HEARING CONDUCTED BY THE
TEXAS STATE OFFICE OF ADMINISTRATIVE HEARINGS
SOAH DOCKET NO. 503-18.0892.MD
TEXAS MEDICAL LICENSE NO. G-0049

IN THE MATTER OF THE	
	BEFORE THE
COMPLAINT AGAINST	
PATRICIA SALVATO, M.D.	TEXAS MEDICAL BOARD

COMPLAINT

TO THE HONORABLE TEXAS MEDICAL BOARD AND THE HONORABLE ADMINISTRATIVE LAW JUDGE:

COMES NOW, the Staff of the Texas Medical Board ("Board Staff"), and files this Complaint against Patricia Salvato, M.D. ("Respondent"), based on Respondent's alleged violations of the Medical Practice Act (the "Act"), Tex. Occ. Code, Title 3, Subtitle B (West 2016) and Tex. Admin. Code, Title 22, Part 9 ("Board Rules"), and would show the following:

I. SUMMARY OF FACTUAL ALLEGATIONS

It is alleged that that Respondent failed to meet the standard of care for one patient seeking treatment for neuralgia and fatigue symptoms. Specifically, it is alleged that Respondent prescribed a medication to the patient without adequate medical justification and that Respondent failed to maintain an adequate medical record. It is also alleged that Respondent ordered unnecessary, duplicative lab testing which had recently been performed.

II. LEGAL AUTHORITY AND JURISDICTION

1. Respondent is a Texas Physician and holds Texas Medical License No. G-0049, originally issued by the Board on August 23, 1981. Respondent's license was in full force and effect at all times material and relevant to this Complaint.

2. Respondent received appropriate notice of an Informal Settlement Conference (ISC). The Board complied with all procedural rules, including but not limited to, Board Rules 182 and 187, as applicable.

3. No agreement to settle this matter has been reached by the parties.

4. All jurisdictional requirements have been satisfied.

5. The filing of this Complaint and the relief requested are necessary to protect the health and public interest of the citizens of the State of Texas, as provided in Section 151.003 of the Act.

III. APPLICABLE STATUTES AND STATUTORY VIOLATIONS

The following Statutes, Rules, and Agency Policy are applicable to the procedures for conduct of the hearing this matter:

A. General Statutes and Rules:

1. Section 164.007(a) of the Act requires that the Board adopt procedures governing formal disposition of a contested case before the State Office of Administrative Hearings.

2. Chapter 187 of the Board Rules sets forth the procedures adopted by the Board under the requirement of Section 164.007(a) of the Act.

3. Chapter 190 of the Board Rules sets forth aggravating factors that warrant more severe or restrictive action by the Board.

4. 1 Tex. Admin. Code, Chapter 155 sets forth the rules of procedure adopted by SOAH for contested case proceeding.

5. 1 Tex. Admin. Code § 155.507, requires the issuance of a Proposal for Decision (PFD) containing Findings of Fact and Conclusions of Law.

6. Section 164.007(a) of the Act, Board Rule 187 et. seq. and Board Rule 190 et. seq., provide the Board with the sole and exclusive authority to determine the charges on the merits, to impose sanctions for violation of the Act or a Board Rule, and to issue a Final Order.

B. Specific Violations Cited:

1. Section 164.051(a)(1) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's commission of an act prohibited under Section 164.052 of the Act.

2. Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of a Board rule, specifically Board Rule 165.1, which requires the maintenance of adequate medical records.

3. Section 164.051(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's failure to practice medicine in an acceptable professional manner consistent with public health and welfare, as further defined by Board Rules 190.8(1)(A), failure to treat a patient according to the generally accepted standard of care; 190.8(1)(B), negligence in performing medical services; 190.8(1)(C), failure to use proper diligence in one's professional practice; 190.8(1)(D), failure to safeguard against potential complications; and 190.8(1)(H), failure to disclose reasonable alternative treatments to a proposed procedure or treatment.

4. Section 164.052(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent based on unprofessional or dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient.

IV. FACTUAL ALLEGATIONS

Based on information and belief, Board Staff alleges the following:

1. On July 18, 2016, Patient 1 visited her gynecologist and reported she had developed fatigue and diffuse body pains after a vacation to Montana two months earlier.[1] The physician ordered blood work, including a test for the Epstein Barr virus. On July 22, 2016, the test results came back indicative of an infection with Epstein Barr virus in the past, which ruled out a current infection of the virus. The physician prescribed doxycycline, an antibiotic, to treat Patient 1 for potential exposure to Lyme disease. Patient 1 was then referred to an infectious diseases physician for further evaluation.
2. On August 12, 2016, Patient 1 visited a physician who is board certified in in internal medicine and infectious diseases. Patient 1 continued to have complaints of fatigue and pain. The physician ordered additional blood work, including testing for blood parasites, Rocky Mountain spotted fever, and Lyme disease (Western blot, serum; Lyme Ag IgM by WB). On August 16, 2017, the blood work results were negative for each test.
3. Patient 1 continued to experience musculoskeletal pain and fatigue which Patient 1 believed could be related be related to chronic Lyme disease, which in medical literature is known as "post-treatment Lyme disease syndrome." According to the Centers of Disease Prevention and Control (CDC), it is not uncommon for patients to have continued symptoms of pain and fatigue for a number of years after having been treated for Lyme disease.
4. Patient 1 then sought out Respondent for a second opinion as to whether she had been infected with Lyme disease.
5. Respondent initially treated Patient 1 on October 6, 2016. Respondent noted that Patient 1's chief complaint was neuralgia of the left extremity and face. Respondent noted that the pain began in 2011. Respondent reviewed Patient 1's previous lab results from July and August and then provided Patient 1 with a prescription for cefuroxime (Ceftin), an antibiotic. Respondent also ordered repeat testing for blood parasites, Rocky Mountain spotted fever, and Lyme disease (Western blot, serum; Lyme Ag IgM by WB).
6. Respondent's medical records for this appointment were inadequate for the following reasons: 1) failure to document a diagnosis before prescribing Ceftin; 2) failure to document

[1] Patient 1 will be identified in the Patient Identification List, which will be filed confidential and under seal.

a written plan for care to include treatments and medications (prescriptions and samples) and specifying amount, frequency, number of refills, and dosage; 3) failure to obtain written consent to treatment; 4) failure to document that Patient 1 was provided patient education for the Ceftin.

7. Respondent's failure to create and maintain an adequate medical record is a violation of the Act and Board Rules, specifically:

> Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of a Board rule, specifically Board Rule 165.1, which requires the maintenance of adequate medical records.

8. Respondent failure to arrive at a diagnosis before prescribing Ceftin was also a violation of the standard of care. In addition, Respondent failed to disclose reasonable alternative treatments with Patient 1 at the initial visit. Respondent's failure to diagnose and failure to disclose alternative treatments constitute violations of the Act and Board Rules, specifically:

> Section 164.051(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's failure to practice medicine in an acceptable professional manner consistent with public health and welfare, as further defined by Board Rules 190.8(1)(A), failure to treat a patient according to the generally accepted standard of care; 190.8(1)(B), negligence in performing medical services; 190.8(1)(C), failure to use proper diligence in one's professional practice; 190.8(1)(D), failure to safeguard against potential complications; and 190.8(1)(H), failure to disclose reasonable alternative treatments to a proposed procedure or treatment.

9. Respondent's order for the same lab testing as had been performed only two months prior was unnecessary. The lab results in question were not likely to change in a significant manner in that span of time. It is a violation of the Act and Board Rules to order unnecessary medical testing, specifically:

> Section 164.052(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent based on unprofessional or dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient.

10. Patient 1 reports that she did not take the Ceftin because she was concerned Respondent had prescribed it to her without having the results of the new blood work first and without a definitive diagnosis of Lyme disease.

11. On October 28, 2016, Patient 1 had a follow-up visit with Respondent. Respondent noted that Patient 1's chief complaint was "diffuse pain." Respondent reviewed lab results of the blood work taken on October 6, 2016, which was negative for Rocky Mountain spotted fever, blood parasites, and Lyme.
12. It was Respondent's medical opinion that Patient 1's symptoms could be caused by "chronic Lyme disease" despite the negative test results because of Patient 1's history of tick bites as a child, symptoms, and other testing results which Respondent states is linked to symptoms of post-treatment Lyme disease syndrome (elevated transforming growth factor-beta 1, TGF-β1; and low CD57-NK).
13. Respondent states that she informed Patient 1 that there is "considerable uncertainty" regarding the diagnosis and treatment of Lyme disease.
14. Respondent provided reasonable treatment options to Patient 1 and documented a discussion of the two standards of care for the treatment of chronic Lyme disease. Specifically, Respondent documented that she discussed the risks of antibiotic treatment versus holistic treatment.
15. Respondent's treatment plan was to start Tindamax, an antibiotic, for two weeks and then follow up with Ceftin, which had been prescribed at the initial visit. Respondent did not document why the prescription for Ceftin had been prescribed at the initial visit when it was intended to be used after the Tindamax provided at the follow-up visit.
16. The standard of care required that Respondent document both antibiotic prescriptions in the chart. The medication list only contains the prescription for Tindamax at this visit. In addition, Respondent was negligent and/or failed to act with due diligence by failing to ask Patient 1 about whether the Ceftin prescription was filled and what effect the Ceftin had on Patient 1's symptoms. Respondent's actions constitute violations of the Act and Board Rules, specifically:

> Section 164.051(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's failure to practice medicine in an acceptable professional manner consistent with public health and welfare, as further defined by Board Rules 190.8(1)(A), failure to treat a patient according to the generally accepted standard of care; 190.8(1)(B), negligence in performing medical services; 190.8(1)(C), failure to use proper diligence in one's professional practice; and 190.8(1)(D), failure to safeguard against potential complications.

17. Before leaving Respondent's medical office on October 28, 2016, Patient 1 requested a copy of her lab results.
18. After the passage of about 10 minutes, Respondent's office staff stated that Respondent had reviewed incorrect lab results due to a sample labeling error committed by the lab. The office staff then provided Patient 1 with a set of lab results which were different from those reviewed by Respondent.
19. Patient 1 states that she asked whether Respondent wanted to go over the correct lab results with her and whether she should take the antibiotics. Patient 1 reports that the office staff told her that Respondent did not need to go over the correct results with her and that she should take the antibiotics. A follow-up appointment was not made.
20. Patient 1 reports that she understood that she was to take the Tindamax for two weeks and then take the Ceftin for four to six weeks.
21. Patient 1 reports that she chose not to take the Tindamax and Ceftin based on her concerns about Respondent's choice to prescribe the Ceftin before the Tindamax and Respondent's failure to go over the other set of lab results with her. Patient 1 reports that she decided to treat her symptoms with self-care (diet, exercise, etc.) and that her symptoms improved over time.
22. Respondent denies that her office staff instructed Patient 1 to take the antibiotic after having discovered a lab error. Respondent states that her nurse practitioner instructed Patient 1 to hold off on the antibiotics. However, Respondent did not document that Patient 1 was informed on October 28, 2016, that she was to hold off on the antibiotics. A phone note from the nurse practitioner states only that a message was left to request that Patient 1 return for repeat testing due to a "possible lab error."
23. The next phone messages are dated November 7-8, 2016, and state that messages were left with Patient 1 informing her that the lab was "sorting through the results" and that Patient 1 should hold off on the antibiotics.
24. Respondent mailed a certified letter informing Patient 1 of the lab error and that Patient 1 should hold off on taking the antibiotics because "it is not an emergency to treat Lyme disease immediately." Although the letter is dated October 31, 2016, records from the United States Postal Service reflect that the certified letter was mailed on November 7, 2016, which

is three days after the Board mailed a letter to Respondent which notified her of Patient 1's complaint.

25. Although it is possible that Respondent's nurse practitioner verbally informed Patient 1 on October 28, 2017, not to take the antibiotics prescribed by Respondent, the medical documentation is inadequate to establish that Patient 1 was informed of this. In addition, the medical records themselves do not contain an order for repeat testing.

26. After the discovery of the lab error, Respondent's records should have contained specific instructions for Patient 1's follow-up care, including contemporaneous documentation that Patient 1 was instructed to hold off on the antibiotics and that repeat testing was required. The records also should have reflected which set of lab results were provided to Patient 1 after the appointment. The failure to include new instructions to Patient 1 and to identify which lab results were provided constitutes a violation of the Act and Board Rules, specifically:

> Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of a Board rule, specifically Board Rule 165.1, which requires the maintenance of adequate medical records.

27. The records should also have contained contemporaneous documentation explaining how the lab results differed and what the labeling error was. Specifically, Respondent's certified letter dated October 31, 2016, states that the lab results reviewed during the appointment reflected Patient 1's CD-57 was 14, which Respondent stated is consistent with Lyme disease and that the lab results discovered after the appointment reflected Patient 1's CD-57 as 157. This error was not identified in the medical record for the October 28, 2016, nor was the clinical significance documented.

28. The failure to contemporaneously document a lab error and the clinical significance of that error constitutes a violation of the Act and Board Rules, specifically:

> Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of a Board rule, specifically Board Rule 165.1, which requires the maintenance of adequate medical records.

V. AGGRAVATING AND MITIGATING FACTORS

Board Rule 190.14 provides that the Board may impose more restrictive sanctions when there are multiple violations of the Act. Board Rule 190.15 provides that the Board may consider aggravating factors in reaching a determination of sanctions. In this case, the facts warrant more severe or restrictive disciplinary action. This case includes the following aggravating factors: increased potential for harm to the public; economic harm to any individual or entity and the severity of such harm; grossly negligent act constituting a violation; other prior similar violations, and other relevant circumstances increasing the seriousness of the misconduct.

Respondent has previously received a non-disciplinary Remedial Plan from the Board, to wit: On June 10, 2016, the Board approved a Remedial Plan which required Respondent to take 16 hours of continuing medical education, divided equally between the topics of risk management and medical recordkeeping. The Remedial Plan was based on a finding that Respondent failed to adequately document physical examinations for several patients.

Board staff is aware of no mitigating factors that apply and demand that Respondent submit proof to substantiate any alleged mitigating factors.

VI. NOTICE TO RESPONDENT

IF YOU DO NOT FILE A WRITTEN ANSWER TO THIS COMPLAINT WITH THE STATE OFFICE OF ADMINISTRATIVE HEARINGS WITHIN 20 DAYS AFTER THE DATE OF RECEIPT, A DEFAULT ORDER MAY BE ENTERED AGAINST YOU, WHICH MAY INCLUDE THE DENIAL OF LICENSURE OR ANY OR ALL OF THE REQUESTED SANCTIONS, INCLUDING THE REVOCATION OF YOUR LICENSE. A COPY OF ANY ANSWER YOU FILE WITH THE STATE OFFICE OF ADMINISTRATIVE HEARINGS SHALL ALSO BE PROVIDED TO THE HEARINGS COORDINATOR OF THE TEXAS MEDICAL BOARD.

VII. PRAYER

WHEREFORE, PREMISES CONSIDERED, Board Staff requests that an administrative law judge employed by the State Office of Administrative Hearings conduct a contested case hearing on the merits of the Complaint, and issue a Proposal for Decision (PFD) containing Findings of Fact and Conclusions of Law necessary to support a determination that Respondent violated the Act as set forth in this Complaint.

Respectfully submitted,

TEXAS MEDICAL BOARD

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THE STATE OF TEXAS §
§
COUNTY OF TRAVIS §

SUBSCRIBED AND SWORN to before me by the said Ann Skowronski, J.D., on November 7, 2017.

Sonja Aurelius
Notary Public, State of Texas

SONJA AURELIUS
Notary Public
STATE OF TEXAS
Commission Exp. FEB. 25, 2018
Notary without Bond

Filed with the Texas Medical Board on Nov 6th, 2017.

Scott M Freshour

Scott Freshour, J.D.
Interim Executive Director
Texas Medical Board

CERTIFICATE OF SERVICE

On this 7th day of November 2017, I certify that a true and correct copy of this First Amended Complaint has been served on the following individuals at the locations and the manner indicated below.

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Ann Skowronski, J.D.