

**STATE OF FLORIDA
DEPARTMENT OF HEALTH**

DEPARTMENT OF HEALTH,

PETITIONER,

v.

CASE NO. 2017-21484

SHERYL MARIE HAKALA, M.D.,

RESPONDENT.

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ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint ("Complaint") before the Board of Medicine ("Board") against Respondent, Sheryl Marie Hakala, M.D., and alleges:

1. Petitioner is the state agency charged with regulating the practice of medicine pursuant to section 20.43, Florida Statutes; Chapter 456, Florida Statutes and Chapter 458, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed physician within the State of Florida, having been issued license number ME 88217.

3. Respondent's address of record is 701 S. Howard Avenue, 06-301, Tampa, FL 33606.

4. On or about February 6, 2011, Patient C.S. presented to Respondent with complaints of opiate withdrawal, anxiety, depression, and sleep disturbances.

5. From on or about February 6, 2011 through August 4, 2018 (hereinafter "the treatment period"), Respondent treated Patient C.S. for numerous complaints.

6. During the treatment period, Respondent prescribed Suboxone¹, Subutex², Adderall³, Xanax⁴, Valium⁵, Ambien⁶, and Tramadol⁷ to Patient C.S. in various quantities and doses.

¹ Suboxone contains buprenorphine and is prescribed to treat pain. According to Section 893.03(5), Florida Statutes, buprenorphine is a Schedule V controlled substance that has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States, and abuse of buprenorphine may lead to limited physical or psychological dependence relative to the substances in Schedule IV. Suboxone also contains naloxone (Narcan) an opioid antagonist that minimizes the CNS effects of opioid drugs – often used to manage chronic pain in an opioid/opiate dependent person or to wean an opioid/opiate dependent person)

² Subutex is the brand name for buprenorphine.

³ Adderall is the brand name for a drug that contains amphetamine, commonly prescribed to treat attention deficit disorder. According to Section 893.03(2), Florida Statutes, amphetamine is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States, and abuse of amphetamine may lead to severe psychological or physical dependence.

⁴ Xanax is the brand name for alprazolam. Alprazolam is prescribed to treat anxiety. According to Section 893.03(4), Florida Statutes, alprazolam is a Schedule IV controlled substance that has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III.

⁵ Diazepam, commonly known by the brand name Valium, is prescribed to treat anxiety. According to Section 893.03(4), Florida Statutes, diazepam is a Schedule IV controlled substance that has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States, and abuse of diazepam may lead to limited physical or psychological dependence relative to the substances in Schedule III.

⁶ Zolpidem, commonly known by the brand name Ambien, is prescribed to treat insomnia. According to Title 21, Section 1308.14, Code of Federal Regulations, zolpidem is a Schedule IV controlled substance. Zolpidem can cause dependence and is subject to abuse.

⁷ Tramadol, commonly known by the brand name Ultram, is an opioid class medication prescribed to treat pain. Tramadol is a legend drug, but not a controlled substance. Tramadol, like all opioid class drugs, can affect mental alertness, is subject to abuse, and can be habit forming.

7. At no point during the treatment period did Respondent appropriately diagnose, or document appropriately diagnosing, Patient C.S. with attention-deficit hyperactivity disorder (ADHD).

8. At no point during the treatment period did Respondent appropriately diagnose, or document appropriately diagnosing, Patient C.S. with insomnia.

9. During the treatment period, Respondent prescribed Tramadol to Patient C.S., specifically for the treatment of obsessive compulsive disorder.

10. At no point during the course of treatment did Respondent appropriately diagnose, or document appropriately diagnosing, Patient C.S. with obsessive compulsive disorder.

11. At no point during the treatment period did Respondent perform, or document performing, an appropriate assessment to determine whether the aforementioned controlled substances were appropriate treatments for Patient C.S.

12. During the treatment period, Respondent prescribed the aforementioned controlled substances inappropriately and/or without justification.

13. At no point during the treatment period did Respondent develop and execute, or document developing and executing, a mutually agreed upon treatment plan for Patient C.S.'s treatment with the aforementioned controlled substances.

14. Respondent prescribed the aforementioned controlled substances to Patient C.S. in the absence of a signed patient treatment contract.

15. After the patient treatment contract was executed, Respondent did not adhere to the signed patient treatment contract.

16. Respondent saw Patient C.S. infrequently, and in an erratic and inconsistent manner.

17. At no point during the treatment period did Respondent attempt to, or document attempting to, coordinate with Patient C.S.'s other treating physicians and medical providers.

18. At no point during the treatment period did Respondent utilize, or document utilizing, non-pharmacological psychosocial treatments for Patient C.S.'s complaints.

19. At no point during the treatment period did Respondent establish and/or enforce, or document establishing and/or enforcing, consequences for non-compliance, relapse, and/or treatment failure.

20. At no point during the treatment period did Respondent appropriately treat, or document appropriately treating, Patient C.S.'s withdrawal symptoms.

21. At no point during the treatment period did Respondent adequately monitor, or document adequately monitoring, Patient C.S.'s ongoing drug abuse.

22. At no point during the treatment period did Respondent recognize, or document recognizing, Patient C.S.'s failure to progress with the treatment Respondent provided.

23. At no point during the treatment period did Respondent address, or document addressing, Patient C.S.'s multiple relapses.

24. At no point during the treatment period did Respondent monitor, or document monitoring, Patient C.S. for illicit drug use, non-compliance, and/or diversion.

25. Respondent did not consider and/or discuss, or did not document considering and discussing, the risks, benefits, and side effects of the aforementioned controlled substances with Patient C.S.

26. Respondent prescribed Adderall to Patient C.S. in excessive quantities.

27. Respondent adjusted the dosages of the aforementioned controlled substances based solely on Patient C.S.'s requests and without medical justification.

28. Respondent provided refills and changed Patient C.S.'s medications and dosages without seeing Patient C.S. for an office visit.

29. At no point during the treatment period did Respondent obtain, or document obtaining, a thorough medical history.

30. At no point during the treatment period did Respondent obtain, or document obtaining, Patient C.S.'s pharmacy profile.

31. Respondent prescribed the aforementioned controlled substances, despite evidence of their ineffectiveness and evidence of tolerance, dependence, and abuse.

32. During the treatment period, Respondent failed to maintain appropriate physician-patient boundaries with Patient C.S.

33. Respondent has only received training and education in psychiatry.

34. During the treatment period, Respondent prescribed Linzess⁸ to Patient C.S. for his complaints of gastrointestinal issues.

35. During the treatment period, Respondent also prescribed Amitiza⁹ to Patient C.S. for his complaints of gastrointestinal issues.

36. Based on her lack of training and experience, Respondent was not competent to treat, and/or to prescribe medication for the treatment of, gastrointestinal issues.

37. During the treatment period, Respondent prescribed Podofilox¹⁰ to Patient C.S. for complaints on an infection on his inner thigh.

38. Based on her lack of training and experience, Respondent was not competent to treat, and/or to prescribe medication for the treatment of, external genital warts.

39. During the treatment period, Respondent prescribed Valtrex¹¹ to Patient C.S. for the treatment of blisters in his genital area.

⁸Linzess is a medication prescribed for the treatment of irritable bowel syndrome and chronic idiopathic constipation.

⁹ Amitiza is a medication used to treat chronic idiopathic constipation and irritable bowel syndrome with constipation.

¹⁰ Podofilox is a medication used to treat external genital warts.

¹¹ Valtrex is a medication used to treat herpes.

40. Respondent also prescribed Valtrex to Patient C.S. for the treatment of shingles.

41. Based on her lack of training and experience, Respondent was not competent to treat, and/or to prescribe medication for the treatment of, herpes.

42. Based on her lack of training and experience, Respondent was not competent to treat, and/or to prescribe medication for the treatment of, shingles.

43. During the treatment period, Respondent prescribed Cialis to Patient C.S. for complaints related to Patient C.S.'s Peyronie's disease¹².

44. Based on her lack of training and experience, Respondent was not competent to treat, and/or to prescribe medication for the treatment of, Peyronie's disease.

45. During the treatment period, Respondent prescribed Zithromax¹³ to Patient C.S. without sufficient documentation and justification.

¹² Peyronie's disease is the development of scar tissue inside the penis, which results in erectile dysfunction.

¹³ Zithromax is the brand name of azithromycin, an antibiotic.

46. During the treatment period, Respondent prescribed clindamycin¹⁴ to Patient C.S. without sufficient documentation and justification.

47. Based on her lack of training and experience, Respondent was not competent to prescribe antibiotics to Patient C.S.

48. During the treatment period, Respondent prescribed anastrozole¹⁵ to Patient C.S. for complaints of depression.

49. Based on her lack of training and experience, Respondent was not competent to prescribe anastrozole.

50. During the treatment period, Respondent prescribed buprenorphine to Patient C.S. for complaints of acute pain.

51. Based on her lack of training and experience, Respondent was not competent to treat, and/or to prescribe medication for, acute pain.

52. During the treatment period, Respondent failed to keep legible and complete records that justified the course of treatment.

53. The prevailing professional standard of care required Respondent to:

¹⁴ Clindamycin is an antibiotic.

¹⁵ Anastrozole is an estrogen blocker and is commonly used to treat breast cancer.

- a. Appropriately diagnose Patient C.S. with attention-deficit hyperactivity disorder (ADHD);
- b. Appropriately diagnose Patient C.S. with insomnia;
- c. Appropriately diagnose Patient C.S. with obsessive compulsive disorder;
- d. Perform an appropriate assessment to determine whether the aforementioned controlled substances were appropriate treatments for Patient C.S.;
- e. Prescribe the aforementioned controlled substances appropriately and/or with justification;
- f. Develop and execute a mutually agreed upon treatment plan for Patient C.S.'s treatment with the aforementioned controlled substances;
- g. Prescribe the aforementioned controlled substances under a signed patient treatment contract;
- h. Adhere to the signed patient treatment contract;
- i. See Patient C.S. frequently and regularly;
- j. Attempt to coordinate with Patient C.S.'s other treating physicians and medical providers;

- k. Utilize non-pharmacological psychosocial treatments for Patient C.S.'s complaints;
- l. Establish and/or enforce, consequences for non-compliance, relapse, and/or treatment failure;
- m. Appropriately treat Patient C.S.'s withdrawal symptoms;
- n. Adequately monitor Patient C.S.'s ongoing drug abuse;
- o. Recognize Patient C.S.'s failure to progress with the treatment Respondent provided;
- p. Address Patient C.S.'s multiple relapses;
- q. Monitor Patient C.S. for illicit drug use, non-compliance, and/or diversion;
- r. Consider and/or discuss the risks, benefits, and side effects of the aforementioned controlled substances with Patient C.S.;
- s. Refrain from prescribing Adderall to Patient C.S. in excessive quantities;
- t. Refrain from adjusting the dosages of the aforementioned controlled substances based solely on Patient C.S.'s requests and without medical justification;

- u. Refrain from providing refills and changing Patient C.S.'s medications and dosages without seeing Patient C.S. for an office visit;
- v. Obtain a thorough medical history;
- w. Obtain Patient C.S.'s pharmacy profile;
- x. Cease prescribing the aforementioned controlled substances, when faced with evidence of their ineffectiveness and evidence of tolerance, dependence, and abuse;
- y. Maintain appropriate physician-patient boundaries with Patient C.S.

COUNT ONE
Section 458.331(1)(t)

54. Petitioner re-alleges and incorporates paragraphs one (1) through fifty-three (53) as if fully set forth herein.

55. Section 458.331(1)(t), Florida Statutes (2013-2018), subjects a doctor to discipline for committing medical malpractice as defined in Section 456.50. Section 456.50, Florida Statutes (2013-2018), defines medical malpractice as the failure to practice medicine in accordance with the level of care, skill, and treatment recognized in general law related to health care licensure.

56. Level of care, skill, and treatment recognized in general law related to health care licensure means the standard of care specified in Section 766.102. Section 766.102(1), Florida Statutes, defines the standard of care to mean "that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar healthcare providers...."

57. Respondent failed to meet the required standard of care in one or more of the following ways:

- a. By failing to correctly diagnose Patient C.S. with ADHD;
- b. By failing to diagnose Patient C.S. with insomnia;
- c. By failing to appropriately diagnose Patient C.S. with obsessive compulsive disorder;
- d. By failing to perform an appropriate assessment to determine whether the aforementioned controlled substances were appropriate treatments for Patient C.S.;
- e. By prescribing the aforementioned controlled substances inappropriately and/or without justification;
- f. By seeing Patient C.S. infrequently, erratically, and/or inconsistently;

- g. By failing to develop and execute a mutually agreed upon treatment plan for Patient C.S.'s treatment with the aforementioned controlled substances;
- h. By prescribing the aforementioned controlled substances to Patient C.S. in the absence of a signed patient treatment contract;
- i. By failing to adhere to the signed patient treatment contract after it was signed;
- j. By seeing Patient C.S. infrequently, and in an erratic and inconsistent manner;
- k. By failing to attempt to coordinate with Patient C.S.'s other treating physicians and medical providers;
- l. By failing to utilize non-pharmacological psychosocial treatments for Patient C.S.'s complaints;
- m. By failing to establish and/or enforce consequences for non-compliance, relapse, and/or treatment failure;
- n. By failing to appropriately treat Patient C.S.'s withdrawal symptoms;

- o. By failing to adequately monitor Patient C.S.'s ongoing drug abuse;
- p. By failing to recognize Patient C.S.'s failure to progress with the treatment Respondent provided;
- q. By failing to address Patient C.S.'s multiple relapses;
- r. By failing to monitor Patient C.S. for illicit drug use, non-compliance, and/or diversion;
- s. By failing to consider and/or discuss the risks, benefits, and side effects of the aforementioned controlled substances with Patient C.S.;
- t. By prescribing Adderall to Patient C.S. in excessive quantities;
- u. By failing to address Patient C.S.'s non-compliance in relation to his prescription for Adderall;
- v. By adjusting the dosages of the aforementioned controlled substances based solely on Patient C.S.'s requests and without medical justification;
- w. By providing refills and changing Patient C.S.'s medications and dosages without seeing Patient C.S. for an office visit;
- x. By failing to obtain a thorough medical history;

- y. By failing to obtain Patient C.S.'s pharmacy profile;
- z. By continuing to prescribe the aforementioned controlled substances despite evidence of their ineffectiveness and evidence of tolerance, dependence, and abuse;
- aa. By prescribing Zithromax to Patient C.S. without justification;
- bb. By prescribing clindamycin to Patient C.S. without justification; and/or
- cc. By failing to maintain appropriate physician-patient boundaries with Patient C.S.

58. Based on the foregoing, Respondent has violated section 458.331(1)(t), Florida Statutes (2013-2018), by committing medical malpractice.

COUNT TWO
Violation of Section 458.331(1)(m)
and/or Section 458.331(1)(nn)

59. Petitioner re-alleges and incorporates paragraphs one (1) through fifty-three (53) as if fully set forth herein.

60. Section 458.331(1)(m), Florida Statutes (2013-2018), subjects a licensee to discipline for failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed

physician or the physician extender and supervising physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

61. Section 458.331(1)(nn), Florida Statutes (2013-2018), provides that violating any provision of Chapter 458 or 456, or any rules adopted pursuant thereto constitutes grounds for disciplinary action by the Board of Medicine.

62. Chapter 64B8-9.003(d)(3), Florida Administrative Code (2006), provides that medical records shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; reports of consultations and hospitalizations; and copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician

and relied upon by the physician in determining the appropriate treatment of the patient.

63. Respondent failed to create and/or maintain adequate, legible medical records that justify the course of treatment of Patient C.S. and/or satisfy the requirements of Chapter 64B8-9.003(d)(3), Florida Administrative Code (2006), in one or more of the following ways:

- a. By failing to create and/or maintain adequate, legible medical records that document correctly diagnosing Patient C.S. with ADHD;
- b. By failing to create and/or maintain adequate, legible medical records that document diagnosing Patient C.S. with insomnia;
- c. By failing to create and/or maintain adequate, legible medical records that document appropriately diagnosing Patient C.S. with obsessive compulsive disorder;
- d. By failing to create and/or maintain adequate, legible medical records that document performing an appropriate assessment to determine whether the aforementioned controlled substances were appropriate treatments for Patient C.S.;

- e. By failing to create and/or maintain adequate, legible medical records that document developing and executing a mutually agreed upon treatment plan for Patient C.S.'s treatment with the aforementioned controlled substances;
- f. By failing to create and/or maintain adequate, legible medical records that document attempting to coordinate with Patient C.S.'s other treating physicians and medical providers;
- g. By failing to create and/or maintain adequate, legible medical records that document utilizing non-pharmacological psychosocial treatments for Patient C.S.'s complaints;
- h. By failing to create and/or maintain adequate, legible medical records that document establishing and/or enforcing, consequences for non-compliance, relapse, and/or treatment failure;
- i. By failing to create and/or maintain adequate, legible medical records that document appropriately treating Patient C.S.'s withdrawal symptoms;

- j. By failing to create and/or maintain adequate, legible medical records that document adequately monitoring Patient C.S.'s ongoing drug abuse;
- k. By failing to create and/or maintain adequate, legible medical records that document recognizing Patient C.S.'s failure to progress with the treatment Respondent provided;
- l. By failing to create and/or maintain adequate, legible medical records that document addressing Patient C.S.'s multiple relapses;
- m. By failing to create and/or maintain adequate, legible medical records that document monitoring Patient C.S. for illicit drug use, non-compliance, and/or diversion;
- n. By failing to create and/or maintain adequate, legible medical records that document considering and discussing, the risks, benefits, and side effects of the aforementioned controlled substances with Patient C.S.;
- o. By failing to create and/or maintain adequate, legible medical records that document obtaining a thorough medical history;

- p. By failing to create and/or maintain adequate, legible medical records that document prescribing Zithromax to Patient C.S.;
- q. By failing to create and/or maintain adequate, legible medical records that document prescribing clindamycin to Patient C.S.;
and/or
- r. By failing to create and/or maintain adequate, legible medical records that document obtaining Patient C.S.'s pharmacy profile.

64. Based on the foregoing, Respondent violated section 458.331(1)(m), Florida Statutes (2013-2018), and/or section 458.331(1)(nn), Florida Statutes (2013-2018).

COUNT THREE
Section 458.331(1)(v)

65. Petitioner re-alleges and incorporates paragraphs thirty-three (33) through fifty-three (53) as if fully set forth herein.

66. Section 458.331(1)(v), Florida Statutes (2013-2018), subjects a licensee to discipline for accepting and performing professional responsibilities which she knows or has reason to know that she is not competent to perform.

67. Respondent accepted and performed professional responsibilities which she knows or has reason to know that she is not competent to perform in one or more of the following ways:

- a. By treating, and/or prescribing medication for the treatment of, gastrointestinal issues;
- b. By treating, and/or prescribing medication for the treatment of, external genital warts;
- c. By treating, and/or prescribing medication for the treatment of, herpes;
- d. By treating, and/or prescribing medication for the treatment of, shingles;
- e. By treating, and/or prescribing medication for the treatment of, Peyronie's disease;
- f. By prescribing antibiotics;
- g. By prescribing anastrozole; and/or
- h. By treating, and/or prescribing medication for the treatment of, acute pain.

68. Based on the foregoing, Respondent violated section 458.331(1)(v), Florida Statutes (2013-2018).

WHEREFORE, the Petitioner respectfully requests that the Board of Medicine enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 9th day of SEPTEMBER, 2019.

Scott Rivkees, M.D.
State Surgeon General



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FILED

DEPARTMENT OF HEALTH
DEPUTY CLERK

CLERK: 

DATE: SEP 09 2019

SEC/

PCP: September 6, 2019

PCP Members: Mark Avila, M.D.; Zachariah Zachariah, M.D.

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested. A request or petition for an administrative hearing must be in writing and must be received by the Department within 21 days from the day Respondent received the Administrative Complaint, pursuant to Rule 28-106.111(2), Florida Administrative Code. If Respondent fails to request a hearing within 21 days of receipt of this Administrative Complaint, Respondent waives the right to request a hearing on the facts alleged in this Administrative Complaint pursuant to Rule 28-106.111(4), Florida Administrative Code. Any request for an administrative proceeding to challenge or contest the material facts or charges contained in the Administrative Complaint must conform to Rule 28-106.2015(5), Florida Administrative Code.

Please be advised that mediation under Section 120.573, Florida Statutes, is not available for administrative disputes involving this agency action.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition any other discipline imposed.