IN THE MATTER OF	*	**BEFORE THE**
DONALD WILLIAM ALVES, M.D.	*	**MARYLAND STATE**
Respondent	*	**BOARD OF PHYSICIANS**
License Number: D57744	*	**Case Number: 2222-0109 B**

* * * * * * * * * * * * *

CHARGES UNDER THE MARYLAND MEDICAL PRACTICE ACT

Disciplinary Panel B of the Maryland State Board of Physicians (the "Board") hereby charges **DONALD WILLIAM ALVES, M.D.** (the "Respondent"), License Number D57744, under the Maryland Medical Practice Act (the "Act"), Md. Code Ann., Health Occ. ("Health Occ.") §§ 14-101 *et seq.* (2021 Repl. Vol.).

Specifically, Disciplinary Panel B charges the Respondent with violating the following provisions of the Act under Health Occ. § 14-404:

> (a) *In general.* -- Subject to the hearing provisions of § 14-405 of this subtitle, a disciplinary panel, on the affirmative vote of a majority of the quorum of the disciplinary panel, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee:
>
> (3) Is guilty of:
>
> (ii) Unprofessional conduct in the practice of medicine;[1]
>
> …
>
> (18) Practices medicine with an unauthorized person or aids an unauthorized person in the practice of medicine; [and]

[1] "Unprofessional conduct in the practice of medicine, Health Occupations Article, § 14-404(a)(3), Annotated Code of Maryland, includes the failure of a physician to comply with the statute and regulations governing the physician's duty to supervise the physician assistant." COMAR 10.32.03.11C.

…

(28) Fails to comply with the provisions of § 12-102 of this article[.][2]

ALLEGATIONS OF FACT[3]

Disciplinary Panel B bases its charges on the following facts that it has reason to believe are true:

Background

1. At all times relevant to these charges, the Respondent was and is licensed to practice medicine in the State of Maryland. The Respondent initially was licensed to practice medicine in Maryland on June 21, 2001, under License Number D57744. The Respondent's license is current until September 30, 2024. The Respondent also is licensed in Virginia and Delaware.

2. The Respondent is board-certified in Emergency Medicine.

The Complaints

3. On or about September 29, 2020, the Board received a complaint ("Complainant No. 1") concerning a Clinic (the "Clinic") located in Baltimore County, Maryland that offered medical treatment to men for erectile and sexual dysfunction.

[2] § 12-102(c)(2)(i)(3) of the Health Occupations Article requires a physician to obtain a written permit from the Board to dispense prescription drugs.

[3] The allegations set forth in these charges are intended to provide the Respondent with reasonable notice of the asserted facts. 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 these charges.

Complainant No. 1 stated that he was a prostate cancer survivor and started going to the Clinic for erectile dysfunction treatment. Complainant No. 1 shared this information with his urologist who informed him the Clinic "is out to get over on people and he told me to stop going there because it's not safe." Complainant No. 1 also stated he spoke to his insurance company who informed him the Clinic was "a Scam Organization," and was told to "contact the Attorney General Office and the Better Business Bureau." Complainant No. 1 provided an invoice that he was billed $2,700.00 for treatment at the Clinic, and stated the Clinic "would not take my insurance."

4. On or about October 29, 2020, the Board received a second complaint ("Complainant No. 2") concerning the Clinic. Complainant No. 2 stated the Clinic "advertises that: 'Our doctors will provide a personal diagnosis and treatment plan.'" However, Complainant No. 2 stated he "visited the clinic and was examined by a Physician Assistant…." Complainant No. 2 stated he "was never seen by an M.D. or D.O. Does the Board consider a P.A. to be a doctor? This clinic continues to advertise on [a] Baltimore radio station."

5. On or about January 14, 2021, the Board received a third complaint ("Complainant No. 3") concerning the Clinic. Complainant No. 3 stated he had filed a medical malpractice case against the Clinic and a Physician Assistant who worked at the Clinic (the "P.A."). In part, Complainant No. 3 stated the Clinic "is owned and operated by a convicted felon…[who] operate[s] multiple erectile dysfunction Clinics across the country." Complainant No. 3 further stated Clinics in other states allowed "non-physician

Clinic staff 'determine treatment eligibility and dosing and even allowed them to administer the injection to patients' penises.'"

6. After reviewing these Complaints, the Board opened an investigation of the Respondent.

The Board Investigation

7. In furtherance of its investigation, Board staff in part interviewed the Respondent, the P.A., Complainant No. 2 and Complainant No. 3. Board staff also subpoenaed medical records from the Clinic for Complainant No. 1, Complainant No. 2 and Complainant No. 3. The Board also received a written summary of care from the P.A. for Complainant No. 1, Complainant No. 2 and Complainant No. 3. The Board also received appointment logs from the Clinic, and records from the Prescription Drug Monitoring Program ("PDMP") for the P.A. The Board also received a response to the Complaints from the Respondent and the P.A. The Board also received the personnel files from the Clinic for the Respondent, the P.A. and a staff member ("Staff Member No. 1"). The Board also received policies and procedures from the Clinic. The Board also conducted an onsite inspection of the Clinic with the Maryland Office of Controlled Substances Administration ("OCSA").

The Investigation

8. The investigation revealed that since approximately 2017, the Clinic was registered with the State of Maryland to conduct business. The Clinic advertised that its "goal is to provide the best treatment options for erectile dysfunction. Our licensed physicians provide real, long lasting solutions for erectile dysfunction, premature

ejaculation, and low testosterone. Our doctors will provide a personal diagnosis and treatment plan to safely awaken your sex life in just one visit." The treatments included penile injection therapy called an intracavernosal injection ("ICI"), and prescribing medication to assist men in having and maintaining erections. The Clinic charged thousands of dollars for these treatments.

9. An ICI is a combination of drugs including alprostadil, papaverine, phentolamine, and atropine that are injected directly into the penis to provide an erection immediately after injection.

10. Through at least August 19, 2021, the Respondent was listed as the Medical Director of the Clinic on its website. The Respondent stated he was unaware of being advertised as the Medical Director and stated he did not serve in this capacity.

11. At all relevant times, the P.A. provided treatment to Complainant No. 1, Complainant No. 2, Complainant No. 3 and other individuals at the Clinic. At all relevant times, the Respondent was the supervising physician for the P.A. at the Clinic pursuant to a Delegation Agreement.

12. On July 24, 2020, Complainant No. 1 was treated at the Clinic by the P.A. During this visit, Complainant No. 1 received an ICI that was performed by the P.A. The P.A. stated that the "only person that injects the patients…is the physician assistant in this office that is authorized by my supervising physician."

13. On September 30, 2020, Complainant No. 2 was treated at the Clinic by the P.A. During this visit, Complainant No. 2 received an ICI that was performed by the P.A.

Complainant No. 2 paid $500.00 as a down payment for his recommended treatment and was provided an invoice in the amount of $4,430.00.

14. Complainant No. 3 was treated by the P.A. at the Clinic in July and August 2020. Complainant No. 3 received ICI injections that resulted in him developing priapism, ultimately resulting in hospitalization and injury to his penis. (See summary of care for Complainant No. 3 *infra*.)

15. On April 19, 2022, Board staff interviewed the Respondent under oath. In the interview, the Respondent stated since 2009, he has been the medical director of a State of Maryland government agency. In addition, the Respondent testified that in approximately 2016, he was hired by the Clinic to work "one to two days a month." The Respondent stated the Clinic is "an erectile dysfunction clinic. It fills an itch between the little blue pill, when the oral agents aren't working, and for individuals who aren't ready to get surgical procedures done. So it provides them with injection therapy." The Respondent stated he did not have any "specific training in erectile dysfunction." The Respondent stated as "an ER doctor it's within my scope to do the rescue procedures for priapism."

16. The Respondent testified that he is "in the clinic usually a part day every week to two weeks." The Respondent stated he is paid "a flat rate of $250 a week basically to provide supervision and follow up and guidance for [the P.A.]…. I just supervise the P.A. now." The Respondent has not performed any clinical duties at the Clinic since approximately 2020. The Respondent stated "I function as [the P.A.'s] oversight and supervisor, supervision. I'm not Clinically in the Clinic – I won't say never, but any

extensive period of time." The Respondent has been supervising the P.A. pursuant to a Delegation Agreement since 2018.[4]

17. The Delegation Agreement identified the Respondent's primary practice areas as urology and internal medicine. The Respondent admitted that his primary practice area is emergency medicine, and that the Delegation Agreement was "errantly marked" by someone other than himself. The Respondent also stated in the Delegation Agreement that he would review the P.A.'s practice via "chart review, observation of clinical practice" and provide supervision via on site, electronic means and written instructions. The Respondent admitted that he never provided written instructions to the P.A. The Respondent stated that he occasionally talked to the P.A. on the telephone. The Respondent stated he initially provided "chart review, and now that's predominantly verbal conversation regarding patients who present issues." The Respondent testified he looks at charts by the P.A. "only infrequently, if there is a specific issue with them."

18. In the Delegation Agreement, the Respondent and the P.A. did not seek approval from the Board for the P.A. to treat priapism. Additionally, the Respondent and the P.A. did not seek approval from the Board for the P.A. to delegate treatment of priapism to medical assistants. Despite this, the P.A. treats priapism with phenylephrine injections without seeking permission from the Respondent or having been approved to do so by the Board.

[4] A "Delegation Agreement" is "a document that is executed by a primary supervising physician and a physician assistant containing the requirements of § 15-302 of this title." Md. Health Occ. Code Ann. § 15-101(i). (Note: § 15-302 sets forth the requirements of a delegation agreement and practice).

19. Rather than see a licensed physician, patients of the Clinic are treated by the P.A. Also, Staff Member No. 1, who does not hold a license in any medical field, and a CNA/Phlebotomist (Staff Member No. 2) assist the P.A.

20. In his interview, the P.A. testified all staff follow a script written by the Owner of the Clinic. The Owner is not a trained medical professional. The P.A. stated "[t]here's a script for everything…There's a script for answering the phone, there's a script for therapy coordinator, there's a script for me."

21. The Clinic has guidelines written by the Owner that every patient receives an ICI consisting of a mix of mostly non-FDA approved vasodilators to cause the patients to obtain immediate erections. The P.A. stated he prescribed ICIs to 75-80% of his patients and is aware that compared to oral medications like Viagra, the ICI he administers carries an increased risk of priapism. Priapism is a medical emergency and may cause permanent tissue damage and loss of penile function (fibrosis) if not successfully treated within 36-48 hours of onset. Despite being the only healthcare provider onsite at the Clinic for treating priapism, the P.A. stated he did not know how long it takes priapism to cause fibrosis.

22. When a patient reports priapism, Clinic staff, including Staff Member No. 1, first tell the patient to take Sudafed, drink water and take warm baths. If these methods do not relieve the priapism, the Clinic does not tell the patient that they are facing a medical emergency and to go to the emergency room for prompt treatment. Staff Member No. 1 stated that "I do not advise patients to go to the ER. I have always talked to [the P.A.] before recommending anything in that area." Instead, Clinic staff instructs the patient to

return to the Clinic where he will receive a shot of phenylephrine in an attempt to relieve the priapism.

23. While the Clinic prepares emergency room referral forms for all of its patients prescribed ICIs, it is not Clinic policy and practice to send patients to an emergency room for priapism. The P.A. testified that if a patient experienced priapism following an ICI, he would expect the patient to call the Clinic first. The P.A. stated he recalls referring two patients of the Clinic to the emergency department. However, this was only after the patients returned to the Clinic and were administered phenylephrine that did not relieve the priapism. Additionally, the Respondent testified that he only is contacted by the P.A. every three to four months regarding a patient with priapism.

24. The P.A. stated he is responsible for supervising the medical assistants at the Clinic, including Staff Member No. 1 and Staff Member No. 2. Although Staff Member No.1 and Staff Member No. 2 are not licensed to practice medicine, the P.A. testified that the "medical assistants are trained in giving phenylephrine shots to treat priapism. They come in in the middle of the night sometimes, when I'm not available. They come in on weekends, when I'm not available. I'm always apprised of it."

25. Staff Member No. 1 stated that his role at the Clinic was limited. "Yeah, I prepare-stock the rooms. Just escort patients to the rooms to meet with [the P.A.]. Sterilize the office and all that." Nevertheless, Staff Member No. 1 acknowledged that the Clinic trained him to administer phenylephrine injections into the penises of Clinic patients experiencing priapism. Staff Member No. 1 claimed that he had never administered phenylephrine to any patients. However, Complainant No. 3, his fiancée, and the P.A.

testified that Staff Member No. 1 administered phenylephrine to Complainant No. 3 to treat his priapism. (See summary of care for Complainant No. 3 *infra*.)

26. Staff Member No. 2 denied that he ever gave a patient any ICIs or phenylephrine shots.

27. The Respondent stated that he was unaware the P.A. allowed medical assistants to administer phenylephrine, and that medical assistants should not be administering phenylephrine when the P.A. was unavailable.

Complainant No. 3

28. On July 20, 2020, Complainant No. 3 contacted the Clinic concerning his erectile dysfunction after hearing radio advertisements. On July 21, 2020, Complainant No. 3 initially met with the Clinic Manager who told him "a physician will attend to you shortly."

29. Complainant No. 3 met with the P.A. for his initial consultation. During the consultation, the P.A. only recommended an ICI. The P.A. admittedly did not discuss less-invasive oral erectile dysfunction medications such as Viagra with Complainant No. 3. At the initial consultation, Complainant No. 3 received an ICI as the P.A. advised. However, the ICI failed to produce an erection while Complainant No. 3 was at the Clinic. The P.A. instructed Complainant No. 3 to administer two ICIs himself at home during the week. Complainant No. 3 self-administered the ICI on July 23, 2020 and July 26, 2020, both times without results.

30. On Tuesday July 28, 2020, Complainant No. 3 returned to the Clinic for a scheduled follow-up appointment. On this day, Complaint No. 3 met with Staff Member No. 1. Although Staff Member No. 1 is not licensed in any health field, Staff Member No.

1 demonstrated a technique to improve the effectiveness of the ICI at causing an erection, and provided Complainant No. 3 with additional ICIs and a supply of Cialis for use if the injections again proved ineffective. During the investigation, the Clinic produced three different notes for this visit, two of which appear to have been prepared during the pendency of the investigation.

31. Thereafter, on July 28, 2020 at 1:00 pm, Complainant No. 3 again self-administered the ICI and developed an erection. The erection continued for hours and developed into painful priapism. Per the instructions provided by the P.A., Complainant No. 3 called the Clinic for assistance and was advised to take 4-8 Sudafeds, drink 6-10 cups of water and return to the Clinic on July 29, 2020. Complainant No. 3 reported he did as he was advised, but the priapism did not abate.

32. On the morning of July 29, 2020, Complainant No. 3 arrived at the Clinic at 9:00 am and was administered a shot of phenylephrine in an attempt to relieve the priapism. The shot did not relieve the priapism. Complainant No. 3 asked the P.A. how long it would take for the priapism to resolve and was told by the P.A. that it depends. Complainant No. 3 was sent home by the P.A. who instructed him to drink a lot of water, take a sitz bath and take Sudafed.

33. On July 30, 2020, Complainant No. 3 returned to the Clinic with priapism. Complainant No. 3 testified the P.A. again administered a shot of phenylephrine that failed to relieve the priapism. Complainant No. 3 testified the P.A. again instructed Complainant No. 3 to take sitz baths and drink plenty of water. During his interview, the P.A. denied

that he administered the phenylephrine on July 30, 2020 and stated he was unaware of this visit occurring. Rather, the P.A. stated that Staff Member No. 1 administered the shot.

34. On Friday, July 31, 2020, Complainant No. 3 returned to the Clinic again with priapism. Complainant No. 3 was accompanied by his fiancee at this visit. The Complainant and his fiancée stated that the P.A. came into the room, had a conversation with Staff Member No. 1, and then left the room. Then, Staff Member No. 1 administered a phenylephrine shot into Complainant No. 3's penis. Again, there was no relief; however Complainant No. 3 experienced severe pain when the shot was administered. The P.A. then returned to the room and gave Complainant No. 3 and his fiancee instructions to purchase and administer Sudafed before they left the Clinic.

35. The priapism continued and on Saturday, August 1, 2020, Complainant No. 3 and his fiancee called the Clinic for advice on how much Sudafed to take. Staff Member No. 1 responded with dosage instructions and asked Complainant No. 3 to return to the Clinic so he could give him another phenylephrine shot before Staff Member No. 1 left for the day. Complainant No. 3 did not return to the Clinic that day.

36. On Sunday, August 2, 2020, Complainant No. 3 sought treatment at a local Health Care Facility for priapism. The Health Care Facility documented it was unable "to get priapism to resolve as expected due to the long duration of 5 days." A specialist informed Complainant No. 3 that he likely will require a penile prosthesis due to the development of fibrosis from prolonged priapism.

37. During the treatment of Complainant No. 3, no one from the Clinic including the P.A. contacted the Respondent. The Respondent stated the P.A. should have contacted

him since Complainant No. 3 was not responding to usual priapism treatment. The Respondent also stated that had he been contacted by the P.A. or Clinic staff, he would have referred Complainant No. 3 to the emergency department or a urologist. Both the Respondent and the P.A. admitted that the Respondent did not supervise the P.A. during his treatment of Complainant No. 3.

Clinic Site Inspection

38. On December 14, 2021, Board staff and a representative from the Maryland Office of Controlled Substances Administration ("OCSA") conducted an unannounced site visit at the Clinic. The purpose of the OSCA presence was to investigate whether any prescription drugs were being directly dispensed to or prescribed to patients of the Clinic.

39. During this site visit, the P.A. informed OCSA that the drugs involved in the ICI are compounded by an out-of-state pharmacy (the "Pharmacy"). The P.A. informed the OCSA that the Pharmacy shipped the drugs both directly to patients and also to the Clinic which then would dispense to patients onsite. The P.A. said prescriptions were not provided to patients by the Clinic. The P.A. admitted to the OSCA that neither he nor the Respondent had a dispensing permit issued by the Board to dispense prescriptions drugs directly to patients of the Clinic.

40. The OCSA also learned during the onsite inspection that the Clinic also directly dispensed testosterone injections, generic Levitra and generic Cialis to patients. Testosterone is a Schedule III controlled dangerous substance. Testosterone only for direct administration in the Clinic was ordered using the DEA number of the Respondent.

Testosterone ordered to be dispensed directly to patients was ordered under the DEA number of the P.A.

41. Based on its inspection, OCSA concluded that the "clinic practitioners are dispensing prescription drugs, including CDS medications, directly to patients without any of the practitioners possessing a dispensing permit issued by the Maryland Board of Physicians." This is in violation of "COMAR 13.01.04 B." The OCSA also concluded the "clinic provides an injection to patients with a dosage significantly higher than the highest recommended dosage in a commercially available product containing the same ingredient. This compounded product was involved with medical emergencies involving priapism for patients of the clinic."

Practice Review of the P.A.

42. As part of its investigation, the Board issued subpoenas to the Clinic for 16 patient records in total and supporting materials and ordered a practice review (referred to *infra* as "Patients 1 through 16"). The review was performed by a physician assistant delegated to work in urology.[5] The patients whose cases were reviewed were adult male patients to whom the P.A treated at the Clinic, including Complainant No. 1, Complainant No. 2 and Complainant No. 3. The P.A. provided a summary of care for the 16 patients. The reviewer concluded that in nine (9) of the cases reviewed, the P.A. failed to meet appropriate standards for the delivery of quality medical care. The reviewer also concluded that in eleven (11) of the cases reviewed, the P.A. failed to keep adequate medical records.

[5] The specific findings of the reviewer pertaining to the 16 patients reviewed are set forth completely in the Report which will be provided to the Respondent upon request.

43. Specifically, the reviewer found the P.A. failed to meet appropriate standards for the delivery of quality medical care and/or failed to keep adequate medical records in that the P.A.:

a) failed to treat priapism as a medical emergency (Patients 4, 5, and 11);

b) failed to change or alter ICI dosage after adverse events (Patients 6, 11, 13 and 16);

c) failed to order appropriate laboratory tests when prescribing testosterone (Patients 7, 11 and 16);

d) provided ICI before recommending oral/non-invasive interventions (Patient 3);

e) no evidence the P.A. had any interaction with patient (Patient 15);

f) failed to document physical examination findings, vital signs, laboratory results, prescriptions and/or antidote dosing for priapism (Patients 1, 3, 5, 6, 8, 9, 12, 13, 15); and

g) failed to document who saw patient as records not signed (Patient 4).

Grounds for Discipline

44. The Respondent's actions, as described above, constitute, in whole or in part, a violation of the following provisions of the Act under Health Occ. § 14-404(a): (3)(ii) Unprofessional conduct in the practice of medicine; (18) Practices medicine with an unauthorized person or aids an unauthorized person in the practice of medicine; and (28) Fails to comply with the provisions of § 12-102 of this article.

NOTICE OF POSSIBLE SANCTIONS

If, after a hearing, a disciplinary panel of the Board finds that there are grounds for action under Health Occ. § 14-404(a)(3)(ii), § 14-404(18) and/or § 14-404(28), the disciplinary panel may impose disciplinary sanctions in accordance with the Board's regulations under Md. Code Regs. 10.32.02.10, including reprimanding the Respondent, placing the Respondent on probation, or suspending or revoking the Respondent's license, and may place the Respondent on probation, and/or may impose a monetary penalty.

NOTICE OF DISCIPLINARY COMMITTEE FOR CASE RESOLUTION

The Respondent may appear before Disciplinary Panel B, serving as the Disciplinary Committee for Case Resolution ("DCCR") in this matter, on **WEDNESDAY, MARCH 22, 2023, 9:00 A.M.**, at the Board's offices, 4201 Patterson Avenue, Baltimore, Maryland 21215. The nature and purpose of the DCCR is described in the attached letter to the Respondent. If this matter is not resolved before the DCCR, a prehearing conference and hearing will be scheduled before an Administrative Law Judge at the Office of Administrative Hearings, 11101 Gilroy Road, Hunt Valley, Maryland 21031. The hearing will be conducted in accordance with the Administrative Procedure Act, Md. Code Ann., State Gov't §§ 10-201 *et seq.* (2021 Repl. Vol.).

BRIAN E. FROSH
ATTORNEY GENERAL

December 12, 2022

Gregory L. Lockwood

Date

Gregory L. Lockwood
Assistant Attorney General
Office of the Attorney General
Health Occ. Prosecution & Litigation
300 West Preston Street, Suite 201
Baltimore, Maryland 21201
410-767-1865
gregory.lockwood@maryland.gov