 350 mg – 3,000 tablets
Ultram (Tramadol) 50 mg – 434,070 tablets
Cyclobenzaprine – 30, 230 tablets

30. The pharmacist on duty was Pharmacist A, a relief pharmacist, who works only two to three days per month. She was unable to answer any of the DDC inspector's questions regarding the Internet pharmacy operation.

31. On March 29, 2012, three DDC inspectors returned to the Respondent-Pharmacy to review Internet prescriptions that were unavailable on previous visits.⁴

⁴ The Respondent-Pharmacy stores some files off-site.

32. The Respondent, with additional information provided by the DDC inspectors, located a prescription filled by the Respondent-Pharmacy on December 1, 2011 for Patient A for Tramadol 50mg #90.

33. Mr. Elliott advised the DDC inspectors that the telephone number printed on prescription labels and affixed to bottles shipped from the Respondent-Pharmacy is not that of the Respondent-Pharmacy, but rather, a customer service number for the Internet intermediary.

34. The DDC inspectors called the telephone number on a prescription label and reached a customer service representative, who stated that there was no pharmacist present to speak with him.

35. In a written statement dated March 29, 2012, Mr. Elliott stated that the Board had given him "the verbal okay" to continue an Internet presence while the committee and attorneys determined the proper procedures.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Respondent violated the following provisions of the Act:

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H.O. §12-409. Suspensions and revocations – Grounds.

(a) *In general.* – Subject to the hearing provision of §12-411 of this subtitle, the Board may suspend or revoke any pharmacy permit, if the pharmacy:

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ORDER

Based on agreement of the parties, it is therefore this 28th day of November 2012, by an affirmative vote of the Board, hereby:

ORDERED that the Respondent-Pharmacy's license to operate a pharmacy in the State of Maryland is hereby placed on **PROBATION** for a period of at least **three (3) years**, subject to the following terms and conditions:

1. During the probationary period, the Respondent-Pharmacy shall be subject to random inspections by the Board; and
2. The Respondent-Pharmacy shall provide training to all pharmacy staff members regarding valid prescriber-patient relationships and non-scheduled drugs of abuse. Such training shall occur within ninety (90) days of the date of this Order and yearly thereafter for the duration of the probationary period;

ORDERED that the Respondent-Pharmacy shall pay a fine in the amount of \$10,000, payable to the Maryland Board of Pharmacy, within ninety (90) days of the date of this Order; and it is further

ORDERED that the Respondent-Pharmacy agrees not to own or operate an Internet pharmacy operation, although nothing in this Order shall prohibit the Respondent-Pharmacy from receiving and processing electronic prescriptions and refills in a manner consistent with applicable laws and regulations; and it is further

ORDERED that the Respondent-Pharmacy shall bear all expenses associated with this Order; and it is further

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

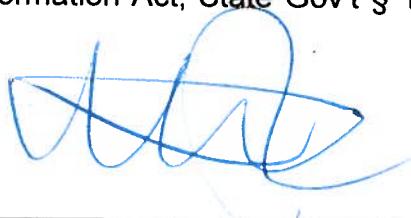
ORDERED that after three (3) years from the date of this Consent Order, the Respondent-Pharmacy may submit a written petition to the Board requesting termination of probation. After consideration of the petition, the probation may be terminated, through an order of the Board. The Board shall grant the termination if the Respondent-Pharmacy has fully and satisfactorily complied with all of the probationary terms and conditions and there are no pending complaints related to the charges; and it is further

ORDERED that if the Respondent-Pharmacy violates any of the terms and conditions of Probation and this Consent Order, 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, including an additional probationary term with conditions of probation, reprimand, suspension, revocation and/or a monetary penalty; and it is further

ORDERED that the Respondent-Pharmacy shall operate according to the Maryland Pharmacy Act and in accordance with all applicable laws, statutes and regulations pertaining to the practice of pharmacy; and it is further

ORDERED that this document constitutes a formal disciplinary action of the Maryland State Board of Pharmacy and is therefore a public document for purposes of

public disclosure, pursuant to the Public Information Act, State Gov't § 10-611 et seq.
and COMAR 10.34.01.12.



Michael N. Souranis, President
State Board of Pharmacy

CONSENT

I, William R. Elliott, P.D., owner and operator of Eastern Shore Pharmacy, acknowledge that I have had the opportunity to consult with counsel before signing this document. By this Consent, I accept to be bound by this Consent Order and its conditions and restrictions. I waive any rights I may have had to contest the Findings of Fact and Conclusions of Law.

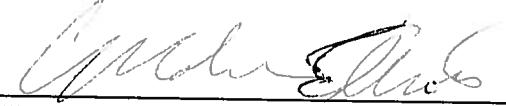
I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other substantive and procedural protections as provided by law. I acknowledge the legal authority and the jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. I also affirm that I am waiving my right to appeal any adverse ruling of the Board that might have followed any such hearing.

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

terms of this Consent Order. I voluntarily sign this Order, and understand its meaning and effect.

Date

11/19/12



William R. Elliott, P.D., owner and operator
Eastern Shore Pharmacy, Respondent-Pharmacy

Reviewed and approved by:

M. Natalie McSherry
M. Natalie McSherry, Attorney for the Respondent-Pharmacy

NOTARY

STATE OF MARYLAND

CITY/COUNTY OF Wicomico:

I HEREBY CERTIFY that on this 19th day of November, 2012, before me, a Notary Public of the foregoing State personally appeared William R. Elliott P.D. License Number 066640, 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.

Sandra L. Elliott
Notary Public

My Commission Expires: _____

