

HEARING CONDUCTED BY THE
TEXAS STATE OFFICE OF ADMINISTRATIVE HEARINGS
SOAH DOCKET NO. _____
TEXAS MEDICAL LICENSE NO. D-6119

IN THE MATTER OF THE
COMPLAINT AGAINST
KENNETH W. O'NEAL, M.D.

BEFORE THE
TEXAS MEDICAL BOARD

COMPLAINT

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

COMES NOW, the Staff of the Texas Medical Board (the "Board"), and files this Complaint against Kenneth W. O'Neal, M.D., ("Respondent"), based on Respondent's alleged violations of the Medical Practice Act ("the Act"), Title 3, Subtitle B, Texas Occupations Code, and would show the following:

I. INTRODUCTION

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.

II. LEGAL AUTHORITY AND JURISDICTION

Respondent is a Texas physician and holds Texas Medical License No. D-6119, issued by the Board on August 27, 1969, which was in full force and effect at all times material and relevant to this Complaint. All jurisdictional requirements have been satisfied.

III. PROCEDURAL BACKGROUND

1. The Board received information that Respondent may have violated the Act and, based on that information, conducted an investigation. The investigation compiled evidence that support allegations of a violation.

2. Respondent's Texas Medical License was suspended by the Board on October 28,

2005, which was conducted in accordance with §164.059 of the Act. The Board representatives, including at least one physician, reviewed and considered evidence from the investigation. The Board representatives determined that Respondent's continued practice of medicine would, by his continuation in practice, constitute a continuing threat to the public welfare and the Panel suspended Respondent's license without notice.

3. Respondent waived his right to a Temporary Suspension Hearing With Notice and Respondent was invited to attend an Informal Show Compliance Proceeding and Settlement Conference ("ISC"). ISCs were held on February 17, 2006 and November 17, 2006, which were conducted in accordance with §2001.054(c), TEX. GOV'T CODE and §164.004 of the Act. The Board representatives, including at least one physician ("Panel"), reviewed and considered evidence from the investigation, as well as any information presented by Respondent. The Panel determined that Respondent had not shown compliance with all requirements of the Act and directed that a Complaint be filed against Respondent at the State Office of Administrative Hearings ("SOAH").

IV. FACTUAL ALLEGATIONS

Board Staff has received information and on that information believes that Respondent has violated the Act. Based on such information and belief, Board Staff alleges:

1. Respondent is a general practitioner who utilized alternative medicine in his practice. Specifically, Respondent provided intravenous vitamin treatments to his patients. Respondent also worked as a contract physician in rural emergency rooms around the Abilene, Texas area.

2. The allegations against Respondent concern the deaths of four patients shortly after Respondent administered intravenous vitamin treatments to those patients.

Patient K.S.

3. K.S. (deceased) was an eighty-three year old female with a medical history of congestive heart failure, chronic obstructive pulmonary disease, gastroesophageal reflux disease, and aortic stenosis. K.S. began seeing Respondent in February, 2005, to improve the quality of her life.

4. According to Respondent's medical record, Respondent saw K.S. on March 9, 2005; May 4, 2005 and May 12, 2005. The only physical examination recorded for these appointments are vital signs.

5. On June 12, 2005, Respondent administered "Myers in normal saline" to K.S. According to Respondent's Formulary, Myers Cocktail contains vitamin C, B-complex, magnesium sulfate, calcium gluconate, pyridoxine, methylcobalamine, folic acid, B5, Isotonic Quintin, and normal saline. Respondent did not document the time the Myers Cocktail was administered to K.S.

6. Upon administration of the Myers Cocktail, K.S. became tachypenic. According to the medical records, Respondent left the room to obtain Decadron and returned within three minutes to find that K.S. had "increased distress, altered level of consciousness, cyanosis, and increased difficulty breathing." K.S.'s oxygen saturation, on room air, was 75%. Cardiopulmonary resuscitation was initiated and emergency services were called.

7. According to the records of the Abilene Fire Department, upon arrival at Respondent's clinic, K.S. had no respirations and no pulse. K.S. was transported to Hendrick Medical Center where she was pronounced dead at 1250 hours with the cause of death identified as cardiopulmonary arrest. No autopsy was performed on K.S.

8. Respondent violated the standard of care in his treatment of K.S. when he failed to adequately perform a physical examination on K.S. and when he failed to properly diagnose and treat her respiratory distress. Additionally, Respondent violated the standard of care when he failed to timely notify emergency services when K.S. experienced a reaction to intravenous therapy.

Patient A.P.

9. A.P. (deceased) was eighty-five years old when she first began treatment with Respondent on August 6, 2003. A.P. had a medical history of severe, symptomatic aortic stenosis, congestive heart failure, and severe hypertension.

10. Over the next two years, A.P. received numerous intravenous infusions of various mixtures from Respondent. These solutions included: Freamine; an IBM mixture which, according to Respondent's Formulary, contained vitamins, magnesium sulfate, selenium, zinc, and Isotonic Quintin; and Myers Cocktail.

11. On August 3, 2005, A.P. presented to Respondent and received an intravenous infusion of Freamine, IR, Taurine, NaCHO₃, and IBM. Ten minutes into the infusion, A.P. reported itching and experienced a drop in blood pressure to 80/40. Respondent administered Decadron at 1415 and 1420. At 1420, A.P. complained of severe back pain and emergency services were called.

12. A.P. was transported to Hendrick Memorial Hospital via the Abilene Fire Department.

13. According to medical records from Hendrick Medical Center, A.P. was experiencing shortness of breath, diaphoresis, and mid-sternal pain. The emergency physician's clinical impression was that A.P. had suffered a cardiovascular incident after receiving alternative medicine intervention – intravenous vitamins. A.P. died at 1612 hours. No autopsy was performed.

14. Respondent violated the standard of care in regard to his treatment of A.P. when he failed to complete a physical examination and failed to properly diagnose and treat A.P.'s respiratory distress.

Patient D.T.

15. D.T. (deceased) was a fifty-two year old male when he first began treatment with Respondent. D.T. had a history of severe hypertension and hyperlipidemia. Respondent's first encounter with D.T. was on December 15, 2004. Other than taking D.T.'s vital signs, there is no documentation that Respondent completed a physical examination on D.T.

16. From December 15, 2004 through July 2, 2005, Respondent's medical records indicate that D.T. received twenty-two treatments of intravenous vitamins. The majority of these treatments were identified by Respondent as following the "Chelation Protocol." Although D.T. received twenty-two intravenous infusions as documented on Respondent's "Chelation Log," Respondent made only four narrative entries in D.T.'s medical record.

17. D.T. presented to Respondent's clinic on June 2, 2005, for Chelation treatment. Prior to starting the treatment, D.T. told Respondent's staff he was nauseated due to some chicken he had eaten at lunch; however, the Chelation treatment was administered as planned.

18. At 1550, shortly after the administration of the solution, D.T. began to experience burning eyes and tongue, vomiting and diaphoresis. D.T. was given Phenergan due to the vomiting. At 1625 hours, D.T.'s blood pressure was 152/88, with a pulse rate of 92 beats per

minute. At 1650 hours, D.T.'s blood pressure was 167/90, with a pulse rate of 103 beats per minute. D.T.'s wife was called to transport D.T. home.

19. D.T. continued to experience difficulty breathing. At 1740 hours, D.T.'s medical records indicates that D.T.'s vital signs were "within normal limits," however, no blood pressure reading was recorded in the medical record for this time.

20. At 1800 hours, over 2 hours after D.T. had begun to experience medical problems, emergency services were called to transport D.T. to the emergency room. Therefore, Respondent had attempted to manage D.T.'s medical condition in his clinic for over two hours.

21. According to the records of the Abilene Fire Department, D.T. was in respiratory distress upon their arrival to Respondent's clinic, and emergency personnel were unable to get a blood pressure reading on D.T.

22. Respondent provided D.T.'s history to the Abilene Fire Department and identified that D.T. had presented to Respondent with nausea, vomiting, and diarrhea. There is no documentation that Respondent informed emergency personnel that D.T. had undergone intravenous chelation treatment while at Respondent's clinic.

23. Enroute to Hendrick Medical Center, D.T. became unresponsive and cardiopulmonary resuscitation was initiated. D.T. arrived at Hendrick Medical Center in cardiopulmonary arrest. Aggressive attempts to revive D.T. were unsuccessful and he was pronounced dead at 1853 hours. The autopsy report identified D.T.'s cause of death as "severe occlusive coronary atherosclerosis."

24. Respondent violated the standard of care when he failed to perform an adequate physical examination on D.T., and failed to adequately treat D.T.'s hypertension and hyperlipidemia. Respondent also violated the standard of care when he failed to recognize D.T.'s life-threatening reaction to the Myers Cocktail that was administered by Respondent. Respondent also violated the standard of care when he delayed transporting D.T. to the emergency room for over two hours even though D.T. was critically ill.

Patient W.B.

25. W.B. (deceased) was a sixty-eight year old male with a long-standing history of atrial fibrillation, congestive heart failure, high blood pressure, enlarged prostate, and osteoarthritis.

26. Respondent initially saw W.B. on April 13, 2005, and the plan for treatment was for intravenous therapy. W.B. saw Respondent on May 12, 2005, with worsening symptoms of congestive heart failure and increasing shortness of breath. Respondent did not document any vital signs or a physical examination at this appointment.

27. On May 20, 2005, W.B. presented to Respondent with a temperature of 100 degrees, blood pressure 107/72, and pulse oximeter reading of 87%, on room air. Respondent did not complete an adequate physical examination on W.B. at this appointment. Respondent administered intravenous Chelation treatment to W.B. at this appointment.

28. W.B. died within 24 hours of receiving this Chelation administration.

29. Respondent violated the standard of care when he failed to complete an adequate physical examination on W.B., and failed to address W.B.'s pulmonary and cardiovascular issues. Respondent also violated the standard of care when he failed to consider that W.B. may not be a good candidate for intravenous treatment given that the fluids administered to W.B. may have the potential to worsen W.B.'s pulmonary and cardiovascular conditions.

Consecutive Deaths of Patients:

30. Both patient K.S. and patient D.T. died on the same day – June 2, 2005 – approximately five hours apart after receiving intravenous treatments from Respondent.

Respondent's Formulary:

31. Respondent's Formulary for the intravenous treatments for all the patients discussed herein were contained on typed sheets that appear to have been generated by Respondent. The Formulary does not contain or refer to any professional medical literature or research that supported the medical benefits of the intravenous treatments. Respondent's Formulary did not identify specific medical conditions in which these treatments would be contraindicated in patients.

Aggravating Factors:

32. The aggravating factors in this case include: harm to one or more patients; severity of harm to the patients; one or more violations that involve one or more patients; and increased potential for harm to the public.

V. APPLICABLE STATUTES, RULES, AND AGENCY POLICY

Respondent's conduct, as described above, constitutes grounds for the Board to revoke or suspend Respondent's Texas medical license or to impose any other authorized means of discipline upon the Respondent. The following statutes, rules, and agency policy are applicable to this matter:

A. Procedures for the Conduct of this Hearing:

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. 22 TEX. ADMIN. CODE, Chapter 187 sets forth the procedures adopted by the Board under the requirement of Section 164.007(a) of the Act.
3. 1 TEX. ADMIN. CODE §155.3(c) provides that the procedural rules of the state agency on behalf of which the hearing is conducted govern procedural matters that relate to the hearing as required by law, to wit: Section 164.007(a) of the Act, as cited above.
4. 1 TEX. ADMIN. CODE, CHAPTER 155 sets forth the rules of procedure adopted by SOAH for contested case proceedings.

B. Violations Warranting Disciplinary Action:

1. 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.
2. Section 164.052(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent based upon Respondent's unprofessional or dishonorable conduct that is likely to deceive or defraud the public or injure the public.
3. Sections 164.052(a)(5) and 164.053(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent prescribing

or administering a drug or treatment that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed.

4. Sections 164.052(a)(5) and 164.053(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent prescribing, administering, or dispensing in a manner inconsistent with public health and welfare, dangerous drugs as defined by Chapter 483, Health and Safety Code; or controlled substances scheduled in Chapter 481 Health and Safety Code; or controlled substances scheduled in the Comprehensive Drug Abuse Prevention and Control Act of 1970, (21 U.S.C. § 801 et seq.).
5. Sections 164.001(g), (h), and (i) of the Act require the Board to consider more severe disciplinary action, including revocation of Respondent's license, if Respondent is being disciplined for multiple violations, or has previously been the subject of disciplinary action by the Board.
6. Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of Board Rule 165, which requires the maintenance of adequate medical records.
7. Board Rule 190.8(1) defines failure to practice in an acceptable professional manner consistent with public health and welfare including failure to meet the generally accepted standard of care and failure to safeguard against potential complications.

C. Sanctions that May Be Imposed:

1. Section 164.001 of the Act authorizes the Board to impose a range of disciplinary actions against a person for violation of the Act or a Board rule. Such sanctions include: revocation, suspension, probation, public reprimand, limitation or restriction on practice, counseling or treatment, required educational or counseling programs, monitored practice, public service, and an administrative penalty.
2. Chapter 165, Subchapter A of the Act sets forth statutory requirements for the amount and basis of an administrative penalty.

3. 22 TEX. ADMIN. CODE § 187.39 authorizes the Board to assess, in addition to any penalty imposed, costs of the investigation and administrative hearing in the case of a default judgment or upon adjudication that Respondent is in violation of the Act after a trial on the merits.
4. 22 TEX. ADMIN. CODE Chapter 190 provides disciplinary guidelines intended to provide guidance and a framework of analysis for administrative law judges in the making of recommendations in contested licensure and disciplinary matters and to provide guidance as to the types of conduct that constitute violations of the Act or board rules.
5. In determining sanctions against Respondent, the following factors may be taken into consideration under the Act:
 - a. harm to one or more patients;
 - b. severity of harm to the patients;
 - c. one or more violations that involve one or more patients; an
 - d. increased potential for harm to the public.

VI. NOTICE TO RESPONDENT

IF YOU DO NOT FILE A WRITTEN ANSWER TO THIS NOTICE WITH THE STATE OFFICE OF ADMINISTRATIVE HEARINGS WITHIN 20 DAYS OF THE DATE NOTICE OF SERVICE WAS MAILED, A DEFAULT JUDGMENT 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. IF YOU FILE A WRITTEN ANSWER, BUT THEN FAIL TO ATTEND THE HEARING, A DEFAULT JUDGMENT 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 RESPONSE YOU FILE WITH THE STATE OFFICE OF ADMINISTRATIVE HEARINGS SHALL ALSO BE PROVIDED TO THE HEARINGS COORDINATOR OF THE TEXAS STATE BOARD OF MEDICAL EXAMINERS.

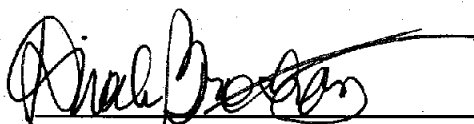
PURSUANT TO 22 TEX. ADMIN. CODE § 187.27(a)(2), A WRITTEN ANSWER SHALL SPECIFICALLY ADMIT OR DENY EACH FACTUAL ALLEGATION MADE AGAINST THE RESPONDENT.

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, in accordance with Section 164.007(a) of the Act. Upon final hearing, Board Staff requests that the Honorable Administrative Law Judge issue a Proposal for Decision ("PFD") that reflects Respondent's violation of the Act as set forth in this Complaint. Following issuance of the PFD, Board Staff requests that the Board, pursuant to § 164.001 and § 165.003 of the Act and Board Rules 187.30, 187.39, 190.8, 190.14, 190.15 and 190.16, enter an Order revoking Respondent's license and including any and all sanctions or disciplinary measures necessary to protect health and public welfare, along with the imposition on Respondent of SOAH hearing costs and an administrative penalty.

Respectfully submitted,

TEXAS MEDICAL BOARD

By:



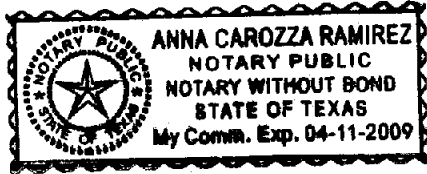
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THE STATE OF TEXAS

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COUNTY OF TRAVIS

SUBSCRIBED AND SWORN to before me by the said Dinah Brothers on April 17
2007.



Anna Carozza Ramirez
Notary Public, State of Texas

Filed with the Texas Medical Board on April 9, 2007.

Donald W. Patrick

Donald W. Patrick, M.D., J.D.
Executive Director
Texas Medical Board