IN RE: PETITION FOR DECLARATORY
STATEMENT OF RICARDO MEJIA, M.D.

FINAL ORDER ON PETITION FOR DECLARATORY STATEMENT

This matter came before the Board of Medicine (hereinafter the "Board") on April 8, 2016, in Altamonte Springs, Florida, for consideration of the Petition for Declaratory Statement Before the Florida Board of Medicine Addressing § 458.3485, Florida Statutes, On Behalf of Ricardo Mejias, M.D. (attached hereto as exhibit A). The Notice of petition for declaratory Statement was published on March 14, 2016, in Vol. 42, No. 50, of the Florida Administrative Register.

The Petition, filed by Ricardo Mejia, M.D. (hereinafter the "Petitioner"), inquires as to whether as a licensed Florida physician he may, delegate to a medical assistant the excision and harvesting of hair follicles and the performance of incisions for the follicular unit recipient sites to medical assistants in an office setting under his direct supervision and responsibility pursuant to Section 458.3485, Florida Statutes.

FINDINGS OF FACT

1. The facts set forth in the Petition (exhibit A) and attachments are hereby adopted and incorporated herein by reference as the findings of fact by the Board.

CONCLUSIONS OF LAW

2. 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.
3. 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.

4. 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 he allows his medical assistants to undertake responsibilities in contravention of §458.3485, Florida Statutes, he may possibly be subject to disciplinary action by the Board for violating Sections 458.331(1)(w), and 456.072(1)(p), Florida Statutes (2015).

5. In Florida, medical assistants are unlicensed health care personnel regulated pursuant to Section 458.3485 Florida Statutes. 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 and 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.

6. The Board notes that the procedures set forth in the inquiry are surgical procedures. While the Board recognizes that under Section 458.3485(1) Florida Statutes, medical assistants may perform clinical procedures, the performance of surgical procedures is not included in the list of clinical procedures unlicensed medical assistants are permitted to perform as set forth in Section 458.3485(2)(a) Florida Statutes, and is not reasonably incorporated within any of the other specifically identified duties that a medical assistant may do pursuant to Section 458.3485(2)(b)-(i), Florida Statutes.

7. While medical assistants clearly are allowed to assist "in all aspects of medical practice under the direct supervision and responsibility of a physicians," the delegating of the responsibility to perform surgical excisions and incisions related to the transplantation of skin grafts goes well beyond the assisting of physicians. The Board does not find any authority for the proposition that an unlicensed allied health professional is authorized by law to perform surgical procedures.

8. Therefore, the Board is of the opinion that Section 458.3485, Florida Statutes, does not authorize the Petitioner to delegate the task of harvesting follicular units consisting of the excision of skin, subcutaneous tissue and hair follicles by use of a scalpel, micro-punch, motorized surgical extraction device or similar surgical instrument or device and incising the scalp for transplanting such grafts, to a medical assistant, or any other person who is not licensed as a health care practitioner and appropriately trained or otherwise experienced in the performance of such surgical procedures, in an office setting.
9. 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 13th day of January, 2016.

BOARD OF MEDICINE

Claudia Kemp, Executive Director
For Steven Rosenberg, M.D., Chair

NOTICE OF APPEAL RIGHTS

Pursuant to Section 120.569, Florida Statutes, Petitioner is hereby notified that he 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.
CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by email transmission to: Allen R. Grossman, Esquire, at A.Grossman@gfblawfirm.com, and to Edward A. Tellechea, Chief Assistant Attorney General, at Ed.Tellechea@myfloridalegal.com, on this 14th day of June, 2016.

[Signature]
Deputy Agency Clerk
PETITION FOR DECLARATORY STATEMENT

COMES NOW Petitioner, Ricardo Mejia, M.D. (Hereinafter "Petitioner") a licensed physician in Florida, by and through undersigned legal counsel and pursuant to §120.565, Florida Statutes and administrative rule 28-105, F.A.C., and hereby petitions the Florida Board of Medicine (Hereinafter "Board") for a Declaratory Statement setting forth whether he is permitted pursuant to §458.3485, Florida Statutes (A copy of the statute is attached as Exhibit A.) to utilize the services of a medical assistant in his office and under his direct supervision and responsibility to perform the harvesting of skin and subcutaneous tissue containing hair follicles as part of a hair transplant procedure. In support thereof, Petitioner states as follows:

1. Petitioner has been a licensed physician in Florida for 17 years and maintains his medical license (ME78182) in good standing. He is board certified by the American Board of Dermatology and is also a Diplomate of the American Board of Hair Restoration Surgery and a Fellow of the American Society for Mohs Surgery. Petitioner is owner and director of Group M Dermatology, PA, d/b/a Jupiter Dermatology & Hair Restoration, located at 2101 S. U.S. Highway 1,
Jupiter, Florida 33477. 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 is considering the delegation of certain aspects of the hair restoration surgery known as Follicular Unit Transplantation ("FUT") utilizing the Follicular Unit Extraction ("FUE") technique to medical assistants under his direct supervision pursuant to §458.3485, F.S.

3. Petitioner performs hair restoration surgery, utilizing a traditional method involving strip excision of skin and hair down to subcutaneous fat, as well as the newer FUE surgical technique, which removes individual hair follicles from subcutaneous fat with a small circular punch excision of skin for the purpose of donor hair harvesting. Petitioner submits this Petition requesting the Board’s determination regarding his ability to delegate certain aspects of the FUT utilizing the FUE technique to medical assistants under his direct supervision pursuant to §458.3485, F.S. The Board’s determination substantially affects Petitioner because he wishes to practice and in that practice delegate duties only in compliance with Chapter 458, F.S. and the administrative rules of the Board.

4. Hair restoration surgery is a surgical technique used to treat male pattern hair loss ("MPHL"), which involves surgical removal of follicular units ("FU(s)"), and associated removal of skin and subcutaneous tissue, from the back or sides of the head. FUs are small full thickness skin grafts containing hair follicles or hair bundles, which usually consist of 1 - 4 hair follicles. Following surgical removal, the FUs are then harvested and transplanted into incision sites.
in recipient areas of hair loss of the scalp or face (i.e., eyebrows, eyelashes, moustache or beard). A total of up to 3,000 or more recipient sites are surgically created using an incision blade that cuts through the skin deep to the subcutaneous tissue.

5. FUE is a technique used to excise FUs, which requires use of a punch-like “circular scalpel” to score and excise the skin and mid-dermis around an FU to the subcutaneous plane to facilitate its extraction within the scored or excised circle. The FUE surgical technique is similar to the traditional punch biopsy to excise skin and subcutaneous tissue. The FUE surgical technique is performed manually, with an extraction tool known as a micro punch, or with a motorized surgical extraction device or with medical devices, which provide combined excision and suction to remove the FUs, and associated skin and subcutaneous tissue.

6. Hair Restoration Surgery includes the following medical tasks:

(a) Developing, based on the patient’s diagnosed cause of hair loss and discussions with the patient, a surgical transplant and treatment plan including:

(i) Identifying the best type of hair transplant procedure (e.g., FUT utilizing strip harvesting or FUE) to achieve the patient’s short-term and long-term hair restoration goals.

(ii) Identifying the patient’s “safe” donor area based on the patient’s medical history and potential for future hair loss to determine if it is sufficient to
meet the surgical plan's requirements necessary to achieve the patient's short-
term and long-term hair restoration goals.

(iii) Evaluating the patient's anatomical facial features to plan the
distribution and orientation of the FU placements for an appropriate new hairline
that is consistent with the patient's age, expectations, and potential for future loss
of hair.

(b) Excising required FUs, which may exceed 3,000 extractions, with
the associated removal of skin and subcutaneous tissue, from the donor area,
either with strip harvesting or FUE.

(c) Determining and creating incisions of skin in the appropriate
recipient site to the subcutaneous plane (i.e., direction, angle, and depth) for
each FU graft, based on the patient's hair plan and facial symmetry, which may
require in excess of 3,000 incisions.

(d) Determining and managing the appropriate volume amount,
concentration, and type of local anesthesia required during the procedure.

7. 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. (emphasis added)

Subsection (2) describes various clinical procedures that can be performed by a
medical assistant under the direct supervision and responsibility of a licensed
physician, specifically including, 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 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.

8. It has been suggested to Petitioner by colleagues and by business representatives that in Florida medical assistants are permitted to perform under direct supervision medical tasks that are part of clinical procedures and to operate office medical equipment, including motorized or suction surgical devices such as those used to perform the FUE surgical technique.

9. However, it is Petitioner’s concern that the Board may more narrowly construe the tasks medical assistants are specifically permitted to perform under direct supervision pursuant to §458.3485, F.S. Specifically, Petitioner is concerned about the interplay of §458.3485, F.S. with other statutory provisions, including §458.305(3), F.S. (definition of the practice of medicine); §458.331(1)(f), F.S. (prohibition against aiding and assisting in the unlicensed practice of medicine); §458.331(1)(w), F.S. (prohibiting improper delegation of duties) and with Board administrative rules such as 64B8-9.00(2)(a) 64B8-9.009(1)(a), F.A.C. (definitions of surgery, both of which appear to include incisions and extraction of tissue).

10. Although Petitioner would be willing to train and directly supervise his medical assistants in the proper use of such equipment in the office setting, Petitioner believes it is appropriate and necessary to obtain a determination from
the Board as to whether such tasks can be delegated to a medical assistant, prior to actually investing in such training and prior to delegating to a medical assistant the tasks of harvesting hair follicles or making incisions in preparation for transplanting FUs in his office and under his direct supervision.

11. To the best of Petitioner's knowledge the Board 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, Ricardo Mejia, M.D., respectfully requests that pursuant to §120.565, Florida Statutes, the Board of Medicine issue a Declaratory Order setting forth whether it is permissible for Petitioner to delegate the excision and harvesting of hair follicles or the performance of incisions for the follicular unit recipient sites to medical assistants in an office setting under his direct supervision and responsibility pursuant to §458.3485, F.S.

Respectfully submitted, this 7th day of March, 2016.

Allen R. Grossman
Fla. Bar No. 382388
Grossman, Furlow & Bayó, L.L.C.
2022-2 Raymond Diehl Road
Tallahassee, FL 32308
(850)385-1314/fax (850)385-4240

On behalf of
Ricardo Mejia, M.D.
Medical assistant.—

(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.

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   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.

History.—s. 7, ch. 84-543; s. 7, ch. 84-553; ss. 21, 26, ch. 86-245; s. 4, ch. 91-429; s. 28, ch. 97-264; s. 113, ch. 2007-5.
TO: Agency Clerk
Florida Department of Health

FAX #: 413-8743

DATE: March 9, 2016

FROM: Allen R. Grossman

RE: Petition for Declaratory Statement on Behalf of Ricardo Mejia, M.D. (ME78182)

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