

Appendage #2 from Tab #2

STATE OF FLORIDA
BOARD OF MEDICINE

PETITION FOR DECLARATORY
STATEMENT OF YVONNE
SMALLWOOD SHERRER, M.D.

FINAL ORDER ON PETITION FOR DECLARATORY STATEMENT

This matter came before the Board of Medicine (hereinafter the "Board") on February 7, 2009, in Tampa, Florida, for consideration of the above-referenced Petition for Declaratory Statement (attached hereto as exhibit A). The Notice of Petition for Declaratory Statement was published on January 23, 2009, in Vol. 35, No. 3, of the Florida Administrative Weekly.

The petition, filed by Yvonne Smallwood Sherrer, M.D., sets forth the following inquiry: Is she, as a licensed Florida physician, permitted pursuant to §458.3485, Florida Statutes, to employ medical assistant to provide IV infusion therapy to patients under her direct supervision and responsibility?

FINDINGS OF FACT

1. Petitioner is a Florida licensed physician in good standing. She is a board certified Rheumatologist who treats numerous patients suffering from arthritis and participates in numerous pharmaceutical studies related to arthritis treatments. IV infusion therapy is commonly used by the Petitioner as a treatment modality in her Rheumatology practice and in the various pharmaceutical studies in which she participates.

2. Petitioner has been an active participant in Institutional Review Board (IRB) approved pharmaceutical studies involving double-blind, placebo controlled, safety, efficacy and tolerability trials of numerous drug therapies being tested for conditions suffered by her

patients.

3. As a board certified Rheumatologist, Petitioner is trained and experienced in the administration, potential side effects, and complications related to IV infusion therapy. Her medical assistants involved in the performance of IV infusion therapy have received training and certification in IV procedures.

4. The routine provision of IV infusion therapy in Petitioner's office requires the performance of a venipuncture with a butterfly to draw blood from the patient. The butterfly is then left in place and used as an access point for the IV infusion, which is performed by the operation of office medical equipment to administer, by means of intravenous infusion, medication to a patient as directed by Petitioner. All IV infusion therapy is provided either by Petitioner or by a medical assistant under her direct supervision and responsibility. Petitioner is always present in the office whenever a medical assistant is providing IV infusion therapy to a patient.

CONCLUSIONS OF LAW

5. The Board of Medicine has authority to issue this Final Order pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

6. The Petition filed in this cause is in substantial compliance with the provisions of 120.565, Florida Statutes, and Rule 28-105.002, Florida Administrative Code.

7. For purposes of determining standing in this matter, the individual Petitioner, an allopathic physicians licensed pursuant to Chapter 458, Florida Statutes, is a substantially affected persons due to the fact that if she allows her medical assistants to undertake responsibilities in contravention with Section 458.3485, Florida Statutes, she may be subject to disciplinary action by the Board.

8. Section 458.3485, Florida Statutes addresses the use of medical assistants in Florida.

The statute reads as follows:

(1) DEFINITION.--As used in this section, "medical assistant" means a professional multiskilled person dedicated to assisting in all aspects of medical practice under the direct supervision and responsibility of a physician. This practitioner assists with patient care management, executes administrative and clinical procedures, and often performs managerial and supervisory functions. Competence in the field also requires that a medical assistant adhere to ethical and legal standards of professional practice, recognize and respond to emergencies, and demonstrate professional characteristics.

(2) DUTIES.--Under the direct supervision and responsibility of a licensed physician, a medical assistant may undertake the following duties:

(a) Performing clinical procedures, to include:

1. Performing aseptic procedures.
2. Taking vital signs.
3. Preparing patients for the physician's care.
4. Performing venipunctures and nonintravenous injections.
5. Observing and reporting patients' signs or symptoms.

(b) Administering basic first aid.

(c) Assisting with patient examinations or treatments.

(d) Operating office medical equipment.

(e) Collecting routine laboratory specimens as directed by the physician.

(f) Administering medication as directed by the physician.

(g) Performing basic laboratory procedures.

(h) Performing office procedures including all general administrative duties required by the physician.

(i) Performing dialysis procedures, including home dialysis.

(3) CERTIFICATION.--Medical assistants may be certified by the American Association of Medical Assistants or as a Registered Medical Assistant by the American Medical Technologists.

9. The Board notes that Section 458.3485 does not explicitly preclude medical assistants from performing IV infusion therapy. Subsection (2)(a)4. does however seem to restrict the administration of intravenous injections but IV infusion is clearly not an injection. An intravenous injection is the forced administration of a liquid medication into a vein. In contrast to injection, infusion

involves the introduction of a larger volume of a less concentrated solution over a more protracted period. Rather than forcing the medication into the vein, infusion permits gravity to introduce the medication into the vein through some type of port access.

10. The rest of subsection (2) outlines other various basic duties that may be performed by a medical assistant under the direct supervision and responsibility of a licensed physician. Some of these duties are elements of IV infusion therapy such as the performance of venipunctures; assisting with patient treatments; operating office medical equipment; and administering medication as directed by the physician. Subsection (2)(i) also specifically permits medical assistants to perform dialysis procedures, part of which also includes IV infusion.

11. Given the range of basic duties medical assistants are allowed to perform under Section 458.3485(2), the Board believes that medical assistants may lawfully perform IV infusion therapy as long as it performed under the direct supervision and responsibility of a Florida licensed physician that is always present in the office whenever a medical assistant is providing the therapy to a patient.

12. This conclusion is bolstered by the fact that the performance of Home Drug Infusion Therapy (HDIT) by patients themselves or family member care providers is generally acceptable in modern day medicine. Medicare and Blue Cross/Blue Shield of Florida both cover HDIT when medically justified. If it is established that IV infusion therapy is appropriate and safe for home administration by family members and other unlicensed care givers, it seems both logical and reasonable that IV infusion can also be performed by a trained medical assistant in a physician's office and under the direct supervision and responsibility of the physician.

13. The Board's response to this Petition addresses solely the question propounded by

the Petitioners and only addresses issues regarding the practice of medicine. The Board's conclusion is based solely on the Board's application of the factual circumstances outlined in the Petition to the pertinent statutory and rule provisions set forth above.

This Final Order shall become effective upon filing with the Clerk of the Department of Health.

DONE AND ORDERED this _____ day of _____, 2009.

BOARD OF MEDICINE

Larry McPherson, Jr., Executive Director
For Fred Bearison, M.D., Chair

NOTICE OF APPEAL RIGHTS

Pursuant to Section 120.569, Florida Statutes, Respondents are hereby notified that they may appeal this Final Order by filing one copy of a notice of appeal with the Clerk of the Department of Health and the filing fee and one copy of a notice of appeal with the District Court of Appeal within 30 days of the date this Final Order is filed.