

**STATE OF FLORIDA  
DEPARTMENT OF HEALTH**

**DEPARTMENT OF HEALTH,**

**PETITIONER,**

**v.**

**CASE NO. 2010-03687**

**CAROL ROBERTS, M.D.,**

**RESPONDENT.**

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**ADMINISTRATIVE COMPLAINT**

Petitioner, Department of Health, by and through its undersigned counsel, files this Administrative Complaint before the Board of Medicine against Respondent, Carol Roberts, M.D., and in support thereof 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 32984.

3. Respondent's address of record is 1209 Lakeside Drive, Brandon, Florida 33510.

4. Respondent is board certified in Otolaryngology.
5. From about April 6, 2009 through April 24, 2009, Respondent held herself out as the medical director of Wellness Works Holistic Medicine Center (Wellness Works) in Brandon, Florida.
6. Because Respondent was holding herself out as the medical director of Wellness Works, she was responsible for all activities related to treatment provided at the facility. Respondent was also responsible for ensuring compliance with the respective practice acts and rules adopted under Chapter 400.
7. Wellness Works offered chelation therapy and the administration of supplements, vitamins, and minerals by intravenous injection (IV).
8. Wellness Works purchased supplies of vitamins and pharmacological agents used in the IV therapies provided by the clinic. Many of the vitamins were supplied in 50 milliliter single dose vials. The label on the front of the vial stated "single dose vial" indicating that the vial should only be accessed once to administer one dose to one patient.
9. Multi-dose vials are labeled accordingly and contain additives that inhibit the growth of bacteria.

10. Single dose vials are labeled accordingly and do not contain additives that inhibit the growth of bacteria.

11. In or about July 2008, Nurse B.M. was hired as a registered nurse by Wellness Works. Nurse B.M. was responsible for, among other things, drawing patients' blood, inserting intravenous (IV) catheters, and the IV injection or IV infusion of supplements, minerals, and vitamins.

12. On or about April 22, 2009, Patient M.F. presented to Wellness Works for an evaluation for hormone therapy. A physician at Wellness Works recommended that M.F. undergo vitamin IV fusion to give M.F. energy.

13. On that same date, M.F. was instructed to go to the infusion room where Nurse B.M. would administer the treatment. Nurse B.M. administered the vitamin IV fusion treatment to M.F.

14. At all times material to this complaint, the supply of vitamins and agents used in IV therapies at Wellness Works were stored in the patient treatment area.

15. Nurse B.M. used a syringe and needle combination, to draw fluid from each vial. Nurse B.M. did not cleanse the tops of the vials with a sterile alcohol wipe.

16. Nurse B.M. mixed IV solutions with vitamins and/or other pharmacological agents at the table at which she injected the solution mixture of vitamins.

17. Nurse B.M. used the single dose vials as multi-dose vials, accessing the vials multiple times to administer multiple doses to multiple patients.

18. Nurse B.M. injected the vitamins into a bag of IV fluids and connected the vitamin solution to M.F.'s IV catheter and infused the solution through M.F.'s IV.

19. The patient treatment room did not have a sink as required under Florida Statutes.

20. In or about May 2009, M.F. began to have symptoms of pain in her side, a stomach ache and vomiting. On or about June 30, 2009, M.F. presented to the Mayo Clinic where she was tested and diagnosed with HCV.

21. Nurses are obligated to follow, Universal Precautions, as described by the Occupational Safety and Health Standards (OSHA) regulations located in Title 29, Code of Federal Regulations, Section 1910.1030. Universal Precautions is an approach to infection control where

all human blood and certain human body fluids are treated as if known to be infectious for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens.

22. Hepatitis C virus (HCV) is another known bloodborne pathogen.

23. According to Title 29, Code of Federal Regulations, Section 1910.1030(b), contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

24. According to the principles of Universal Precautions, any item that has the presence, or reasonably anticipated presence, of blood, must be treated as if known to be infectious for bloodborne pathogens such as HIV, HBV, or HCV.

25. Sterile equipment and sterile technique must be used when performing IV injection to avoid the introduction of any pathogens into a patient's bloodstream.

26. Section 458.331(1)(t)1, Florida Statutes (2009), subjects a doctor to discipline for committing medical malpractice as defined in Section 456.50. Section 456.50, Florida Statutes (2009), 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.

27. 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(1), Florida Statutes (2009), that defines the standard of care to mean “. . . The prevailing professional standard of care for a given health care provider shall be 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 health care providers. . . .”

28. Respondent failed to meet the prevailing standard of care by failing to institute, monitor, and use acceptable infection prevention practices.

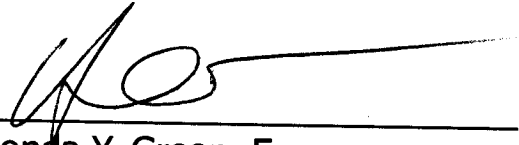
29. Based on the foregoing, Respondent violated Section 458.331(1)(t)1, Florida Statutes (2009), by committing medical malpractice as defined in Section 456.50.

WHEREFORE, 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 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 23<sup>rd</sup> day of June, 2011.

H. Frank Farmer, Jr., M.D., Ph.D.  
State Surgeon General



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CLERK *Sandra Soto*  
DATE JUN 24 2011

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PCP: June 23, 2011  
PCP Members: Leon, Orr & Goersch

**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.**

**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 to any other discipline imposed.**