STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF OSTEOPATHIC MEDICINE AND SURGERY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

KERI B. TOPOUZIAN, D.O.
License No. 51-01-008226,

File No. 51-20-000314

Respondent.

CONSENT ORDER AND STIPULATION

CONSENT ORDER

On April 4, 2022, the Department of Licensing and Regulatory Affairs executed a First Superseding Administrative Complaint charging Respondent with violating the Public Health Code, MCL 333.1101 *et seq*.

Respondent neither admits nor denies the facts alleged in the First Superseding Complaint but agrees that the Board of Osteopathic Medicine and Surgery Disciplinary Subcommittee may treat them as true and find they constitute violations of MCL 333.16221(a).

The Board of Osteopathic Medicine's Disciplinary Subcommittee (DSC) has reviewed this Consent Order and Stipulation and agrees that the public interest is best served by resolution of the outstanding First Superseding Complaint.

Therefore, IT IS FOUND that the facts alleged in the Complaint are true and constitute violations of MCL 333.16221(a).

Accordingly, IT IS ORDERED that for the cited violations of the Public Health Code, Respondent is placed on PROBATION for a period of one year, commencing on the effective date of this Order. The terms of probation shall be as follows:

1. UNANNOUNCED INSPECTIONS: Respondent's IV infusion practice will be subject to four unannounced inspections by the Department's Pharmacy Specialist during the period of probation. The Pharmacy Specialist's inspections shall include, but may not be limited to, the following topics:

    a. Comparing the amount of IV medication compounded for a patient to documentation of the amount administered and billed to that patient

    b. Inspecting the premises for sanitary conditions

    c. Reviewing policies and procedures regarding staff supervision, cleaning, and disposal of medical waste and ensuring that staff are aware of and complying with those policies

2. COMPLIANCE WITH THE PUBLIC HEALTH CODE: Respondent shall comply with all applicable provisions of the Public Health Code and rules promulgated thereunder.

IT IS FURTHER ORDERED that Respondent shall be responsible for all costs and expenses incurred in complying with the terms and conditions of this consent order.

IT IS FURTHER ORDERED that if Respondent violates any term or condition set forth in this Order, Respondent will be in violation of Mich Admin Code, R

338.1632 and MCL 333.16221(h).

Respondent shall be automatically discharged from probation upon receipt by the Department of satisfactory evidence of the successful completion of the probationary terms as set forth above, PROVIDED compliance occurs within one (1) year, Respondent has paid the fine as set forth below, has complied with the terms of this Order and has not violated the Public Health Code.

IT IS FURTHER ORDERED that Respondent is FINED two-thousand five-hundred dollars ($2,500.00), to be paid to the State of Michigan within 90 days of the effective date of this Order. Respondent shall direct payment to the Department of Licensing and Regulatory Affairs, Enforcement Division, Compliance Section, P.O. Box 30189, Lansing, MI 48909. The fine shall be paid by check or money order, made payable to the State of Michigan, and shall clearly display **File Number 51-20-000314**.

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the DSC, as set forth below.

MICHIGAN BOARD OF Osteopathic Medicine and Surgery

By: _____ for
Chairperson, Disciplinary Subcommittee

Dated: June 2, 2022

STIPULATION

1. Respondent neither admits nor denies the facts alleged in the First Superseding Administrative Complaint but agrees that the Disciplinary Subcommittee may find that the allegations are true for the purposes of resolving this matter and that the allegations constitute a violation of MCL 333.16221(a).

2. Respondent understands and intends that by signing this Stipulation, Respondent is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act, MCL 24.201 *et seq*, to require the Department to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent is waving the right to appear with an attorney and such witnesses as Respondent may desire to present a defense to the charges.

3. This matter is a public record required to be published and made available to the public pursuant to the Michigan Freedom of Information Act, MCL 15.231 *et seq*; and this action will be reported to the National Practitioner Data Bank, and any other entity as required by state or federal law.

4. Respondent approves the form and substance of this Order to be entered as the final order of the DSC in this matter.

5. The DSC may enter the above Order, supported by Board conferee Stephen Bell, D.O. Dr. Bell or a Department representative may discuss this matter with the DSC in order to recommend acceptance of this resolution.

6. After a compliance conference, Dr. Bell and the parties considered the following factors in reaching this agreement:

a) Respondent provided an expert letter indicating that the standard of care in Michigan for IV infusion: (a) does not require the physician to be present for the check of the solution, the start of the IV, and the administration of the IV solution, (b) for a vitamin does not require a nurse or physician to perform the infusion, and (c) can be performed by an unlicensed medical assistant as long as it is done under the delegation and supervision requirements set forth in the PHC;

b) Respondent engaged in a very transparent discussion of the events and circumstances regarding the subject allegations with the LARA representative and described steps he has put in place to avoid any similar issues from arising in the future;

c) Respondent undertook 34 hours of continuing medical education in the areas of medical record keeping and medical error prevention;

d) Respondent provided numerous letters of support from physicians and other health care professionals attesting to his reputation as a skilled professional of high moral character;

e) Respondent provided revised documentation templates to help improve his medical record keeping and examples showing improved documentation;

f) Respondent provided proof of increased cleaning of the IV suite by an outside company;

g) Respondent provided numerous IV suite surveys from patients attesting to the cleanliness of the IV suite and professionalism of the medical assistant;

h) Respondent purchased new furniture for the IV suite that can be more easily cleaned.

i) Respondent implemented a policy to no longer use a port-a-cath for IV access.

7. This proposal is conditioned upon acceptance by the DSC. Respondent and the Department expressly reserve the right to further proceedings without prejudice should the Order be rejected.

AGREED TO BY:

signing for

Forrest Pasanski, Director
Enforcement Division
Bureau of Professional Licensing
Department of Licensing and
Regulatory Affairs

Dated: 4/4/22

AGREED TO BY:

Keri B. Topouzian, D.O.
Respondent

Dated: 4/1/22

Robert Iwrey (P48688)
Attorney for Respondent

Dated: 4/4/22

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF OSTEOPATHIC MEDICINE AND SURGERY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

KERI B. TOPOUZIAN, D.O.
License No. 51-01-008226, File No. 51-20-000314

Respondent.

FIRST SUPERSEDING ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs, by Forrest Pasanski, Director, Enforcement Division, Bureau of Professional Licensing, complains against Respondent Keri B. Topouzian, D.O., as follows:

1. The Michigan Board of Osteopathic Medicine and Surgery is an administrative agency established by the Public Health Code, MCL 333.1101 *et seq*. Pursuant to MCL 333.16226, the Board's Disciplinary Subcommittee (DSC) is empowered to discipline licensees for Code violations.

2. Respondent holds a license to practice osteopathic medicine and surgery in the state of Michigan. Respondent also holds a controlled substance license and a drug control location license.

3. At all relevant times, Respondent practiced at multiple locations throughout Michigan.

4. Alpha Lipoic Acid is a non-controlled medication used to treat nerve related symptoms of diabetes. It can be administered orally or intravenously (IV).

5. Ozone Therapy is an alternative medicine practice that uses ozone gas to fight disease.

PATIENT NH[1]

6. Respondent treated NH from April 2019 to November 2019. Respondent's assistant LG administered Alpha Lipoic Acid treatments to NH approximately two times per week and at least one ozone treatment and approximately seven vitamin C IV infusions.

7. After her initial visit with Respondent, all of NH's medical visits were with Respondent's assistant LG

8. NH received her treatments in the IV room, which was located within the same building as one of Respondent's practice locations. According to NH, the IV room was in an unsanitary state with trash and medical waste on the floor.

9. NH observed that LG would:

a. not always use protective equipment such as gloves when performing treatments.

b. put medical waste, such as bloody gauze, in a paper bag on the floor, instead of using a medical waste container.

c. not clean equipment after use on a patient.

10. NH was administered and paid for multiple infusions of IV Alpha Lipoic Acid, yet NH's pharmacist told her that there was only one recorded order for Alpha Lipoic Acid for NH.

11. NH questioned LG about the pharmacy only having one order for Alpha Lipoic Acid under NH's name. LG stated that sometimes he would use Alpha Lipoic Acid obtained for another patient for NH's infusions.

[1] Initials used for privacy.

12. NH requested her medical record multiple times from Respondent, but Respondent failed to provide the records to NH.

13. A Department investigator interviewed the pharmacist-in-charge (PIC) at the pharmacy Respondent used to obtain Alpha Lipoic Acid and other treatment supplies.

14. The PIC explained that Respondent is their largest prescriber of Alpha Lipoic Acid.

15. The PIC explained that Alpha Lipoic Acid comes in a multi-dose vial but can only be used for three days after it is opened.

16. The PIC stated that when the pharmacy dispenses medication, it expects that the medication will be used for the patient to whom it was prescribed, so that drug utilization reviews and allergy checking can be performed prior to dispensing. There is a caution label on the vials that states federal law prohibits transfer of this drug to any person other than the patient for whom it is prescribed.

PATIENT RB

17. A Department investigator interviewed DB, a family member of patient RB. DB stated the following:

a. On or about November 14, 2019, patient RB received a vitamin infusion from Respondent's employee LG. LG used a port that RB had from a previous medical procedure to administer the treatment.

b. On or about November 24, 2019, RB went to the emergency room with severe pain. Doctors discovered RB had an infection and that the infection came from

the port. The port had not been used since the vitamin infusion ten days earlier.

c. Due to the infection, RB became septic and had to have several medical procedures.

18. While hospitalized, RB tested positive for staphylococcus bacteremia. The port was also tested, and it was positive for staphylococcus bacteremia. No other sources of infection were found.

19. An infection disease specialist at the hospital confirmed that RB's infection came from the port, and the port was likely infected at the time of the last infusion on November 14, 2019. These infections take about 10-14 days to develop, and the infusion was ten days prior.

WITNESS BM

20. Respondent hired a company to provide biofeedback to patients[2]. BM was the biofeedback machine operator that provided biofeedback data to Respondent's patients. BM worked in the same IV room as LG

21. BM had complained to Respondent about LG's unsafe and unsanitary conditions in the IV room where she and LG worked. Some of the unsafe are unsanitary conditions BM identified were:

a. LG did not clean up and sanitize equipment after each patient.

b. LG threw used IV needles in the regular garbage receptacle instead of using a sharps container.

c. LG would sometimes fail to sanitize patients' arms before starting an IV for an infusion.

[2] Biofeedback is a non-drug treatment in which patients learn to control bodily processes that are normally involuntary.

d. LG did not always wear protective gloves while starting an IV for an infusion or during administration of the treatment.

22. BM witnessed LG give patients vitamin infusions and ozone therapy. BM observed that Respondent never directly supervised LG and on Thursdays and Fridays, Respondent was not in the office while LG performed these procedures.

INTERVIEW WITH RESPONDENT

23. Respondent met with a Department investigator. Respondent made the following statements:

a. Respondent provided IV treatments of supplements and vitamins for patients.
b. LG was hired as a medical assistant
c. Respondent had a delegation agreement with LG that authorized LG to perform port access and IV-line procedures on his own even if Respondent was not in the building.
d. Other than Respondent, LG was the only one who performed procedures in the IV room, and LG is responsible for keeping the IV room clean.
e. Respondent learned that RB was in the hospital by speaking with JR. Respondent learned that RB likely was infected during the November 14, 2019 infusion. Respondent stated that he should have contacted RB after she left the hospital, but he did not.

EXPERT REVIEW

24. An expert was retained to review the medical records and investigative file and provide an expert opinion as to Respondent's practice and treatment of patients NH and RB.

25. The expert found:

a. Respondent failed to keep adequate medical records. There was no documented medical history or physical examination of the patients.

b. The records indicated that NH had multiple visits for Alpha Lipoic Acid treatment, but there was only one order for Alpha Lipoic Acid in the record. Although it was a multi-dose vial, it could not have been used for the number of treatments NH received.

c. The standard of care for an IV infusion would be for the physician to be present for the check of the solution, the start of the IV, and administration of the IV solution. Respondent failed to supervise LG during the procedures. LG, a medical assistant, was not qualified to start or administer an IV or to infuse an IV solution.

d. The administration of a vitamin infusion should be done with someone who is trained such as a L.P.N., R.N. or a physician. LG was not a nurse or physician.

e. The IV room was unsanitary.

COUNT I

Respondent's conduct constitutes a violation of a general duty, consisting of negligence or failure to exercise due care, including negligent delegation to or supervision of employees or other individuals, or a condition, conduct, or practice that impairs, or may impair, the ability safely and skillfully to engage in the practice of the health profession in violation of MCL 333.16221(a).

RESPONDENT IS NOTIFIED that, pursuant to MCL 333.16231(8), Respondent has 30 days from the date of receipt of this Complaint to submit a written response to the allegations contained in it. Pursuant to section 16192(2) of the Code, Respondent is deemed to be in receipt of the complaint three (3) days after the date of mailing listed in the attached proof of service. The written response shall be submitted by email to the Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing to BPL-DMS@michigan.gov. If unable to submit a response by email, Respondent may submit by regular mail to the Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing, P.O. Box 30670, Lansing, MI 48909.

Respondent's failure to submit an answer within 30 days is an admission of all Complaint allegations. If Respondent fails to answer, the Department shall transmit this complaint directly to the Board's Disciplinary Subcommittee to impose a sanction pursuant to MCL 333.16231(9).

The Administrative Complaint executed November 27, 2020 in this matter is hereby withdrawn and replaced by this First Superseding Complaint.

MICHIGAN DEPARTMENT OF
LICENSING AND REGULATORY AFFAIRS

Dated: 4/4/22

signing for

By: Forrest Pasanski, Director
Enforcement Division
Bureau of Professional Licensing

Pc/jp