IN THE MATTER OF	*	**BEFORE THE**
RALPH B. EPSTEIN, M.D.	*	**MARYLAND STATE**
Respondent	*	**BOARD OF PHYSICIANS**
License Number: D08249	*	**Case Numbers: 2005-0861, 2009-0661, 2010-0635, 2013-0885, 7713-0049**

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CONSENT ORDER

PROCEDURAL BACKGROUND

On December 13, 2013, the Maryland State Board of Physicians (the "Board") charged Ralph B. Epstein, M.D. (the "Respondent"), License Number D08249, with violating the terms and conditions imposed under the Consent Orders, dated October 1, 2007 and November 14, 2012; and with violating the Maryland Medical Practice Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") §§ 14-101 *et seq.* and Md. Regs. Code ("COMAR") tit. 10, § 13.01 *et. seq.*

VIOLATION OF CONSENT ORDER, DATED OCTOBER 1, 2007

The Board charged the Respondent with violating the following term/condition of the Consent Order, dated October 1, 2007:

> **ORDERED** that the Respondent shall comply with all laws governing the practice of medicine under the Maryland Medical Practice Act and all rules and regulations promulgated thereunder;

VIOLATION OF CONSENT ORDER, DATED NOVEMBER 14, 2012

The Board charged the Respondent with violating the following probationary term/condition of the Consent Order, dated November 14, 2012:

4. The Respondent shall practice according to the Maryland Medical Practice Act and in accordance with all applicable laws, statutes, and regulations pertaining to the practice of medicine;

VIOLATION OF H.O. § 14-404

The Board charged the Respondent with violating the following provisions of the Act under H.O. § 14-404(a):

(2) Fraudulently or deceptively uses a license;

(3) Is guilty of: (ii) unprofessional conduct in the practice of medicine;

(11) Willfully makes or files a false report or record in the practice of medicine;

(12) Willfully fails to file or record any medical report as required under law, willfully impedes or obstructs the filing or recording of the report, or induces another to fail to file or record the report;

(17) Makes a willful misrepresentation in treatment;

(23) Willfully submits false statements to collect fees for which services are not provided; [and]

(28) Fails to comply with the provisions of § 12-102 of this article[.]

The pertinent provisions under H.O. § 12-102 provide the following:

(c) *Preparing of prescriptions by licensed veterinarian, dentist, physician, etc.* -- This title does not prohibit:

(2) A licensed dentist, physician, or podiatrist from personally preparing and dispensing the dentist's, physician's, or podiatrist's prescriptions when:

(i) The dentist, physician, or podiatrist:

1. Has applied to the board of licensure in this State which licensed the dentist, physician, or podiatrist;

2. Has demonstrated to the satisfaction of that board that the dispensing of prescription drugs

or devices by the dentist, physician, or podiatrist is in the public interest;

3. Has received a written permit from that board to dispense prescription drugs or devices except that a written permit is not required in order to dispense starter dosages or samples without charge; and

4. Posts a sign conspicuously positioned and readable regarding the process for resolving incorrectly filled prescriptions or includes written information regarding the process with each prescription dispensed;

(ii) The person for whom the drugs or devices are prescribed is a patient of the prescribing dentist, physician, or podiatrist;

(iii) The dentist, physician, or podiatrist does not have a substantial financial interest in a pharmacy; and

(iv) The dentist, physician, or podiatrist:

1. Complies with the labeling requirements of § 12-505 of this title;

2. Records the dispensing of the prescription drug or device on the patient's chart;

3. Allows the Division of Drug Control to enter and inspect the dentist's, physician's, or podiatrist's office at all reasonable hours;

4. Except for starter dosages or samples without charge, provides the patient with a written prescription, maintains prescription files in accordance with § 12-403(b)(13) of this title, and maintains a separate file for Schedule II prescriptions[;].

Effective July 1, 2013, H.O. 12-102 was amended, in pertinent part:

(c) *Preparing of prescriptions by licensed veterinarian, dentist, physician, etc.* -- This title does not prohibit:

(2) A licensed dentist, physician, or podiatrist from personally preparing and dispensing the dentist's, physician's, or podiatrist's prescriptions when:

(i) The dentist, physician, or podiatrist:

1. Has applied to the board of licensure in this State which licensed the dentist, physician, or podiatrist;

2. Has demonstrated to the satisfaction of that board that the dispensing of prescription drugs or devices by the dentist, physician, or podiatrist is in the public interest;

3. Has received a written permit from that board to dispense prescription drugs or devices except that a written permit is not required in order to dispense starter dosages or samples without charge; and

4. Posts a sign conspicuously positioned and readable regarding the process for resolving incorrectly filled prescriptions or includes written information regarding the process with each prescription dispensed;

(ii) The person for whom the drugs or devices are prescribed is a patient of the prescribing dentist, physician, or podiatrist;

(iii) The dentist, physician, or podiatrist does not have a substantial financial interest in a pharmacy; and

(iv) The dentist, physician, or podiatrist:

1. Complies with the labeling requirements of this title;

2. Records the dispensing of the prescription drug or device on the patient's chart;

3. Allows the Division of Drug Control to enter and inspect the dentist's, physician's, or podiatrist's office at all reasonable hours and in accordance with § 12-102.1 of this subtitle;

4. On inspection by the Division of Drug Control, signs and dates an acknowledgment form provided by the Division of Drug Control relating to the requirements of this section;

5. Except for starter dosages or samples without charge, provides the patient with a written prescription, maintains prescription files in accordance with § 12-403(b)(13) of this title, and maintains a separate file for Schedule II prescriptions;

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10. Maintains biennial inventories and complies with any other federal and State record-keeping requirements relating to controlled dangerous substances[.]

The pertinent provisions under H.O. § 12-505 provide:

(a) *Label required.* -- Except for a drug or device dispensed to an inpatient in a hospital or related institution, each container of a drug or device dispensed shall be labeled in accordance with this section.

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(d) *Medication dispensed by an authorized prescriber.* -- (1) Except as provided in this subsection, if an authorized prescriber dispenses a drug or device, the prescriber shall label each container of the drug or device.

(2) In addition to any other information required by law, the authorized prescriber shall include on the label:

(i) The name and strength of the drug or device;
(ii) The date the prescription is dispensed;
(iii) An expiration date of the drug or device which shall be the lesser of:

1. 1 year from the date of dispensing;
2. The month and year when the drug or device expires; or
3. A shorter period as determined by the authorized prescriber; and

(iv) Any appropriate handling instructions regarding proper storage of the drug or device.

The Board charged the Respondent with violating COMAR 10.13.01 as follows:

VIOLATION OF COMAR 10.13.01

.01 Scope.

This chapter defines the parameters under which a licensee may dispense prescription drugs in accordance with Health Occupations Article, § 12-102, Annotated Code of Maryland.

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.03 Application for Dispensing Permit.

A. The licensee shall complete an application on a form approved by the appropriate Board and pay a fee in accordance with the fee schedule for:

(1) Physicians at COMAR 10.32.01.11;

.04 Dispensing Requirements.

A. A licensee shall submit an application to the appropriate Board on the form that the Board requires.

B. A licensee may not dispense prescription drugs until a written permit is received from the appropriate Board, except that a written permit is not required in order to dispense starter dosages or samples provided without charge.

C. A licensee shall dispense prescription drugs only to the patients of the licensee.

D. A licensee shall comply with the labeling requirements of Health Occupation Article, § 12-509, Annotated Code of Maryland.

E. A licensee shall record the dispensing of the prescription drug on the patient's chart.

F. A licensee may not have a substantial financial interest in a pharmacy.

G. A licensee shall allow the Division of Drug Control to enter and inspect the licensee's office at all reasonable hours.

H. A licensee shall, except for starter dosages or samples provided without charge, provide the patient with a written prescription.

I. A licensee shall maintain a separate file for Schedule II prescriptions. All other prescriptions shall be kept:

(1) In another file; and

(2) For 5 years.

J. A licensee shall dispense prescription drugs to a patient only when a pharmacy is not conveniently available to the patient. The decision whether a pharmacy is conveniently available shall be made by the patient based on factors to be determined solely in the discretion of the patient.

K. A licensee shall maintain a single form in each patient's chart for each patient to whom prescriptions drugs are dispensed. At a minimum, the form shall:

(1) Indicate that a pharmacy is not conveniently available to the patient;

(2) State that the determination that a pharmacy is not conveniently available was made solely by the patient; and

(3) Be signed and dated by the patient before dispensing prescription drugs to the patient for the first time.

L. A licensee shall display prominently a sign which informs the patient that prescription drugs can be purchased from the permit holder if the patient determines that a pharmacy is not conveniently available to the patient.

.05 Failure to Comply with Dispensing Requirements.

A licensee who fails to comply with the requirements governing dispensing of prescription drugs may be subject to disciplinary action pursuant to Health Occupations Article, § 4-315(a), 14-404, or 16-312, Annotated Code of Maryland.

On March 26, 2014, Disciplinary Panel B was convened as a Disciplinary Committee for Case Resolution ("DCCR") in this matter. Based on negotiations

occurring as a result of this DCCR, the Respondent agreed to enter into this Consent Order, which consists of Procedural Background, Findings of Fact, Conclusions of Law, Order, Consent and Notary.

FINDINGS OF FACT

Disciplinary Panel B makes the following Findings of Fact:

I. BACKGROUND

1. At all times relevant hereto, the Respondent was and is licensed to practice medicine in the State of Maryland. The Respondent was originally licensed to practice medicine in Maryland on August 3, 1970, under License Number D08249. The Respondent's license is currently active and is scheduled for renewal on September 30, 2014.

2. The Respondent is board-certified in obstetrics and gynecology.

3. At all times relevant hereto, the Respondent maintained medical offices at the following locations: 23 Crossroads Drive, Suite 215, Owings Mills, Maryland 21117 (the "Owings Mills" office); and 9110 Philadelphia Road, Suite 108, Rosedale, Maryland 21237 (the "Rosedale" office).

II. PRIOR DISCIPLINARY HISTORY

CONSENT ORDER, DATED OCTOBER 1, 2007

4. In or around May 2005, a Baltimore-area hospital notified the Board that it suspended the Respondent's medical staff privileges and imposed other restrictions on his hospital privileges after its investigation concluded that he performed a surgical procedure (a panniculectomy, commonly referred to as a "tummy tuck") on a patient that he was not credentialed to perform; accepted payment from the patient with

foreknowledge that the procedure he intended to perform was rejected by the insurer for coverage; failed to name the procedure when posting the patient for surgery; failed to obtain proper informed consent; deliberately failed to dictate the procedure into the operative note; and allowed the hospital to bill the insurer for operative time for the non-covered procedure, thereby potentially exposing the hospital to the charge of insurance fraud.

5. The Board investigated this matter and the Respondent's involvement in additional instances of similar misconduct, and on or about May 10, 2007, charged him under Board Case Number 2005-0661 with violating provisions of the Act.

6. The Respondent resolved these charges by entering into a Consent Order with the Board, dated October 1, 2007, in which the Board found that the Respondent violated the following provisions of the Act: Is guilty of unprofessional conduct in the practice of medicine, in violation of H.O. § 14-404(a)(3)(ii); Fails to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care, in violation of H.O. § 14-404(a)(22); and Fails to keep adequate medical records as determined by appropriate peer review, in violation of H.O. § 14-404(a)(40).

7. The Board reprimanded the Respondent and placed him on probation for two years, subject to several probationary conditions, including requiring training in medical ethics.

8. In addition, the Board imposed the following conditions in the Consent Order:

ORDERED that the Respondent shall comply with all laws governing the practice of medicine under the Maryland Medical Practice Act and all rules and regulations promulgated thereunder;

* * *

ORDERED that if the Respondent violates any of the terms of this Order including an unsatisfactory peer review or chart review, the Board may, after notice and an opportunity for a hearing, impose any sanction that the Board may have imposed in this case including probation, a reprimand, suspension, revocation and/or a monetary fine[.]

Consent Order, dated October 1, 2007, pp. 22-23.

9. The Respondent did not petition the Board for termination of his probation after the conclusion of his two year probationary period. As a result, the Respondent remained on probation with the Board.

CONSENT ORDER, DATED NOVEMBER 14, 2012

10. The Board initiated an investigation of the Respondent based on a complaint from several former employees who alleged that he engaged in various unethical practices, including, *inter alia*, ordering non-FDA approved intrauterine devices ("IUDs") through the Internet from Canada but billing for FDA-approved IUDs at a higher rate of reimbursement than the actual purchase price for these non-FDA approved IUDs.

11. As part of its investigation, the Board requested that Permedion, Inc. ("Permedion") perform a peer review the Respondent's practice. This review determined that the Respondent failed to meet appropriate standards for the delivery of quality medical and surgical standards and failed to keep adequate medical records in one case and failed to keep adequate medical records in three cases.

12. The Board's investigation into allegations that the Respondent inserted non-FDA approved IUDs in fifteen patients determined that beginning in or around early

2009, he directed his office staff to order non-FDA approved IUD devices through the Internet from Canada. The Respondent's office staff placed him on notice that the devices in question were not FDA-approved. Despite being placed on notice that the IUDs were not FDA-approved, the Respondent instructed his staff to order them anyway.

13. The Respondent then inserted these non-FDA approved IUDs in at least 15 patients from February through July 2009, without informing them at the time of implantation that the devices were not FDA-approved.

14. The Respondent submitted billings to the patients' insurance companies in which he represented that he implanted FDA-approved IUDs, and billed for implanting FDA-approved devices at a level of reimbursement that was consistent with the cost of FDA-approved devices, even though he purchased the devices for a cost that was significantly lower than for what was billed.

15. On or about May 28, 2010, the Respondent reimbursed his patients' insurance companies for "overpayment to Dr. Ralph Epstein for services rendered for the insertion of an IUD which was later determined to be a non-FDA approved IUD." Board investigation determined that the Respondent was aware that he had inserted non-FDA approved IUDs in patients and had billed the patients' insurance companies for implanting FDA-approved IUDs, but did not reimburse the insurance companies for at least one year afterwards.

16. The Board found that the Respondent inappropriately implanted non-FDA approved IUDs in patients; misrepresented in his patients' medical records that he implanted FDA-approved IUDs when in fact, he implanted non-FDA approved IUDs;

misrepresented to his patients' insurance companies that he implanted FDA-approved IUDs when in fact, he implanted non-FDA approved IUDs; inappropriately billed his patients' insurance companies for implanting FDA-approved IUDs when in fact, he implanted non-FDA approved IUDs; failed to notify his patients in a timely manner that he implanted non-FDA approved IUDs; failed to develop an appropriate and timely plan to notify his patients that he implanted non-FDA approved IUDs; failed to develop and implement an appropriate plan to address his implantation of non-FDA approved IUDs in his patients; and failed to provide timely reimbursement to his patients' insurance companies after billing them and receiving reimbursement for implanting FDA-approved IUDs when in fact, he implanted non-FDA approved IUDs.

17. On or about May 9, 2012, the Board charged the Respondent under Case Numbers 2005-0861, 2009-0661 and 2010-0635 with violating the Consent Order, dated October 1, 2007, and for violating disciplinary provisions of the Act.

18. The Respondent resolved these disciplinary charges by entering into a Consent Order with the Board, dated November 14, 2012.

19. The Board found as a matter of law that the Respondent's actions constituted a violation of the following provisions of the Act: Is guilty of unprofessional conduct in the practice of medicine, in violation of H.O. § 14-404(a)(3)(ii); Willfully makes or files a false report or record in the practice of medicine, in violation of H.O. § 14-404(a)(11); and Willfully submits false statements to collect fees for which services are not provided, in violation of H.O. § 14-404(a)(23).

20. The Board also found as a matter of law that the Respondent violated the terms and conditions of the Consent Order, dated October 1, 2007. The Respondent

violated the Consent Order by: (a) undergoing a peer review that yielded unsatisfactory findings, where it was determined that he failed to meet appropriate standards for the delivery of quality medical and surgical care and failed to keep adequate medical records; (b) by failing to comply with the laws governing the practice of medicine under the Act by being subject to a peer review that determined that he failed to meet appropriate standards for the delivery of quality medical and surgical care and failed to keep adequate medical records, in violation of the Act; and (c) by implanting non-FDA approved IUDs in patients as described in greater detail above.

21. The Respondent violated the terms and conditions of the Consent Order by violating the following provisions of the Act: Is guilty of unprofessional conduct in the practice of medicine, in violation of H.O. § 14-404(a)(3)(ii); Willfully makes or files a false report or record in the practice of medicine, in violation of H.O. § 14-404(a)(11); Fails to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in this State, in violation of H.O. § 14-404(a)(22); Willfully submits false statements to collect fees for which services are not provided, in violation of H.O. § 14-404(a)(23); and Fails to keep adequate medical records as determined by appropriate peer review, in violation of H.O. § 14-404(a)(40).

22. Pursuant to the terms of the Consent Order, the Board reprimanded the Respondent and ordered him to remain on probation pursuant to Case Number 2005-0861 for a minimum period of two years, subject to a series of probationary conditions, including the following:

> 4. The Respondent shall practice according to the Maryland Medical Practice Act and in accordance with all applicable

laws, statutes, and regulations pertaining to the practice of medicine;

Consent Order, dated November 14, 2012, p. 16.

III. CURRENT INVESTIGATION

A. Findings pertaining to IUD placement on May 14, 2013

23. The Board initiated an investigation of the Respondent after receiving a complaint, dated May 14, 2013, from a former employee (the "Complainant"), who alleged that the Respondent acted improperly when placing an IUD in a patient (the "Patient") on May 14, 2013.

24. The Complainant stated that on May 14, 2013, the Patient presented for an office visit for removal of an IUD and placement of a new one. The Complainant stated that the Respondent administered a sedative to the Patient by injection, removed the Patient's existing IUD and implanted a new Mirena[1] IUD.

25. The Complainant observed that the wording on the new IUD box and the instructions were not written in English, which caused her to question the Respondent, who stated that the writing was in Russian. After the Respondent completed the procedure, the Complainant examined the Mirena IUD box further and found that the writing and instructions on it were in Turkish and that the box had an expiration date of March 2012. After the procedure, the Complainant took possession of the box and secured it in her possession.

26. Board staff subsequently interviewed the Complainant, who provided additional details about the incident. The Complainant gave Board staff the box that contained the Mirena IUD the Respondent placed in the Patient. Board staff confirmed

[1] Mirena is a trade name for an IUD that is manufactured by Bayer Health Care Pharmaceuticals.

from the IUD's manufacturer that the IUD was manufactured in Turkey, the box's instructions were in Turkish and the IUD's expiration date was March 2012.

27. The Complainant stated that the Respondent did not use gloves during the procedure. The Complainant stated that when she assisted the Respondent with the procedure, the IUD and box containing it were already in the procedure room, and that she observed the Respondent remove the IUD from the box and insert it in the Patient.

28. The Complainant provided Board staff with a copy of the Patient's medical record and stated that the treatment note for May 14, 2013, had been altered. The Complainant stated that during the procedure, she removed a sticker that came with the Mirena IUD and affixed it to the Patient's chart. The sticker was printed with a serial number that is also printed on the IUD box itself. The Complainant stated that about a week later, she reviewed the Patient's medical record and discovered that it had been altered. The Complainant observed that the Mirena sticker she had placed on the Patient's chart was no longer there and that it had been replaced in the same spot on the chart with a "NovaSure" sticker.[2] This "Nova Sure" sticker had the same serial number as the serial number that was on the Mirena IUD box. The serial number written on the "NovaSure" sticker was written in the Respondent's handwriting.

29. The Complainant stated that she believed that the only way the Respondent could have written the serial number of the Mirena IUD on the "Nova Sure" sticker was to have copied it from the Mirena sticker she previously placed on the chart, since she maintained possession of the Mirena IUD box the entire time after the Respondent implanted the IUD.

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[2] NovaSure is not an IUD product but is the name of an endometrial ablation procedure that is manufactured by Hologic, Inc.

30. The Respondent submitted a bill to the Patient's insurance for services provided on May 14, 2013, in which he used billing codes 58300 (insertion of IUD) and J7300 (intrauterine copper contraceptive), and received remuneration from the insurance company.

31. Board staff interviewed the Respondent about this matter. The Respondent stated that he "borrowed" a Mirena IUD from another colleague whose office is in close proximity to his, without the colleague's knowledge. The Respondent provides office space to the colleague and bills him/her for supplies he provides/purchases and deducts charges for supplies the colleague provides that his office uses. The Respondent stated that when he realized that he took a non-FDA approved IUD, he obtained a second Mirena IUD, again without the colleague's knowledge, which he stated he implanted in the Patient. The Respondent acknowledged that the serial number on the non-FDA approved, Turkish Mirena IUD box matched the serial number on the "NovaSure" sticker on the Patient's chart and that he failed to correct this information in the Patient's medical record. The Respondent admitted he did not tell his colleague that he borrowed a non-FDA approved Mirena IUD from him/her, or that he borrowed a second IUD for implantation in the Patient. He also stated that he deducted the cost of one IUD from his monthly rent to the colleague, despite taking two IUDs from the colleague's supply.

32. Board staff obtained the Respondent's monthly billings to the colleague, which did not reflect that he had deducted the cost of the IUD(s) from the colleague's monthly assessment.

33. Board staff also interviewed the Respondent's colleague, who stated that the Respondent did not inform him/her that he had taken two IUDs from his/her supply, or that one of the IUDs was manufactured in Turkey. The Respondent's colleague confirmed that the Respondent did not deduct any charges from his/her rent for "borrowing" one or more IUDs for the procedure on May 14, 2013.

34. The Respondent addressed this matter in a letter to the Board, dated July 19, 2013, in which he claimed that he implanted an IUD that had an "English insert" and "recorded the lot number in the chart." Board investigation determined that the Respondent wrote the serial number for the Turkish IUD in the Patient's chart, however.

35. Board investigation determined that on May 14, 2013, the Respondent: implanted a non-FDA approved Mirena IUD in the Patient, without the Patient's knowledge or consent; failed to inform the Patient that he implanted a non-FDA approved IUD; billed the Patient's insurance company for implanting an intrauterine copper device that was not approved for use in the United States; altered the Patient's medical record by removing the Mirena IUD sticker and replacing it with a NovaSure sticker; and willfully made material misrepresentations in the Patient's chart regarding the IUD he implanted. Board investigation also determined that the Respondent did not place the correct serial number for the IUD he implanted in the Patient.

36. The Respondent's actions, as described above, a violation of the following provisions of the Act under H.O. § 14-404(a): (2), Fraudulently or deceptively uses a license; (3), Is guilty of: (ii) Unprofessional conduct in the practice of medicine; (11), Willfully makes or files a false report or record in the practice of medicine; (12), Willfully fails to file or record any medical report as required under law, willfully impedes or

obstructs the filing or recording of the report, or induces another to fail to file or record the report; (17), Makes a willful misrepresentation in treatment; and (23), Willfully submits false statements to collect fees for which services are not provided.

37. The Respondent's actions, as described above, constitute a violation of following term/condition of the Consent Order, dated October 1, 2007:

> **ORDERED** that the Respondent shall comply with all laws governing the practice of medicine under the Maryland Medical Practice Act and all rules and regulations promulgated thereunder;

38. The Respondent's actions, as described above, constitute a violation of the following probationary term/condition of the Consent Order, date November 14, 2012:

> 4. The Respondent shall practice according to the Maryland Medical Practice Act and in accordance with all applicable laws, statutes, and regulations pertaining to the practice of medicine;

B. Findings pertaining to dispensing medications without a valid dispensing permit and/or violating dispensing laws/regulations.

39. While investigating the above allegations, Board staff investigated the Respondent's medication dispensing practices and administration of medications to patients.

40. Board investigation determined that the Respondent provided bariatric treatment to patients at his Owings Mills and Rosedale offices from in or around 2010 onward, during which time he dispensed the drug phentermine without a valid dispensing permit and failed to comply with State and federal laws and regulations

when dispensing phentermine, and administering other medications, including diazepam, for in-office procedures.

41. The Respondent typically ordered phentermine 37.5 mg in 1000-pill quantities. The Respondent's practice was then to re-package the phentermine by placing them in smaller bottles (typically, 30 pills per bottle), and maintain the stocks of medications in this form. When seeing a patient, the Respondent placed a label on a pre-filled smaller bottle and dispensed the phentermine to the patient. The Respondent entered the amount of the phentermine he dispensed in the patient's chart but did not keep an inventory log as is required under law.

42. As part of its investigation, Board staff conducted an unannounced inspection of the Respondent's Owings Mills office on July 2, 2013, in conjunction with staff from the Maryland Division of Drug Control ("DDC"). The DDC issued a report in which it found that the Respondent violated State dispensing laws/regulations, including but not limited to the following:

(a) did not obtain a dispensing permit from the Board but dispensed prescription drugs to patients;

(b) did not maintain complete or accurate records of stocks of CDS on hand;

(c) did not provide patients with written prescriptions for the prescription drugs he dispensed;

(c) did not prominently display a sign indicating that prescription drugs may be purchased if a pharmacy was not conveniently available to the patient;

(e) did not maintain a form in the patients' charts indicating that: (i) a pharmacy was not conveniently available to the patient; (ii) the determination that a pharmacy was not conveniently available to the patient was made solely by the patient; and (iii) the signature and date by the patient requesting service before dispensing prescription drugs for the first time;

(f) did not comply with labeling requirements for dispensed drugs by failing to print on the label: (i) the address of the dispenser; (ii) the date dispensed; and (iii) expiration date;

(g) did not document that he made a final check prior to delivering the medication to the patient;

(h) did not write prescriptions and provide them to the patients; and

(i) did not maintain records of CDS purchases and disposition of CDS in accordance with State and federal regulations.

43. On or about July 11, 2013, Board staff conducted an inspection of the Respondent's Rosedale office, during which staff observed an unmarked bottle of phentermine in the Respondent's top desk drawer. The Respondent stated to Board staff that he believed he transported the phentermine from his Owings Mills office on or about June 27, 2013.

44. Board staff observed several expired medications and samples and brought them to the Respondent's attention. In response, the Respondent put the expired medications and samples in a trash can.

45. When asked if he kept medical records and phentermine in his Rosedale office, the Respondent stated that he transported the medical records and phentermine by personal automobile from his Owings Mills office to his Rosedale office. Board staff determined that the Respondent did not have a DDC CDS registration or a United States Drug Enforcement Administration ("DEA") registration for his Rosedale office as is required by Md. Code Ann., Crim. Law § 5-301(a)(1) and (b) and 21 CFR § 1301.12. Board investigation determined that the Respondent handled and dispensed phentermine from his Rosedale office in the same way he handled/dispensed it from his Owings Mills office.

46. The Board also investigated the Respondent's acquisition of diazepam for in-office procedures. Board investigation determined that the Respondent obtained diazepam for in-office use by writing prescriptions for the drug in which he stated that the prescription was for office use and filled the prescriptions at a nearby pharmacy. The Respondent did not keep inventory logs for the diazepam he stored/administered in his office.

47. Board investigation determined that the Respondent:

(a) dispensed prescription drugs, including phentermine, without first applying for, or obtaining, a dispensing permit from the Board;

(b) failed to maintain complete and accurate records of stocks of CDS he kept in his offices;

(c) failed to keep accurate records/logs of the phentermine he kept in his offices;

(d) failed to keep records/logs of any CDS in his offices;

(e) failed to provide patients with written prescriptions for the prescription drugs he dispensed;

(f) failed to prominently display signage indicating that prescription drugs may be purchased if a pharmacy was not conveniently available to the patient;

(g) failed to maintain a form in patient charts indicating that (i) a pharmacy was not conveniently available to the patient; (ii) the determination that a pharmacy was not conveniently available to the patient was made solely by the patient; and (iii) the signature and date by the patient requesting service before dispensing prescription drugs for the first time;

(h) failed to comply with labeling requirements for dispensed prescription drugs by failing to print on the label: (i) the address of the dispenser; (ii) the date dispensed; and (iii) the expiration date required under law;

(i) failed to document that he made a final check prior to dispensing prescription drugs to patients;

(j) failed to write prescriptions and provide them to patients when dispensing phentermine;

(k) failed to maintain records of CDS purchases and disposition of CDS in accordance with State and federal regulations;

(l) failed to obtain the relevant State registration for his Owings Mills office and failed to obtain the relevant State and federal registrations for his Rosedale office;

(m) re-packaged phentermine into pre-packaged smaller bottles without appropriate labeling;

(n) improperly transported phentermine to his Rosedale office and stored/dispensed phentermine from that office without having valid DDC and DEA CDS registrations for that office; and

(o) improperly wrote prescriptions for diazepam for in-office procedures.

48. The Respondent's actions, as described above, constitute a violation of the following provisions of the Act under H.O. § 14-404(a): (3), Is guilty of: (ii) Unprofessional conduct in the practice of medicine; (12), Willfully fails to file or record any medical report as required under law, willfully impedes or obstructs the filing or recording of the report, or induces another to fail to file or record the report; and (28), Fails to comply with the provisions of § 12-102 of this article.

49. The Respondent's actions, as described above, constitute a violation of following term/condition of the Consent Order, dated October 1, 2007:

> **ORDERED** that the Respondent shall comply with all laws governing the practice of medicine under the Maryland Medical Practice Act and all rules and regulations promulgated thereunder;

50. The Respondent's actions, as described above, constitute a violation of the following probationary term/condition of the Consent Order, date November 14, 2012:

> 4. The Respondent shall practice according to the Maryland Medical Practice Act and in accordance with all applicable

laws, statutes, and regulations pertaining to the practice of medicine;

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, Disciplinary Panel B concludes as a matter of law that the Respondent violated:

A. the following condition of the Consent Order, dated October 1, 2007:

> **ORDERED** that the Respondent shall comply with all laws governing the practice of medicine under the Maryland Medical Practice Act and all rules and regulations promulgated thereunder;

B. the following probationary condition of the Consent Order, dated November 14, 2012:

> 4. The Respondent shall practice according to the Maryland Medical Practice Act and in accordance with all applicable laws, statutes, and regulations pertaining to the practice of medicine;

C. the following provisions of the Act under H.O. § 14-404(a):

(2) Fraudulently or deceptively uses a license;

(3) Is guilty of: (ii) unprofessional conduct in the practice of medicine;

(11) Willfully makes or files a false report or record in the practice of medicine;

(12) Willfully fails to file or record any medical report as required under law, willfully impedes or obstructs the filing or recording of the report, or induces another to fail to file or record the report;

(17) Makes a willful misrepresentation in treatment;

(23) Willfully submits false statements to collect fees for which services are not provided; [and]

(28) Fails to comply with the provisions of § 12-102 of this article[.]

D. the following provisions under H.O. § 12-102::

(c) *Preparing of prescriptions by licensed veterinarian, dentist, physician, etc.* -- This title does not prohibit:

(2) A licensed dentist, physician, or podiatrist from personally preparing and dispensing the dentist's, physician's, or podiatrist's prescriptions when:

(i) The dentist, physician, or podiatrist:

1. Has applied to the board of licensure in this State which licensed the dentist, physician, or podiatrist;

2. Has demonstrated to the satisfaction of that board that the dispensing of prescription drugs or devices by the dentist, physician, or podiatrist is in the public interest;

3. Has received a written permit from that board to dispense prescription drugs or devices except that a written permit is not required in order to dispense starter dosages or samples without charge; and

4. Posts a sign conspicuously positioned and readable regarding the process for resolving incorrectly filled prescriptions or includes written information regarding the process with each prescription dispensed;

(ii) The person for whom the drugs or devices are prescribed is a patient of the prescribing dentist, physician, or podiatrist;

(iii) The dentist, physician, or podiatrist does not have a substantial financial interest in a pharmacy; and

(iv) The dentist, physician, or podiatrist:

1. Complies with the labeling requirements of § 12-505 of this title;

2. Records the dispensing of the prescription drug or device on the patient's chart;

3. Allows the Division of Drug Control to enter and inspect the dentist's, physician's, or podiatrist's office at all reasonable hours;

4. Except for starter dosages or samples without charge, provides the patient with a written prescription, maintains prescription files in accordance with § 12-403(b)(13) of this title, and maintains a separate file for Schedule II prescriptions[;].

Effective July 1, 2013, H.O. 12-102 was amended, in pertinent part:

(c) *Preparing of prescriptions by licensed veterinarian, dentist, physician, etc.* -- This title does not prohibit:

(2) A licensed dentist, physician, or podiatrist from personally preparing and dispensing the dentist's, physician's, or podiatrist's prescriptions when:

(i) The dentist, physician, or podiatrist:

1. Has applied to the board of licensure in this State which licensed the dentist, physician, or podiatrist;

2. Has demonstrated to the satisfaction of that board that the dispensing of prescription drugs or devices by the dentist, physician, or podiatrist is in the public interest;

3. Has received a written permit from that board to dispense prescription drugs or devices except that a written permit is not required in order to dispense starter dosages or samples without charge; and

4. Posts a sign conspicuously positioned and readable regarding the process for resolving incorrectly filled prescriptions or includes written information regarding the process with each prescription dispensed;

(ii) The person for whom the drugs or devices are prescribed is a patient of the prescribing dentist, physician, or podiatrist;

(iii) The dentist, physician, or podiatrist does not have a substantial financial interest in a pharmacy; and

(iv) The dentist, physician, or podiatrist:

1. Complies with the labeling requirements of this title;

2. Records the dispensing of the prescription drug or device on the patient's chart;

3. Allows the Division of Drug Control to enter and inspect the dentist's, physician's, or podiatrist's office at all reasonable hours and in accordance with § 12-102.1 of this subtitle;

4. On inspection by the Division of Drug Control, signs and dates an acknowledgment form provided by the Division of Drug Control relating to the requirements of this section;

5. Except for starter dosages or samples without charge, provides the patient with a written prescription, maintains prescription files in accordance with § 12-403(b)(13) of this title, and maintains a separate file for Schedule II prescriptions;

****

10. Maintains biennial inventories and complies with any other federal and State record-keeping requirements relating to controlled dangerous substances[.]

The pertinent provisions under H.O. § 12-505 provide:

(a) *Label required.* -- Except for a drug or device dispensed to an inpatient in a hospital or related institution, each container of a drug or device dispensed shall be labeled in accordance with this section.

****

(d) *Medication dispensed by an authorized prescriber.* -- (1) Except as provided in this subsection, if an authorized prescriber dispenses a drug or device, the prescriber shall label each container of the drug or device.

(2) In addition to any other information required by law, the authorized prescriber shall include on the label:

(i) The name and strength of the drug or device;
(ii) The date the prescription is dispensed;
(iii) An expiration date of the drug or device which shall be the lesser of:

1. 1 year from the date of dispensing;
2. The month and year when the drug or device expires; or
3. A shorter period as determined by the authorized prescriber; and

(iv) Any appropriate handling instructions regarding proper storage of the drug or device.

E. the following provisions of COMAR 10.13.01

.01 Scope.

This chapter defines the parameters under which a licensee may dispense prescription drugs in accordance with Health Occupations Article, § 12-102, Annotated Code of Maryland.

****

.03 Application for Dispensing Permit.

A. The licensee shall complete an application on a form approved by the appropriate Board and pay a fee in accordance with the fee schedule for:

(1) Physicians at COMAR 10.32.01.11;

.04 Dispensing Requirements.

A. A licensee shall submit an application to the appropriate Board on the form that the Board requires.

B. A licensee may not dispense prescription drugs until a written permit is received from the appropriate Board, except that a written permit is not required in order to dispense starter dosages or samples provided without charge.

C. A licensee shall dispense prescription drugs only to the patients of the licensee.

D. A licensee shall comply with the labeling requirements of Health Occupation Article, § 12-509, Annotated Code of Maryland.

E. A licensee shall record the dispensing of the prescription drug on the patient's chart.

F. A licensee may not have a substantial financial interest in a pharmacy.

G. A licensee shall allow the Division of Drug Control to enter and inspect the licensee's office at all reasonable hours.

H. A licensee shall, except for starter dosages or samples provided without charge, provide the patient with a written prescription.

I. A licensee shall maintain a separate file for Schedule II prescriptions. All other prescriptions shall be kept:

(1) In another file; and

(2) For 5 years.

J. A licensee shall dispense prescription drugs to a patient only when a pharmacy is not conveniently available to the patient. The decision whether a pharmacy is conveniently available shall be made by the patient based on factors to be determined solely in the discretion of the patient.

K. A licensee shall maintain a single form in each patient's chart for each patient to whom prescriptions drugs are dispensed. At a minimum, the form shall:

(1) Indicate that a pharmacy is not conveniently available to the patient;

(2) State that the determination that a pharmacy is not conveniently available was made solely by the patient; and

(3) Be signed and dated by the patient before dispensing prescription drugs to the patient for the first time.

L. A licensee shall display prominently a sign which informs the patient that prescription drugs can be purchased from the permit holder if the patient determines that a pharmacy is not conveniently available to the patient.

.05 Failure to Comply with Dispensing Requirements.

A licensee who fails to comply with the requirements governing dispensing of prescription drugs may be subject to disciplinary action pursuant to Health Occupations Article, § 4-315(a), 14-404, or 16-312, Annotated Code of Maryland.

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is hereby:

ORDERED that this Consent Order supersedes all other prior Consent Orders to which the Respondent is subject; and it is further

ORDERED that the Respondent's license to practice medicine in the State of Maryland is hereby **SUSPENDED** for **THIRTY (30) DAYS,** to commence **TEN (10) DAYS** after the date Disciplinary Panel B executes this Consent Order; and it is further

ORDERED that after the conclusion of the entire **THIRTY (30) DAY SUSPENSION** imposed above, the **SUSPENSION** shall be **LIFTED** administratively, upon receipt of a timely written petition from the Respondent for such purpose; and it is further

ORDERED that if Disciplinary Panel B lifts the suspension imposed above, the Respondent will be placed on **PROBATION** for a minimum period of **THREE (3) YEARS,** to commence on the date Disciplinary Panel B lifts the **SUSPENSION**, and continuing until he successfully completes the following probationary terms and conditions:

1. Within **one (1) year** of the date Disciplinary Panel B executes this Consent Order, the Respondent shall pay a civil fine in the amount of $25,000.00, by certified

check or money order, payable to the Maryland Board of Physicians, P.O. Box 37217, Baltimore, Maryland 21297;

2. The Respondent shall practice according to the Maryland Medical Practice Act, the Maryland Pharmacy Act and in accordance with all applicable laws, statutes, and regulations pertaining to the practice of medicine and pharmacy; and

3. Disciplinary Panel B reserves the right to conduct a peer review by an appropriate peer review entity, or a chart review by a Disciplinary Panel B designee, to be determined at the discretion of Disciplinary Panel B.

AND IT IS FURTHER ORDERED that after the conclusion of the entire **THREE (3) YEAR** period of **PROBATION,** the Respondent may file a written petition to Disciplinary Panel B requesting termination of his probation. After consideration of his petition, the probation may be terminated through an order of Disciplinary Panel B or a designated Disciplinary Panel B committee. The Respondent may be required to appear before Disciplinary Panel B or a designated Disciplinary Panel B committee. Disciplinary Panel B, or a designated Disciplinary Panel B committee, will grant the termination if the Respondent has fully and satisfactorily complied with all of the probationary terms and conditions of this Consent Order, including the expiration of the three (3) year period of probation, and if there are no outstanding complaints related to the charges before the Board or Board panel; and it is further

ORDERED that if the Respondent violates any of the terms or conditions of this Consent Order or of probation, Disciplinary Panel B, in its discretion, after notice and an opportunity for a hearing before an administrative law judge at the Office of Administrative Hearings if there is a genuine dispute as to the underlying material facts,

or an opportunity for a show cause hearing before Disciplinary Panel B, may impose any other disciplinary sanctions Disciplinary Panel B may have imposed, including a reprimand, probation, suspension, revocation and/or a monetary fine, said violation being proven by a preponderance of the evidence; and it is further

ORDERED that the Respondent shall not apply for early termination of probation; and it is further

ORDERED that the Respondent shall be responsible for all costs incurred in fulfilling the terms and conditions of the Consent Order; and it is further

ORDERED that the Consent Order is considered a **PUBLIC DOCUMENT** pursuant to Md. State Gov't. Code Ann. § 10-611 *et seq.* (2009 Repl. Vol. and 2013 Supp.).

4/9/14
Date

Christine A. Farrelly, Acting Executive Director
Maryland State Board of Physicians

CONSENT

I, Ralph B. Epstein, M.D., acknowledge that I have had the opportunity to consult with counsel before signing this document. By this Consent, I agree and 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 Disciplinary Panel B 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 Disciplinary Panel A 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.

4/7/14
Date

Ralph B. Epstein, M.D.
Respondent

Read and approved by:

Bruce M. Robinson, Esquire
Counsel for Dr. Epstein

NOTARY

STATE OF Maryland

CITY/COUNTY OF: Baltimore

I HEREBY CERTIFY that on this 7 day of April, 2014, before me, a Notary Public of the State and County aforesaid, personally appeared Ralph B. Epstein, M.D., and gave oath in due form of law that the foregoing Consent Order was his voluntary act and deed.

AS WITNESS, my hand and Notary Seal.

Melissa Layne Canoles
Notary Public

My commission expires: 10/18/15

MELISSA LAYNE CANOLES
Notary Public-Maryland
Baltimore County
My Commission Expires
October 18, 2015