IN THE MATTER OF * BEFORE THE

CAROLYN MURRAY * MARYLAND STATE

Respondent * BOARD OF PHYSICIANS

Unlicensed * Case Number: 2218-0270B

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CEASE AND DESIST ORDER

Pursuant to the authority granted to Disciplinary Panel B ("Panel B") of the Maryland State Board of Physicians (the "Board") under Md. Code Ann., Health Occ. ("Health Occ.") § 14-206(e)(1) (2014 Repl. Vol. & 2018 Supp.), Panel B hereby orders CAROLYN MURRAY (the "Respondent"), unlicensed, to immediately CEASE AND DESIST from the practice of medicine as defined in Health Occ. § 14-101(o).

The pertinent provisions of the Medical Practice Act ("Act") under which Panel B issues this Order provide the following:

Health Occ. § 14-206. Judicial Powers.

- (e) Cease and desist orders; injunctions. A disciplinary panel may issue a cease and desist order or obtain injunctive relief against an individual for:
- (1) Practicing medicine without a license[.]

Health Occ. § 14-601. Practicing without license.

Except as otherwise provided in this title, a person may not practice, attempt to practice, or offer to practice medicine in this State unless licensed by the Board.

Practice medicine is defined as follows:

Health Occ. § 14-101. Definitions.

- (o) Practice medicine (1) "Practice medicine" means to engage, with or without compensation, in medical:
 - (i) Diagnosis;
 - (ii) Healing;
 - (iii) Treatment; or
 - (iv) Surgery.
- (2) "Practice medicine" includes doing, undertaking, professing to do, and attempting any of the following:
 - (i) Diagnosing, healing, treating, preventing, prescribing for, or removing any physical, mental, or emotional ailment or supposed ailment of an individual:
 - 1. By physical, mental, emotional, or other process that is exercised or invoked by the practitioner, the patient, or both; or
 - 2. By appliance, test, drug, operation, or treatment[.]

INVESTIGATIVE FINDINGS¹

Based on the investigatory information received by, made known to, and available to Panel B, there is reason to believe that the following facts are true:

I. BACKGROUND

1. At all times relevant hereto, the Respondent was not and is not a physician licensed to practice medicine in the State of Maryland. The Respondent has no formal

¹ The statements regarding the Respondent's conduct are intended to provide the Respondent with reasonable notice of the basis of the Cease and Desist Order. They are not intended as, and do not necessarily represent a complete description of the evidence, either documentary or testimonial, to be offered against the Respondent in connection with this matter.

training in medicine and does not possess any State-issued health occupations licenses, certificates or registrations.

2. At all times relevant, the Respondent owned and operated a local franchise (the "Clinic") of a company (the "Company") that operates a series of weight loss clinics around the country through the issuance of franchises to franchisees. The Respondent's Clinic is located in Columbia, Maryland.

II. PRIOR BOARD ACTION

3. On December 19, 2012, the Board issued an Advisory Letter to the Respondent in which it notified her that it had initiated an investigation of her based on allegations that as director of the Clinic, she had assisted unlicensed Clinic staff persons to practice medicine. The Board stated that although further investigation of those allegations was not warranted, it was advising her that her employees were obligated to comply with all aspects of the Act and Maryland state law. In addition, the Board specifically notified the Respondent that a physician must be on-site if unlicensed individuals administered injections at the Clinic.

III. THE COMPLAINT

4. The Board initiated an investigation of the Respondent after receiving a complaint, dated March 7, 2018, from a woman (the "Complainant")² who sought weight

² For confidentiality reasons, the names of complainants, physicians, patients or other individuals will not be disclosed in this document. The Respondent may obtain the identity of any individual referenced herein by contacting the assigned administrative prosecutor.

November 2017, she met with the Respondent at the Clinic to begin weight loss treatment there. The Complainant stated that she requested information from the Respondent about the "HCG Diet," which the Respondent's Clinic offers. The Complainant stated that the Respondent explained the HCG Diet to her, after which the Complainant stated she paid the Respondent for a 30-day supply of HCG and 8 "Lipoplex" injections.⁵

- 5. The Complainant stated that she returned to the Respondent's Clinic the following week for a weigh-in, whereupon Clinic staff gave the Complainant her first "Lipoplex" injection and the HCG kit she had ordered and purchased from the Respondent. The Complainant stated that throughout her treatment at the Clinic, Clinic staff did not offer her a physician consultation, provide a physician examination, blood work or an electrocardiogram ("EKG"), or request her to provide any medical records other than the information she noted on her initial intake form. The Complainant stated that after this visit, she started self-administering the HCG injections she received from the Clinic.
- 6. The Complainant reported that she returned to the Clinic on a series of follow-up visits for weigh-ins, during which Clinic staff administered "B12" injections.

³ The complaint was filed against the Respondent's Clinic and two physicians (referred to *infra* as "Physician A" and "Physician B").

⁴ "HCG" stands for human chorionic gonadotropin, which is a hormone produced during pregnancy. The United States Food and Drug Administration ("FDA") classifies HCG as a prescription drug to treat female infertility and other medical conditions. The FDA has not approved HCG for over-the-counter use for any other purpose.

⁵ In her under-oath interview with the Board (see *infra*), the Respondent stated that Lipoplex injections contain "fat-burning amino acids" and B-12.

The Complainant stated that as she was finishing up using her existing HCG, Clinic staff urged her to buy a second supply, which she declined. The Complainant stated that she became disillusioned with the Clinic due to concerns that it provided inadequate services. As a result, the Complainant stopped going to the Clinic for any further weight loss treatment.

IV. BOARD INVESTIGATION

- 7. As part of the Board investigation, Board staff interviewed a series of individuals including the Complainant, the Respondent, and two physicians ("Physicians A and B"), and obtained documentary evidence including but not limited to the Respondent's written response to the complaint, a series of records involving patients who received weight loss treatment at the Clinic, corporate documents from the Company, policies and procedures the Company provided to its franchisees, and the Respondent's invoices for HCG products. Board staff also made unannounced site visits to the Clinic on at least two occasions. The Board also referred this matter to a board-certified physician/consultant (the "Consultant") for an expert review.
- 8. The Board's investigation determined that the Respondent practiced medicine, attempted to practice, and/or offered to practice medicine, without a medical license at the Clinic. The Respondent evaluated individuals who sought weight loss treatment at the Clinic and determined whether they required an evaluation by a physician. The Respondent, without the authorization of a physician, ordered, or decided not to order, medical testing for individuals who sought weight loss treatment at the Clinic. The Respondent determined whether individuals who sought weight loss

treatment at the Clinic were suitable candidates for HCG use. The Respondent permitted Clinic staff to administer B12 injections without the permission or authorization or presence of a physician. The Respondent ordered at least one prescription medication, HCG, under the name of Physician A, who was no longer affiliated with the Clinic, without his permission or authorization. The Respondent dispensed the HCG to individuals, without the authorization of the physician whose name was used to order the HCG.

- 9. The Respondent entered into a franchise agreement with the Company in 2008 and has operated her franchise at the Clinic in Maryland since that time. The franchise agreement was for a 10-year time period.
- 10. The Respondent employs three staff persons, none of whom has any State licenses, certificates or registrations to practice medicine. The Respondent previously employed Physician A on a part-time basis to perform physical examinations of patients. Physician A has not been actively associated with the Clinic since 2014. Since then, the Respondent hired Physician B for this purpose. Physician B reportedly sees weight loss patients for a few hours once every two weeks.
- 11. The Respondent's educational background consists of a bachelor's degree in business. She has no formal medical training, has not earned a degree in medicine, and does not possess a medical license, or any other licenses, certificates or registrations from any other State health occupations licensing board.

Respondent's written response to the Complaint

12. Board staff sent the Respondent the Complainant's complaint and requested a written response. The Respondent responded by letter dated October 15, 2018. The Respondent denied practicing medicine or representing that she was authorized to do so. She stated that she encouraged her "clients" to consult with their personal physicians before starting a weight loss program. With respect to the specific allegations the Complainant raised, the Respondent confirmed that the Complainant consulted her about receiving HCG. The Respondent stated that the Complainant declined to see a Clinic physician or undergo recommended testing but nevertheless "insisted" on obtaining HCG and B12 shots, whereupon the Respondent "agreed to allow her to purchase those items" from her.

Respondent's franchise agreement

- 13. The Respondent's franchise agreement states that she is required to have a signed medical services agreement between the Clinic and a physician, who "... shall have the final authority on all client medical decisions at the [Clinic]." The agreement further requires the physician (an independent contractor) to provide various services including "... initial physical examination, review of clients' blood tests, EKGs, ascertaining and certifying that the health of the client meets the standards required for enrollment in the [Company] System"
- 14. The Board's investigation determined that in or around 2015, the Respondent hired Physician B to serve as the Clinic physician. The Respondent could not produce a medical services contract or agreement with Physician B, however. The

Clinic website advertises "medical supervised weight loss" through a team of physicians and counselors and lists Physician A and Physician B as the team of physicians at the Clinic.

15. Board staff subpoenaed Company policies and procedures for purchasing, ordering, storing, administering and selling of prescription weight loss medications including HCG and methylcobalamin (B12). The Company provided a series of documents that it submits to all franchise owners that noted the proper prescribing and handling of HCG. Specifically, the staff protocol for HCG self-administered injections states, "when the Clinic physician approves the client at the physicians consultation then the doctor can write a prescription for the HCG self-injection kit on their Rx pad." It further states, "there must be a record of a prescription for each kit sold in the Clinic. These HCG kits must be <u>KEPT UNDER LOCK AND KEY</u> at all times (they are a prescription item.)" (emphasis in original)

Site visit, May 11, 2018

16. Board staff made unannounced site visits to the Clinic in May and June 2018. On Board staff's May 11, 2018, visit, the Respondent was the only staff member onsite and patients were in the waiting room. Board staff observed vials of bacteriostatic water, B12 and HCG on a counter outside the examination rooms. The cabinet above the counter contained pre-packaged bags with HCG, syringes, alcohol prep pads and bacteriostatic water labeled with patient initials. During the site visit, the Respondent stated that patients pick up the pre-packaged bags to take home to self-administer the HCG. Board staff also observed prefilled order forms to a specific out-of-state

compounding pharmacy (the "Pharmacy") with Physician A's DEA number, license number and signature in the cabinet. The forms also had the compounding information pre-filled with "ship to doctor" checked off on the form.

17. Board staff subpoenaed the prescription orders and invoices from the Pharmacy from January 1, 2016 through July 27, 2018. The invoices document that the Respondent ordered HCG from the Pharmacy using Physician A's physician license number and contact information, even though he was no longer associated with the Clinic. The documentation indicates that the Pharmacy ships the HCG directly to the Clinic to the Respondent's attention.

Physician A's interview

18. Board staff interviewed Physician A, who was unaware that the Respondent was using his name and licensing information to order HCG from the Pharmacy. Physician A stated that he ceased practicing at the Clinic in or around 2014. Physician A stated that the Respondent did not consult him before ordering the HCG and that he did not authorize the Respondent to order the medication in his name.

Site visit, June 5, 2018

19. On June 5, 2018, Board staff accompanied an inspector (the "Inspector") from Maryland State Office of Controlled Substances Administration to the Clinic, where the Inspector conducted a dispensing inspection. The Respondent was present during the inspection. The Respondent stated that she orders HCG over the telephone from "corporate," and it is mailed to the Clinic. The Respondent stated that the Clinic receives the HCG in powdered form, which the Clinic then gives to patients along with

bacteriostatic water to reconstitute the HCG at home (or it can be reconstituted by Clinic staff in the office). The Respondent stated that she and the "staff counselors" give the HCG to patients. In response to questions about who writes the prescriptions for the HCG, the Respondent stated that Physician B has nothing to do with the HCG. The Inspector noted that the HCG vials were not labeled with patient or prescriber names and the vials were marked "for office use only," even though the Respondent dispenses HCG to patients for home self-injection. The Respondent stated that Physician B does not prescribe the HCG or decide on initial dosing or any dosing, but that she or Clinic staff make decisions on dosing based on recommendations by a physician who resides or practices in another state. The Inspector noted that the Respondent does not maintain any invoices in the office showing the purchases of HCG or the other prescription products such as methylcobalamin.

- 20. The Inspector issued a Dispensing Inspection Report, which noted multiple dispensing violations, including but not limited to: the Clinic does not provide a written prescription to the patient; the Clinic does not prominently display a sign stating prescription drugs may be purchased if a pharmacy is not conveniently available to the patient; the Clinic does not label any dispensed medications according to applicable regulations; the Clinic does not maintain a form in patient files regarding dispensing of medications; and a final check is not made by the prescriber prior to delivery of the medication to the patient.
- 21. The Board issued subpoenas for medical records of the Complainant and three additional Clinic patients. None of the records contain a medical evaluation by a

physician for suitability for HCG use. All of the records state that the Respondent dispensed HCG to the patients.

The Respondent's interview

- 22. Board staff conducted an under-oath interview of the Respondent on October 22, 2018, wherein she stated that she is Clinic manager, acts as a weight loss counselor and "run[s] the center, all of the operations" there. She stated that the Company decided that franchisees would offer various weight loss programs, including the use of HCG. The Respondent stated that she received and was aware of Company protocols regarding HCG. The Respondent stated that she did not consult with the Company for further information or instruction but instead consulted with a physician in another state for additional information about HCG.
- 23. The Respondent stated that at the Clinic, it is not necessary for patients to undergo a physical examination in order to receive HCG, stating that it was a "recommendation," but not a "requirement." The Respondent stated that if a patient declines to have a physical examination, Clinic staff may still dispense HCG to the patient. The Respondent stated that she or other Clinic staff determines whether patients need a physical examination or diagnostic testing, sometimes based on the patient's self-report. The Respondent stated that during a patient's initial consultation at the Clinic, the patient will fill out a medical summary that includes questions about previous treatments received for any health issues (*e.g.*, cancer, liver or kidney "problems," diabetes). The Respondent stated that she independently determines whether patients see Physician B by reviewing the client's medical summary and meeting the client. The Respondent stated

that if a patient answers "yes" to one of the questions on the patient medical summary, she will discuss them with the patient to determine if they should see Physician B.

- 24. The Respondent stated that if the patient refuses or declines to undergo a physical examination or does not provide a medical clearance from his or her personal physician, she may still dispense HCG to the patient. The Respondent stated that she receives HCG in powdered form from the Company, and that either she or her staff reconstitutes it with bacteriostatic water or provides the HCG to patients to reconstitute it at their homes.
- 25. She stated that it was her belief that it was never a requirement for a physician to write a prescription for HCG and that in particular, Physician B does not write prescriptions for it. Specifically, the Respondent stated, "never, ever in our office did the doctor ever write a prescription out and hand it to someone and say well, this is for HCG." The Respondent stated that she did not think that a physician needed to write a prescription for HCG because of her belief that it was not a prescription item. With regard to ordering HCG in the name of Physician A, who was no longer actively involved with the Clinic, the Respondent stated that "the thought never really occurred to [her]" to update the ordering physician's name.
- 26. In response to questions regarding the allegations the Complainant made in her complaint, the Respondent stated that she determined that the Complainant was healthy enough to receive HCG by "... just meeting with her face to face and . . . the insistence, the almost desperateness that she displayed . . .how badly she wanted to do this" The Respondent stated that she did not feel that the Complainant needed to see

a physician prior to using HCG but she recommended it to her. The Respondent stated that the Complainant declined a physical examination due to the cost but that she was "healthy." The Respondent admitted that she did not document the Complainant's refusal to undergo a physical examination in her weight loss record.

The Consultant's findings

27. The Board provided the investigative information to the Consultant for review. The Consultant reviewed materials including but not limited to the Complainant's complaint, interviews of the Complainant, Respondent, physicians who were formerly or are currently affiliated with the Clinic, investigative reports, and weight loss records of four patients who received HCG treatment at the Clinic. The Consultant issued a report dated January 15, 2019, in which she concluded that the Respondent practiced, attempted to practice or offered to practice medicine without a license at the Clinic. The Respondent dispensed HCG and B12 injections that she ordered without physician authorization. The Respondent diagnosed patients and prescribed HCG, a The Respondent independently ordered diagnostic testing, prescription medication. including EKGs and laboratory testing, based on her initial assessment of the patients and further determined whether the patients would see the Clinic physician. The Consultant stated, "Deciding which patients should have an EKG, blood work or be seen by a physician constitutes diagnosing in that [the Respondent] was effectively triaging her clients after obtaining their medical histories. She would make a preliminary determination as to whether it was safe to prescribe HCG. If the patient's medical history was complex or suggested a contraindication to prescribing HCG, she would then order blood work, EKG and further physician consultation." The Consultant reviewed four patient records, including the Complainant's. In each instance, the patients did not see a physician to be evaluated for HCG suitability. In each case, the Respondent dispensed HCG to the patients.

CONCLUSION OF LAW

Based on the foregoing investigative findings, Panel B concludes, as a matter of law, that the Respondent practiced medicine without a license, in violation of Health Occ. § 14-601.

ORDER

Based on the investigative findings and Panel B's conclusion of law that the Respondent practiced medicine without a license, it is hereby:

ORDERED that, pursuant to the authority vested by the Maryland Medical Practice Act, Health Occ. § 14-206(e)(1), the Respondent shall IMMEDIATELY CEASE AND DESIST from the practice of medicine; and it is further

ORDERED that this order is **EFFECTIVE IMMEDIATELY** pursuant to Md. Code Regs. 10.32.02.11E (1)(b); and it is further

ORDERED that this Consent Order is a public document. *See* Md. Code Ann., Health Occ. §§ 1-607, 14-411.1(b)(2) and Gen. Prov. § 4-333(b)(6).

05/09/2019 Date

Christine A. Farrelly

Executive Director

Maryland State Board of Physicians

NOTICE OF OPPORTUNITY FOR A HEARING

The Respondent may challenge the factual or legal basis of this Order by filing a written opposition within 30 days of its issuance. The Respondent has a right to a hearing but must request a hearing within 30 days of the issuance of this Order. The written opposition and/or request for a hearing should be made to: Christine A. Farrelly, Executive Director, Maryland State Board of Physicians, 4201 Patterson Avenue, Baltimore, Maryland 21215, with a copy mailed to Robert J. Gilbert Deputy Counsel, Health Occupations Prosecution and Litigation Division, Office of the Attorney General, 300 West Preston Street, Suite 201, Baltimore, Maryland 21201. If the Respondent files a written opposition, the Board will consider that opposition and will provide a hearing, if requested. If the Respondent does not file a written opposition, the Respondent will lose the right to challenge this Initial Order to Cease and Desist.