

STATE OF FLORIDA  
BOARD OF MEDICINE

IN RE: PETITION FOR DECLARATORY STATEMENT

TIMOTHY HIPPI, M.D.

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**FINAL ORDER**

This matter came before the Board of Medicine (hereinafter the "Board") on April 14, 2011, in Jacksonville, Florida, for consideration of the above referenced Petition for Declaratory Statement. The Notice of Petition for Declaratory Statement was published on March 9, 2012, in Vol. 38, No. 10, in the Florida Administrative Weekly.

The petition filed by Timothy Hipp, M.D. (hereinafter the "Petitioner"), inquires as to whether under circumstances set forth below may Petitioner allow a physician assistant, working under his indirect supervision, perform lapband adjustments in an outpatient clinical setting.

**FINDINGS OF FACTS**

1. Petitioner, Timothy Hipp M.D. is a board certified general surgeon with a sub-specialized bariatric surgical practice. He is an active member of the American Society of Bariatric and Metabolic Surgery, the American Society of Bariatric Physicians, holds a Bariatric Center of Excellence Surgeon designation and practices out of the Surgical Group of Gainesville, P.A. in Gainesville, Florida.
2. Petitioner's bariatric surgery medical practice is conducted at an outpatient hospital clinic under the designation Center for Obesity Surgery & Treatment in Gainesville, Florida
3. Petitioner employs several physician assistants in his bariatric surgery medical practice and desires to utilize them to do lapband adjustments under the indirect supervision of the supervising physician in the outpatient clinical setting. The lapband adjustment

instructions, supplied by the manufacturer Allergan Inc., that will be followed by the Physician Assistant doing the adjustment are as follows:

- a. Shield the reproductive organs of all patients if using radiology to locate the access port.
- b. Wash your hands with a germicidal solution. Sterile gloves must be used.

Penetrate the access port using aseptic technique.

- c. Complete a skin-prep with an antiseptic solution.
- d. Locate the access port radiologically or by manual palpation.
- e. Local anesthesia may be used to eliminate pain during injection.
- f. Position the needle perpendicularly to the septum of the access port.
- g. When adjusting band volume, the needle must be inserted perpendicular to the access port septum. Failure to do so may cause damage to the port and result in leaks.
- h. Use of an inappropriate needle may cause access port leakage and require reoperation to replace the port. Do not use standard hypodermic needles as these may cause leaks. Only LAP-BAND System Access Port Needles or other 20 or 22 gauge non-coring, deflected tip ("Huber tip") needle are to be used.
- i. The radiographic screen must be perpendicular to the needle shaft in order to facilitate adjustment of needle position as needed while moving through the tissue to the port.
- j. When the access port is felt, and just prior to penetrating it, you may confirm radiographically that the needle is properly positioned. Attach a syringe to the needle before penetrating the port. A one-way stopcock can be connected to the needle to prevent fluid loss.
- k. The access port is never to be entered with a "syringeless" needle because the fluid in the device is under pressure and could be released through the needle.

l. When penetrating the access port the port must be penetrated until the needle is stopped by the bottom of the portal chamber. Withdraw some saline to confirm that the bevel of the needle is within the port. If, after penetration, the saline solution cannot be withdrawn or injected, the bevel of the needle may be occluded by the port septum. Try to advance the needle further into the port to the bottom of the portal chamber. If you cannot advance, then re-enter the port with another sterile needle.

m. Once the septum is punctured, do not tilt or rock the needle, as this may cause fluid leakage or damage to the septum.

n. To increase stoma size, taking into account any fluid withdrawn to confirm port penetration, remove fluid to deflate the band and increase the stoma size. Take care to remove only enough fluid to deflate the band; avoid creating a vacuum.

o. To decrease stoma size, taking into account any fluid withdrawn to confirm port penetration, inject additional saline to further Inflate the band and decrease the stoma size.

p. If fluid has been added to decrease the stoma size, it is important to establish that the stoma is not too small, before discharge. Check the adjustment by having the patient drink water. If the patient is unable to swallow, remove some fluid from the port, then recheck. A physician familiar with the adjustment procedure must be available for several days post-adjustment to deflate the band in case of an obstruction.

q. Once significant weight has been lost, it may become possible to palpate and locate the access port without the use of x-ray. If this is the case, complete all the other steps, skin prep, aseptic technique, etc. An evaluation of the stoma and pouch size is recommended via a gastrografin or limited barium swallow prior to and following adjustments. This is important to avoid inadvertent over inflation of the band and possible stoma obstruction.

4. The Petitioner will require Physician Assistant performing such adjustments under his supervision to attend Allergan's training seminar on the proper performance of lapband adjustments prior to performing any adjustments.

5. Prior to performing any lapband adjustments under indirect supervision, the Petitioner will require his Physician Assistants to observe 50 lapband adjustments procedures and perform another 50 under direct supervision.

### **CONCLUSIONS OF LAW**

1. 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.

2. 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.

3. Section 120.565, Florida Statutes, reads as follows:

120.565. Declaratory statement by agencies

(1) Any substantially affected person may seek a declaratory statement regarding an agency's opinion as to the applicability of a statutory provision, or of any rule or order of the agency, as it applies to the petitioner's particular set of circumstances.

(2) The petition seeking a declaratory statement shall state with particularity the petitioner's set of circumstances and shall specify the statutory provision, rule, or order that the petitioner believes may apply to the set of circumstances.

(3) The agency shall give notice of the filing of each petition in the next available issue of the Florida Administrative Weekly and transmit copies of each petition to the committee. The agency shall issue a declaratory statement or deny the petition within 90 days after the filing of the petition. The declaratory statement or denial of the petition shall be noticed in the next available issue of the Florida Administrative Weekly. Agency disposition of petitions shall be final agency action.

4. Rule 28-105.001, Florida Administrative Code, reads as follows:

A declaratory statement is a means for resolving a controversy or answering questions or doubts concerning the applicability of statutory provisions, rules, or orders over which the agency has authority. A petition for declaratory statement may be used only to resolve questions or doubts as to

how the statutes, rules, or orders may apply to the petitioner's particular circumstances. A declaratory statement is not the appropriate means for determining the conduct of another person or for obtaining a policy statement of general applicability from an agency.

5. Rule 64B8-30.012(1) and (2), Florida Administrative Code, reads as follows:

(1) A supervising physician shall delegate only tasks and procedures to the physician assistant which are within the supervising physician's scope of practice. The physician assistant may work in any setting that is within the scope of practice of the supervising physician's practice. The supervising physician's scope of practice shall be defined for the purpose of this section as "those tasks and procedures which the supervising physician is qualified by training or experience to perform."

(2) The decision to permit the physician assistant to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient. Furthermore, the supervising physician must be certain that the physician assistant is knowledgeable and skilled in performing the tasks and procedures assigned.


6. Based on the foregoing statute and rules, the Board is of the opinion that the Petitioner may allow a physician assistant, working under his indirect supervision, to perform lapband adjustments in an outpatient clinical setting under the circumstances set forth in the factual finding section of this Final Order.

7. The Board's response to this Petition answers only the question propounded by the Petitioner and only addresses issues regarding the propriety of physician assistants performing lapband adjustments in an outpatient clinical setting under indirect supervision.

Based on the foregoing, the Board hereby **GRANTS** Dr. Hipp's petition for declaratory statement.

**DONE AND ORDERED** this 20th day of June, 2012.

**BOARD OF MEDICINE**


  
Joy A. Foutle, Executive Director  
For Jason Rosenberg, 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.

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U. S. Mail or by email to: Timothy Hipp, M.D., Surgical Group of Gainesville, P.A., 1143 N.W. 64th Terrace, Gainesville, Florida 32605; Edward A. Tellechea, Senior Assistant Attorney General, PL-01 The Capitol, Tallahassee, Florida 3239-1050, ed.tellechea@myfloridalegal.com; and Nicholas Romanello, General Counsel, Department of Health, 4052 Bald Cypress Way, BIN A02, Tallahassee, Florida 32399-1703, nick.romanello@doh.state.fl.us; on this 11th day of June, 2012



**Deputy Agency Clerk**


Petition For Declaratory Statement before The Board of Medicine

1. Petitioner Timothy Hipp M.D. (ME0081278) of Surgical Group of Gainesville P. A. 1143 NW 64th Terrace Gainesville, Fl. 32605 , (352) 331-1201, fax (352) 331-5273 seeks a declaratory statement from the Board of Medicine with regards to Section 64B8-30.012 of the Florida Administrative Code and Section 458.347 of the Florida Statutes.
2. Petitioner is a board certified general surgeon with a sub specialized bariatric surgical practice. He is an active member of the ASMBS (American Society of Bariatric and Metabolic Surgery), ASBP (American Society of Bariatric Physicians) and holds a Bariatric Center of Excellence Surgeon designation.
3. Petitioner's bariatric surgery medical practice is conducted at an outpatient hospital clinic under the designation Center for Obesity Surgery & Treatment at NFRMC, 6400 Newberry Road Suite 106 Gainesville, FL 32605, (352)-331-5255.
4. Petitioner employs several Physician Assistants in his bariatric surgery medical practice.
5. Petitioner desires to utilize its Physician Assistants to do lapband adjustments under the indirect supervision of the supervising physician in the outpatient clinical setting. The lapband adjustment instructions as supplied by Allergan Inc. (manufacture of the lapband) are as follows:
  - a. Shield the reproductive organs of all patients if using radiology to locate the Access Port.
  - b. Wash your hands with a germicidal solution. Sterile gloves are advised. Always penetrate the Access Port using aseptic technique.
  - c. Complete a skin-prep with an antiseptic solution.
  - d. Locate the Access Port radiologically or by manual palpation.
  - e. Local anesthesia may be used to eliminate pain during injection.
  - f. Position the needle perpendicularly to the septum of the Access Port
  - g. CAUTION: When adjusting band volume, the needle must be inserted perpendicular to the Access Port septum. Failure to do so may cause damage to the port and result in leaks.
  - h. CAUTION: Use of an inappropriate needle may cause Access Port leakage and require reoperation to replace the port. Do not use standard hypodermic needles as these may cause leaks. Use only LAP-BAND® System Access Port Needles or other 20 or 22 gauge non-coring (only), deflected tip ("Huber tip") needle.
  - i. CAUTION: Take care to ensure that the radiographic screen is perpendicular to the needle shaft (the needle will appear as a dot on the screen). This will facilitate adjustment of needle position as needed while moving through the tissue to the port.
  - j. When the Access Port is felt, and just prior to penetrating it, you may confirm radiographically that the needle is properly positioned. Attach a syringe to the needle before penetrating the port. A one-way stopcock can be connected to the needle to prevent fluid loss.
  - k. CAUTION: Never enter the Access Port with a "syringeless" needle. The fluid in the device is under pressure and could be released through the needle.
  - l. Penetrate the Access Port. The port must be penetrated until the needle is stopped by the bottom of the portal chamber. Withdraw some saline to confirm that the bevel of the needle is within the port. If, after penetration, the saline solution cannot be withdrawn or injected, the bevel of the needle may be occluded by the port septum. Try to advance the needle further into

the port to the bottom of the portal chamber. If you cannot advance, then re-enter the port with another sterile needle.

- m. CAUTION: Once the septum is punctured, do not tilt or rock the needle, as this may cause fluid leakage or damage to the septum.
  - n. To increase stoma size: Taking into account any fluid withdrawn to confirm port penetration, remove fluid to deflate the band and increase the stoma size. Take care to remove only enough fluid to deflate the band; avoid creating a vacuum.
  - o. To decrease stoma size: Taking into account any fluid withdrawn to confirm port penetration, inject additional saline to further inflate the band and decrease the stoma size.
  - p. CAUTION: Important: If fluid has been added to decrease the stoma size, it is important to establish that the stoma is not too small, before discharge. Check the adjustment by having the patient drink water. If the patient is unable to swallow, remove some fluid from the port, then recheck. A physician familiar with the adjustment procedure must be available for several days post-adjustment to deflate the band in case of an obstruction.
  - q. Adjustment Following Significant Weight Loss Once significant weight has been lost, it may become possible to palpate and locate the Access Port without the use of x-ray. If this is the case, complete all the other steps, skin prep, aseptic technique, etc. An evaluation of the stoma and pouch size is recommended via a gastrografin or limited barium swallow prior to and following adjustments. This is important to avoid inadvertent over inflation of the band and possible stoma obstruction.
6. Petitioner requires employed Physician Assistant to attend Allergan's training seminar on the proper performance of lapband adjustments.
  7. Petitioner request guidance as to whether it is appropriate to have its Physician Assistants do lapband adjustments in a hospital outpatient clinical setting under the indirect supervision of the supervising physician.

Signed on November 21, 2011

  
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Timothy Hipp M.D.  
Surgical Group of Gainesville P.A.  
1143 NW 64<sup>th</sup> Terrace



**SURGICAL  
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GAINESVILLE, PA**

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November 21, 2011

Department of Health  
Clerk's Office  
4052 Bald Cypress Way, Bin #A02  
Tallahassee, Florida 32399-1703

RE: Petition For Declaratory Statement

Dear Sir or Madam:

Please find enclosed a petition for Declaratory Statement on behalf of Timothy Hipp M.D. and Surgical Group of Gainesville, P.A. Please let me know if there is anything else I need to do or provide. We look forward to the Board's response.

Sincerely,

  
Patrick Bizub  
Practice Administrator

850-488-0595

Feb 21st  
2012  
should  
hear  
back