IN THE MATTER OF	*	**BEFORE THE**
ANNETTE ROYER	*	**MARYLAND STATE**
Respondent	*	**BOARD OF PHYSICIANS**
Unlicensed	*	**Case Number: 2221-0057 B**

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CHARGES UNDER THE MARYLAND MEDICAL PRACTICE ACT

Disciplinary Panel B of the Maryland State Board of Physicians (the "Board") hereby charges **ANNETTE ROYER** (the "Respondent"), an unlicensed individual, under the Maryland Medical Practice Act (the "Act"), Md. Code Ann., Health Occ. ("Health Occ.") §§ 14-101 *et seq.* (2014 Repl. Vol. & 2020 Supp.).

Specifically, Disciplinary Panel B charges the Respondent with violating the following provisions of the Act:

§ 14-101. Definitions.

(o) *Practice medicine*. – (1) "Practice medicine" means to engage, with or without compensation, in medical:

(i) Diagnosis;
(ii) Healing;
(iii) Treatment;
(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[.]

§ 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.

§ 14-602. Misrepresentation as a practitioner of medicine.

(a) *In general*. -- Unless authorized to practice medicine under this title, a person may not represent to the public, by description of services, methods, or procedures, or otherwise, that the person is authorized to practice medicine in this State.

ALLEGATIONS OF FACT[1]

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

Background

1. The Respondent never has been licensed to practice medicine in the State of Maryland. She never has been licensed or certified by any health occupations licensing board in Maryland. Since 2008, the Respondent has been a Certified Associate Alcohol and Drug Counselor through the Maryland Board of Professional Counselors and Therapists.

2. At all times relevant, the Respondent was the owner of an opioid treatment program (the "Program") on the Eastern Shore of Maryland. In part, the Program provides methadone and suboxone treatment to individuals addicted to and dependent on opioids.

[1] 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.

3. At all times relevant, the Respondent hired a physician who is licensed to practice medicine in the State of Maryland to be the Medical Director (the "Medical Director") of the Program.

4. The Medical Director is board-certified in Addiction Medicine, Public Health and General Preventive Medicine, and Occupational Medicine.

The Complaint

5. On or about October 28, 2020, the Board received a forwarded anonymous complaint from the Maryland Board of Professional Counselors and Therapists. The Complaint alleged the Respondent was practicing medicine in Maryland without a license in part by "medicating clients with methadone and suboxone...[she] does not have a nursing or medical license." At the time the Complaint was received, the Medical Director was the Medical Director of the Program. After reviewing this Complaint, the Board, on November 18, 2020, opened an investigation of the Respondent. Thereafter, on December 29, 2020, the Board opened an investigation of the Medical Director.

The Board Investigation

6. In furtherance of its investigation, Board staff interviewed the Medical Director, the Respondent, and the Director (the "Director") of the State Opioid Treatment Authority ("SOTA"). Board staff also subpoenaed and reviewed numerous documents including staff credentials, employee lists, and investigation results from the Maryland Department of Health.

Medical Director's Written Response

7. By email to the Board received on November 29, 2020, the Medical Director submitted a written response in support of the Respondent regarding allegations she was practicing medicine without a license.

8. In the email, the Medical Director stated he served "as the Medical Director for this clinic/program and have done so from the start of the clinic in 2020." The Medical Director stated that on September 14, 2020, one of the Program's nurses resigned which left the Program without a dispensing nurse. The Medical Director stated "patients report (generally), to the clinic 6 days/wk to obtain their daily dose of long terms opioid agonist medication."

9. The Medical Director stated on September 14, 2020, he advised the Respondent to contact the Director of SOTA. The Medical Director admitted his "intention was to have [the Respondent] dispense the medication, according to my previously specified, in the Electronic Health Record (EHR) medication." The Medical Director wrote "the EHR is connected to a dispensing pump, which upon hitting a key, dispenses a measure, pre-authorized level of medication." The Medical Director stated the medication then is given to the patient by a Licensed Practical Nurse ("LPN") or other designated medical provider. The Medical Director stated with "my approval and the SOTA's knowledge, [the Respondent] oversaw the dispensation of medication in 100% accordance with my previously issued and documented orders…that were documented in the EHR." The Medical Director stated "[p]lans were made to secure an LPN for Tuesday (the next

day), and it was known that the LPN would be there by 8:00-8:30AM." Normal dosing hours at the Program were 5:00AM – 10:00 AM.

10. The Medical Director stated that despite efforts to inform patients the dosing window would be changed due to a personnel issue, approximately 10 patients showed up early to the Program on September 15, 2020. The Medical Director stated he "again asked [the Respondent] to speak to the SOTA, and relate that it was my intention to have the EHR-dosed medication be issued, with [the Respondent] ensuring that the machine operated as per design – only for these very few patients." Later, an LPN arrived "at the designated time, and took care of the remaining patients." The Medical Director stated he was unable to come to the Program on September 14-15, 2020 to dispense medication because he lives three (3) hours away and could not arrive in time. The Medical Director admitted the Respondent is not "a health care provider or a licensed practical nurse or a Registered Medical Assistant."

Medical Director's Interview

11. On January 12, 2021, Board staff interviewed the Medical Director under oath. In the interview, the Medical Director stated in November, 2019, the Program hired him as its Medical Director. As he lived three (3) hours away from the Program, the Medical Director's contract did not require in-person services and only required that he provide telehealth services. The Medical Director testified he "could not go there and physically support them, that was never a feasible or plausible mechanism, or was it contractually required." As the Medical Director, the Medical Director stated that he was "responsible for overseeing the delivery of medical services under the OTP [Opioid

Treatment Program],” oversee a Physician Assistant, and be a resource for the nurses and counselors.

12. In his interview, the Medical Director confirmed “the electronic records that’s used there is Methasoft and Methasoft, remember, controls the pump which is the dispensation of the liquid medication which most of our patients are on Methadone, not Suboxone.”

13. The Medical Director stated that on September 14, 2020, the Respondent called and informed him that the dispensing nurse had resigned the night before and the Respondent was unable to arrange for a substitute. The Medical Director instructed the Respondent to call the Director of SOTA and report back to the Medical Director “after you talk to him.” The Respondent called the Medical Director back and asked “can you come over?” The Medical Director stated that he did not know the specific details of what the Director of SOTA told the Respondent but “what I took away was, you know, well, you know, talk to your medical director again. So the key thing for me was [the Director] didn’t say shut the clinic down.” The Medical Director stated the Respondent did not inform him one way or the other that the Director of SOTA told the Respondent she could dose the patients at the Program.

14. Thereafter, the Medical Director stated he “can’t come over,” and to “go ahead and dispense, you know, the medication that’s already in the order, call me if there’s a problem. And then call me after the clinic is over because we’ve got to make heroic efforts to locate a nurse to come in there, that’s the game plan.” The Medical Director admitted he was “the one that directed, given the circumstances and the information I had,

the direction to do this." The Medical Director stated he was not on the telephone the entire time the Respondent dosed patients. Rather, the Medical Director was available to take any telephone calls as needed.

15. The Medical Director stated "sometime later I have communication [with the Respondent] that, you know, okay, I got somebody in, but they're not going to come until 8:00 something, whatever, the next day. I said well let the patients know. Okay, I will."

16. The Medical Director stated that on September 15, 2020, the Respondent telephoned and informed him patients were at the Program to be dosed but the newly-hired dispensing nurse had not yet arrived. The Medical Director once again instructed the Respondent to contact the Director of SOTA. The Respondent thereafter called the Medical Director and "relayed back" that the Director of SOTA said "talk to the medical director." The Respondent also asked the Medical Director to come to the Program. The Medical Director stated he "didn't hear you say shut the clinic down….So then I said okay dose these people and, you know, that was it."

17. The Medical Director stated he did not review any of the records of the patients the Respondent dispensed Methadone to but believes she noted "at the direction of [the Medical Director]" in the EHR. The Medical Director stated "if she doesn't do that and somebody were to review it, it would appear that, you know, she's, without any connection to medical director, she's practicing medicine. That would be very perilous indeed."

18. On December 27, 2020, the Medical Director resigned his employment at the Program.

Respondent's Incident and Risk Identification Reports

19. In two contemporaneous written incident and risk identification reports submitted to SOTA, the Respondent stated on September 14, 2020, a LPN resigned his position, leaving the Program without a dispensing nurse for that morning. The Respondent contacted the Medical Director who directed her to notify SOTA. The Respondent stated she left a voice mail for the Director of SOTA.

20. The Respondent stated that the Director of SOTA called and stated the Program "needs to have a licensed nurse to dispense or the Medical Director." The Respondent informed the Director of SOTA the Medical Director was three (3) hours away from the Program. The Respondent recalled the Director of SOTA "continued to state the regulations of dispensing and under emergency condition[s] this time dosing will be allowed. [The Director] continued to request the Medical Director should be responsible for dosing to continue." The Respondent stated that the Director of SOTA told her: "[Respondent] under emergency condition, I approve for dosing." The Respondent wrote she informed the Medical Director of her conversation with the Director of SOTA.

21. The Respondent stated that when she arrived at the Program on September 15, 2020 at 5:00 a.m., the newly-hired dispensing nurse had not arrived. The Respondent then called the Medical Director and requested him to come dose the patients that morning. The Respondent stated she called the Director of SOTA about the dispensing nurse not being at the Program. The Respondent wrote the Director of SOTA stated "that dosing can not happen and have patients guest dose at another clinic in the area."

22. The Respondent wrote she then contacted the Medical Director about her conversation with the Director of SOTA. The Respondent wrote she informed the Medical Director she would continue to try and find a nurse to dose. The Respondent wrote the Medical Director told her "to stay in dispensing area with the nurse and assist her with step by step procedures but have her do the dosing." The Respondent wrote she "was able to find a nurse to come in at 9AM to start dosing." The Respondent stated all "patients that arrived before 9AM was [sic] informed to come back after 9."

Respondent's Interview

23. On February 25, 2021, Board staff conducted an under oath interview of the Respondent. In her interview, the Respondent stated the Program opened on January 24, 2020 and offers medication assisted treatment as well as counseling, group education, and an intensive outpatient program.

24. The Respondent stated that on September 14, 2020, she dosed all patients that came to the Program and said she was following directions from the Medical Director and the Director of SOTA. The Respondent stated that she called "[the Medical Director] immediately, as well, notified him and I notified [the Director of SOTA] at 5:15 a.m. that I had no nurse presenting. And then [the Director of SOTA] informed me that I needed to have a nurse or [the Medial Director] come in and do the dosing. And I notified [the Director of SOTA] that [the Medical Director] is three hours away, that he wouldn't be able to get there until roughly 9:00, depending on the traffic."

25. The Respondent stated: "[the Director of SOTA] gave me authority to dose under emergency conditions because of the nurse – the nurse not showing up and there

were patients already in the building at the time." After speaking with the Medical Director and Director of SOTA, the Respondent stated that she "set up the dosing area for dispensing according to [the Director of SOTA], he gave me authority under emergency conditions to dispense." The Respondent also testified she kept the Medical Director on speaker phone the whole time in case she had any issues. The Respondent stated she was able to access the EHR because as Respondent and CEO of the Program, she has administrative rights.

26. On September 15, 2020, the Respondent stated she again dosed patients after a newly-hired dispensing nurse did not show up for work. The Respondent testified she called the Medical Director who gave her the approval to dose. The Respondent stated the Medical Director told her, "because we're under emergency, we need to dose." The Respondent stated "I didn't do anything with [the Medical Director] being the medical director."

27. The Respondent also testified she called the Director of SOTA and left a voice mail. The Respondent testified the Director of SOTA called her back and informed her "he didn't have the authority to have me dose for a second day, that we needed to guest dose the patients" at another opioid treatment program. The Respondent stated she stopped dosing at that point and that another LPN arrived by 9:00 a.m. to dose the remaining patients. The Respondent also informed the Medical Director of her call with the Director of SOTA and that the Director "said we can't do the dosing. I need to get a nurse or [the Medical Director] in there, immediately." The Respondent was unable to respond as to why she did not disclose she dosed patients on September 15, 2020 in her written incident and

risk identification report. The Respondent also said she did not recall the Director of SOTA informing her that what she was doing was illegal.

Director of SOTA's Interview

28. On March 24, 2021, Board staff conducted an under oath interview of the Director of SOTA. In his role as Director of Quality Assurance, the Director stated he works with the Drug Enforcement Administration to enforce regulations that govern treatment for methadone patients in Maryland. This includes conducting compliance reviews and investigating complaints. The Director stated that at a Maryland opioid treatment program like the Program, the "people that are authorized to dispense medication are licensed nurses or physicians or nurse practitioners or physician assistants."

29. The Director stated that on September 14, 2020, he received a telephonic complaint from another opioid treatment program stating it heard the Respondent was dispensing Methadone to patients. When the Director called the Respondent, he said "I received information that you are dosing patients. She said, well, yes, my nurses didn't show up." The Director informed the Respondent "what she was doing was illegal, that she could not dose patients. She was in the middle of it, you know… I told her I could not give her authorization [to dose patients] because I don't have that authority to authorize a non-licensed medical person to dispense medications to a patient. You know, that puts people's life and safety at risk."

30. The Director further recalled that on September 14, 2020, he told the Respondent to "make sure she has appropriate medical staff onsite, that she should contact her medical director and have him come in, that she couldn't do that, and she would need

to guest dose her patients to other OTPs." The Director denied giving the Respondent permission to dose, stating, "I would never tell someone that, you know. What I will tell you is that what you're doing is illegal and you do not have the authority to do that."

31. The Director further testified he learned the Respondent again dosed patients on September 15, 2020. The Director informed the Respondent "clearly that I told them what they're doing is illegal, that she can't do that, she needed to stop, that he needed to be there, and pretty much that's what I told them." The Director stated: "In my professional opinion I don't think it's any non-medical person's decision to dose patients. I think because of the severity of, or when you're dispensing that type of medication to someone you can cause death and harm. If they get an incorrect dose, they were supposed to get 30 milligrams and they wind up getting 100 milligrams the patient could die."

32. The Director stated the Respondent made up the fact that he gave her permission to dose, stating "I guess it would be a cover for herself."

Grounds for Discipline

33. 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. § 14-601 by practicing, attempting to practice, or offering to practice medicine in Maryland without a license; and Health Occ. § 14-602 by representing to the public, by description of services, methods, or procedures, or otherwise that Respondent is authorized to practice medicine in Maryland.

NOTICE OF POSSIBLE SANCTIONS

If, after a hearing, a disciplinary panel of the Board finds that there are grounds for action under Health Occ. § 14-601 and/or 14-602, the disciplinary panel may impose a civil fine of no more than $50,000 to be levied by the Board.

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, October 20 , 2021, 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.* (2014 Repl. Vol.).

BRIAN E. FROSH
ATTORNEY GENERAL

July 27, 2021 — *Gregory L. Lockwood*

Date

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