

STATE OF FLORIDA
BOARD OF MEDICINEPETITION 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 physician licensed pursuant to Chapter 458, Florida Statutes, is a substantially affected person 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 is 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.

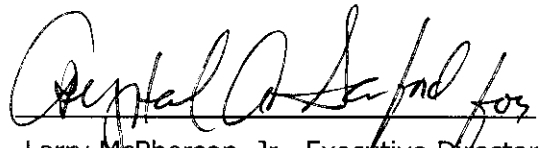
13. The Board's response to this Petition addresses solely the question propounded by

the Petitioner 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 4th day of March, 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.

Sanford, Crystal

From: McPherson, Larry
Sent: Wednesday, March 04, 2009 6:25 AM
To: DL MQA Management Team
Cc: Sanford, Crystal; Prine, Chandra; Taylor, Natalie; 'Ed Tellechea'
Subject: Board of Medicine Delegation

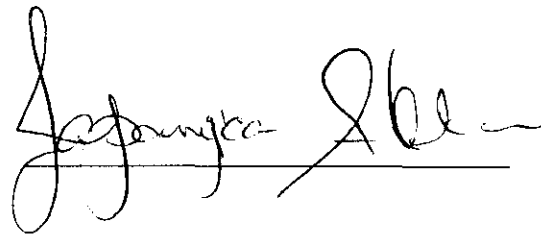
Citizens,

During my absence on March 4, 2009, Board of Medicine Executive Director authority is delegated to Crystal Sanford, CPM, Program Operations Administrator: 245-4132.

Larry McPherson
Executive Director
Florida Board of Medicine

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U. S. Mail to: Allen R. Grossman, Metzger, Grossman, Furlow & Bayo', LLC, 1408 N. Piedmont Way, Tallahassee, Florida 32308; and by interoffice mail to Edward A. Tellechea, Senior Assistant Attorney General, PL-01 The Capitol, Tallahassee, Florida 32399-1050; and Josefina M. Tamayo, General Counsel, Department of Health, 4052 Bald Cypress Way, BIN A02, Tallahassee, Florida 32399-1703, on this 11 day of March, 2009.

A handwritten signature in cursive script, appearing to read "Josefina M. Tamayo", written over a horizontal line.

Deputy Agency Clerk

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Rachel Brooks*
DATE *1.12.09*

STATE OF FLORIDA
BOARD OF MEDICINE

PETITION FOR DECLARATORY
STATEMENT BEFORE THE FLORIDA
BOARD OF MEDICINE ADDRESSING
§458.3485, FLORIDA STATUTES, ON BEHALF
OF YVONNE SMALLWOOD SHERRER, M.D.

Case No.: _____

PETITION FOR DECLARATORY STATEMENT

COMES NOW Petitioner, Yvonne Smallwood Sherrer, M.D. a licensed physician in Florida, by and through undersigned legal counsel and pursuant to §120.565, Florida Statutes, and hereby petitions the Florida Board of Medicine (Hereinafter "Board") for a Declaratory Statement setting forth that she is permitted pursuant to §458.3485, Florida Statutes to utilize the services of a medical assistant in her office and under her direct supervision and responsibility to provide IV Infusion therapy to patients. In support thereof, Petitioner states as follows:

1. Petitioner is a licensed physician in Florida whose license is in good standing. She is a board certified Rheumatologist who treats numerous patients suffering from arthritis and also participates in numerous pharmaceutical studies related to arthritis treatments. IV infusion therapy is commonly used as a treatment modality in her Rheumatology practice and in the various pharmaceutical studies in which she participates. Petitioner's practice is located at 5333 N. Federal Highway, Suite 110, Fort Lauderdale, Florida 33334. For purposes of this Petition all correspondence and communication should be

provided to undersigned counsel for Petitioner at the address, telephone number or facsimile number provided below.

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. Section 458.3485, Florida Statutes addresses the use of medical assistants in Florida. Subsection (1) defines a medical assistant as "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." Subsection (2) describes various duties that can be performed by a medical assistant under the direct supervision and responsibility of a licensed physician, specifically including, the performance of clinical procedures such as performing venipunctures; assisting with patient treatments; operating office medical equipment; and administering medication as directed by the physician. Subsection (2)(i) also specifically permits the performance of dialysis procedures, including home dialysis. There is no requirement in §458.3485, Florida Statutes or anywhere else in Florida law for medical assistants to be licensed in any manner.

4. As a board certified Rheumatologist, Petitioner is extensively trained and experienced in the administration, potential side effects, and complications

related to IV infusion therapy. In addition, each of Petitioner's medical assistants involved in the performance of IV infusion therapy have received training and certification in IV procedures. 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. Although the term "direct supervision and responsibility" is not specifically defined in the statute addressing medical assistants, Petitioner is always present in the office whenever a medical assistant is providing IV infusion therapy to a patient.

5. It is Petitioner's reasonable belief that all of the duties involved in providing IV infusion therapy to her patients fall well within the scope of activities specifically permitted for an unlicensed medical assistant under her direct supervision and responsibility pursuant to §458.3485, Florida Statutes. Medical assistants are specifically permitted by statute to assist in patient treatments; to perform venipunctures¹; to operate office medical equipment; and to administer medication as directed by a physician. Petitioner's belief that it is within the

¹ The statute distinguishes between the performance of venipuncture and intravenous injections. 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. In this case the port access is provided by the venipuncture butterfly that has been left in place.

acceptable scope of duties of a medical assistant to perform IV infusion therapy is further bolstered by the specific authority for medical assistants to perform dialysis procedures both in an office and at the patient's home. Dialysis procedures clearly require the performance of IV infusion therapy.

6. However, Petitioner's understanding of the meaning and application of §458.3485, Florida Statutes has been shaken by reports that the Department of Health has issued an opinion stating that IV infusion therapy cannot be provided by a medical assistant and that in July 2006, the Quality Assurance Committee of the Board of Medicine stated that a medical assistant cannot perform infusion therapy. Allegedly, these positions are based at least in part on a belief that §458.3485(2)(a)4., Florida Statutes, permits only non-intravenous injections. However, IV infusion is not an injection. As discussed above, there are significant differences between injections and infusions and although IV infusion is not specifically mentioned in the statute, all of the components of IV infusion are clearly permitted. Furthermore, if the Legislature had intended to prohibit IV infusion as opposed to IV injections it could have and would have said so. However, it is clear that the Legislature did not intend to prohibit medical assistants from performing IV infusion under the direct supervision and responsibility of a physician because (1) it specifically included all of the elements of IV infusion in the statutory list of duties a medical assistant can perform and (2) it specifically permitted medical assistants to perform dialysis procedures, which includes IV infusion.

7. Furthermore, the performance of Home Drug Infusion Therapy (HDIT) by patients themselves or family member care providers is generally recognized as being within the standard of care in modern day medicine. There have been numerous studies conducted and articles written discussing the efficacy of allowing patients or unlicensed family members of patients who are responsible care providers to perform home IV infusion of drug treatments. Medicare and Blue Cross/Blue Shield of Florida both cover HDIT when medically justified. It is established in practice that IV infusion is appropriate and safe for home administration by family members and other unlicensed care givers (including any capable lay person) and therefore, 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.

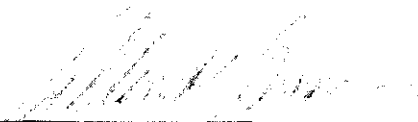
8. Petitioner's Rheumatology practice includes the use of in office IV infusion therapy with Remicade or Boniva for treatment of arthritis; with Reclast for osteoporosis; with Abatacept for rheumatoid arthritis; and other treatments or trials for related conditions. Petitioner wishes to continue the use of unlicensed medical assistants, each of whom has received independent training and certification in the performance of IV procedures, to assist in and provide IV infusion therapy for her patients under her direct supervision and responsibility, but is concerned that the recent statements of the Department of Health and the Quality Assurance Committee of the Board of Medicine suggest a different interpretation as to the meaning of the provisions of §458.3485, Florida Statutes.

pertaining to the scope of duties that may be performed by a medical assistant under the direct supervision and responsibility of a licensed physician.

9. To the best of Petitioner's knowledge the Board of Medicine has never adopted or even proposed any administrative rules intended to explain or clarify the scope of services that may be provided by a medical assistant under the direct supervision and control of a licensed physician.

WHEREFORE, Petitioner, Yvonne Smallwood Sherrer, M.D., respectfully requests that pursuant to §120.565, Florida Statutes, the Board of Medicine issue a Declaratory Order finding that she is authorized within her practice of medicine to delegate the performance of IV infusion therapy, when performed under her direct supervision and responsibility, to an unlicensed medical assistant pursuant to §458.3485, Florida Statutes.

Respectfully submitted, this 12th day of January, 2009.



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On behalf of
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