BEFORE THE DELAWARE BOARD OF MEDICAL LICENSURE AND DISCIPLINE

IN RE: HENRY E. CHILDERS IV, M.D.)
)
) **Cases No.: 10-28-19**
LICENSE NO.: C1-0009809)

ORDER

WHEREAS, the Board of Medical Licensure and Discipline has reviewed this matter; and

WHEREAS, the Board of Medical Licensure and Discipline approves the Consent Agreement of the parties and intends to enter it as an Order of the Board;

IT IS HEREBY ORDERED this 12th day of July, 2022

Stephen Lawless, M.D., President

/s/ Joseph Rubacky
Joseph Rubacky, D.O., Vice-President

/s/ Randeep Kahlon
Randeep Kahlon, M.D., Secretary

/s/ Bryan Villar
Bryan D. Villar, M.D.

Joseph M. Parise, D.O.

/s/ Anna D'Amico
Anna D'Amico, M.D.

/s/ Sharon Williams-Mayo
Sharon Williams-Mayo, Public Member

/s/ Madelyn Nellius
Madelyn Nellius, Public Member

/s/ Lauren Davey
Lauren Davey, PA

/s/ Barry Bakst
Barry L. Bakst, D.O.

/s/ Georges Dahr
Georges A. Dahr, M.D.

/s/ Melissa Warren
Melissa Warren, Public Member

Karyl Rattay, M.D.

/s/ Janice Truitt
Janice Truitt, Public Member

/s/ Mary Lomax
Mary Lomax, Ed.D., Public Member

/s/ Bethany Melo
Bethany Melo, PA

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CONSENT AGREEMENT

A written Complaint was filed with the Delaware Board of Medical Licensure and Discipline ("Board") alleging that Henry E. Childers IV, ("Respondent"), a licensed medical doctor, engaged in conduct that constitutes grounds for discipline pursuant to Delaware's *Medical Practice Act* (24 *Del. C.* Ch. 17).

The State of Delaware, by the undersigned Deputy Attorney General, and Respondent submit this Consent Agreement for approval by the Board as a means of resolving the pending administrative prosecution against Respondent pursuant to 24 *Del. C.* Ch. 17 and 29 *Del. C.* Ch. 101.

IT IS UNDERSTOOD AND AGREED THAT:

1. Respondent is a licensed medical doctor in the State of Delaware. His license, number C1-0009809, was issued on August 29, 2011 and expires on March 31, 2021. His license is currently active.

2. At all times relevant to this Complaint, Respondent maintained a practice, Delaware Integrative Medicine ("DIM"), located in Georgetown, Delaware.

3. Patient C was referred to Respondent by her primary care provider in July of 2015 for treatment of persistent symptoms related to a self-reported previous diagnosis of Lyme disease.

4. Patient C had been treating with her primary care provider from at least August 2007 until June 2015. During that time period, Patient C consistently refused to comply with recommended treatment or medications and refused diagnostic imaging.

5. Patient C was also diagnosed with several co-morbidities, including diabetes, elevated blood pressure and hyperlipidemia.

6. On July 9, 2015, Patient C came to see Respondent for an initial evaluation. The first office visit lasted for 93 minutes according to Respondent's medical records. Respondent did not review or did not document any review of Patient C's treatment records or discussion with Patient C's primary care provider prior to treating Patient C.

7. Respondent did not order any tests or other lab work to confirm Patient C's reported Lyme diagnosis or any other diagnosis he documented in her records.

8. Respondent began using non-traditional therapies on Patient C in July 2015 which included oral and intravenous infusions of Silverstol (silver), as well as ozone therapy, to treat her Lyme disease symptoms.

9. Respondent did not obtain appropriate informed consent for all of the treatments used on Patient C.

10. Patient C's records contain a form entitled "Informed Consent for the American Academy of Ozone-Therapy Sponsored Study of the Safety and Efficacy of Ozone Therapy" ("ozone consent form").

11. The ozone consent form in Patient C's records was not signed by patient C.

12. Ozone therapy is not approved by the Federal Drug Administration ("the

FDA").[1] The process involves drawing blood directly from the patient in sterile fashion and putting the patient's blood into an IV bag. Ozone is then added to the bag. The contact of blood and ozone oxidizes the blood. Then, the oxidized blood only is returned to the patient's body.

13. Patient C paid cash for these treatments, which were not covered by insurance.

14. On or about July 15, 2015, Respondent ordered the placement of a port in Patient C's chest for the purposes of major auto hemotherapy, a treatment regimen wherein Patient C's blood was withdrawn, mixed with ozone, and reinjected into her body. The port was placed by someone other than Respondent at Christiana Care Hospital located in Newark, Delaware.

15. During the course of treatment, Patient C reported to her family that she was improving as a result in the treatment as her confirmed by Patient C's daughter under oath.

16. On or about September 24, 2015, Patient C's port was replaced at Christiana Care Hospital due to malfunction. This procedure was not performed by Respondent. A procedure note from Christiana Care indicates that Patient C was assessed by the vascular interventional radiology team prior to the procedure. Patient C did execute an informed consent document specific to the port replacement prior to the procedure.

17. On September 29, 2015, Patient C reported suffering from flu-like symptoms and fatigue.

18. Patient C's symptoms continued to worsen on September 30, 2015. On that date, she received ozone therapy at DIM.

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[1] 21 C.F.R. sec. 801.415(a)

19. On October 1, 2015, Patient C received ozone therapy at DIM. On that date, Respondent saw Patient C during her office visit and ordered bloodwork.

20. Between September 29, 2015 and October 1, 2015 neither Respondent nor any staff member of DIM took patient C's temperature.

21. On October 2, 2015, Patient C's daughter found her on the floor of the kitchen in poor medical condition and Patient C was transported to Christiana Care's emergency department.

22. Patient C was diagnosed with an infection and ultimately passed away due to sepsis.

23. Analysis of the port after removal confirmed that it contained MRSA.

24. During the course of Patient C's treatment at DIM, Respondent's treatment records for patient C contained multiple inconsistencies.

25. Patient C's death was attributable to the placement of a port for ozone therapy because of the sepsis resulting from the MRSA.

26. The parties agree that Patient C's death was not caused by the ozone therapy in and of itself, and the State confines its allegations to this particular patient's care.

27. Respondent admits that he failed to meet the standard of care in administering an integrative medical treatment, specific to the care of Patient C, in the following ways:

a. he failed to take and/or record Patient C's vital signs when she was showing signs of infection;

b. he failed to document informed consent for a non-FDA approved treatment;

c. he failed to conduct an initial evaluation to determine if Patient C actually

suffered from Lyme disease; and

d. he failed to properly maintain records of Patient C's treatment.

28. Respondent violated 24 *Del. C.* § 1731(b)(3) in that he engaged in conduct likely to deceive, defraud or harm the public, specifically:

a. Respondent violated regulation 8.1.13 in that he failed to adequately maintain and properly document patient records; and

b. Respondent violated 8.1.16 in that he engaged in an act or acts tending to bring discredit upon the profession.

29. By the conduct referenced above, including but not limited to his use of ozone therapy through the placement of a port in a case where the benefits of the treatment did not outweigh the risk of infection or other adverse outcomes to the particular patient, Respondent violated 24 *Del. C.* § 1731(b)(11) in that he engaged in misconduct or a pattern of negligence in the practice of medicine.

30. Respondent admits that the allegations set forth in paragraphs one (1) through twenty-nine (29) above are true and correct.

31. The State and Respondent agree that the appropriate disciplinary sanctions are as follows:

a. Respondent's license shall be suspended for 60 days, which suspension shall be stayed immediately and his license placed on probation for five (5) years with the following conditions:

b. Within 90 (ninety) days of the Board's Order, Respondent shall complete twelve (12) hours of continuing education, of which three (3) hours shall be in documentation practices, three (3) hours in ethics, three (3) hours shall

be in the area of informed consent and three (3) hours shall be on infection control. The twelve hours shall be in addition to the continuing education hours required for license renewal;

c. During the term of probation, Respondent shall disclose this Consent Agreement to other Delaware treatment providers that he is contracted to work with or provide medical services to; and

d. Within ninety (90) days of the date the Board accepts this Agreement and enters it as an Order Respondent shall be required to pay a fine in the amount of $2,500.00. The fine shall be made payable to the State of Delaware and mailed to the Division of Professional Regulation, Delaware Board of Medical Licensure and Discipline, Cannon Building, Suite 203, 861 Silver Lake Boulevard, Dover, Delaware 19904.

32. The parties to this Consent Agreement are the State of Delaware and Respondent. The parties agree and acknowledge that nothing contained in this Consent Agreement shall affect any rights or interests of any person not a party to this Consent Agreement.

33. Respondent acknowledges that he is waiving his rights under 24 *Del. C.* Ch. 17 and *Del. C.* Ch. 101 to a hearing before the Board prior to the imposition of disciplinary sanctions.

34. Respondent hereby acknowledges and agrees that he has carefully read and understands this Consent Agreement, and is entering into this Consent Agreement freely, knowingly, voluntarily, and after having received or having been afforded the opportunity to receive the advice of counsel.

35. Respondent acknowledges that this Consent Agreement is a public record within

the meaning of 29 *Del. C.* § 10002 and will be available for public inspection and copying as provided for by 29 *Del. C.* § 10003.

36. The parties acknowledge and agree that this Consent Agreement is subject to approval by the Board.

37. The parties acknowledge and agree that if the Board does not accept this Consent Agreement, it shall have no force or effect, except as follows:

a. Neither Respondent, nor anyone on his behalf, will in any way or in any forum challenge the ability of the Board or any of its members to conduct an evidentiary hearing relating to the allegations in the subject Complaint;

b. The Consent Agreement, or conduct or statements made in negotiating the Consent Agreement, will be inadmissible at any administrative, civil or criminal legal proceeding; and

c. No provision contained in the Consent Agreement shall constitute or have the effect of an admission by Respondent as to any fact alleged in the Complaint in this matter or in this Consent Agreement.

38. If the Board accepts the Consent Agreement and enters it as an Order, the Consent Agreement shall be admissible as evidence at any future proceedings before the Board.

39. Respondent acknowledges and agrees that the Board will report this Consent Agreement to the licensing authority of any other state in which he is licensed to practice.

40. The parties acknowledge and agree that this Consent Agreement, along with any exhibits, addendums, or amendments hereto, encompasses the entire agreement of the

parties and supersedes all previous understandings and agreements between the parties, whether oral or written. There are no other terms, obligations, covenants, representations, statements or conditions, or otherwise, of any kind whatsoever concerning this agreement.

41. This Consent Agreement, and any disciplinary sanctions contained herein, shall be effective upon acceptance by the Board and entry of the Board's Order.

HE Childers IV, MD

Henry E. Childers IV, M.D.
Respondent

Dated: 6/21/2022

Zoe Plerhoples (I.D. No. 5415)
Deputy Attorney General

Dated: 6/22/2022

Shauna R. Slaughter

Shauna Slaughter
Deputy Director
Delaware Board of Medical Licensure and Discipline

Dated: 7/12/2022