

STATE OF FLORIDA  
BOARD OF MEDICINE

FILED DATE - 8-24-17  
Department of Health

By: Amy L. Cameron  
Deputy Agency Clerk

DEPARTMENT OF HEALTH,

Petitioner,

vs.

DOH CASE NO.: 2012-12955  
DOAH CASE NO.: 16-4348PL  
LICENSE NO.: ME0045186

DOUGLAS M. BURKS, M.D.,

Respondent.

2017 AUG 28 PM 2:01  
DIVISION OF  
ADMINISTRATIVE HEARINGS

FILED

FINAL ORDER

THIS CAUSE came before the BOARD OF MEDICINE (Board of Medicine) pursuant to Sections 120.569 and 120.57(1), Florida Statutes, on June 9, 2017, in Orlando, Florida, for the purpose of considering the Administrative Law Judge's Recommended Order, the Supplement to Recommended Order on Remand, Petitioner's Exceptions to the Recommended Order, Respondents Exceptions to the Recommended Order, Petitioner's Response to Respondent's Exceptions to the Recommended Order, and Respondent's Response to Department of Health's Exceptions to Recommended Order (copies of which are attached hereto as Exhibits A, B, C, D, E, and F respectively) in the above-styled cause. Petitioner was represented by Chad Dunn, Assistant General Counsel. Respondent was represented by Christopher Schulte, Esquire.

Upon review of the Recommended Order, the argument of the parties, and after a review of the complete record in this case, the Board makes the following findings and conclusions.

#### RULING ON EXCEPTIONS

The Board reviewed and considered the Respondent's Exceptions to the Recommended Order and ruled as follows:

1. The Board reviewed and considered the Respondent's exception to Paragraph 17 of the Recommended Order and denied the exception based upon the reasons set forth by the Petitioner in its written and oral response.

2. The Board reviewed and considered the Petitioner's exception to Paragraph 2 of the Recommended Order and denied the exception for the reasons set forth orally by the Board's counsel and because the finding was based on competent substantial evidence.

3. The Board reviewed and considered the Petitioner's exception to Paragraph 25 of the Recommended Order and denied the exception for the reasons set forth orally by the Board's counsel and because the finding was based on competent substantial evidence.

4. The Board reviewed and considered the Respondent's exception to the penalty in the Recommended Order and denied the exception based upon Respondent's counsel's statement that he no

longer objected to the recommended penalty and found it to be justified.

5. The Board reviewed and considered the Petitioner's exception to paragraph 29 of the Recommended Order and denied the exception because the Petitioner did not file exceptions to the Supplement to the Recommended Order and because no findings were made that cited to any other findings in the record that justified an increase in the penalty.

#### FINDINGS OF FACT

1. The findings of fact set forth in the Recommended Order are approved and adopted and incorporated herein by reference.

2. There is competent substantial evidence to support the findings of fact.

#### CONCLUSIONS OF LAW

1. The Board has jurisdiction of this matter pursuant to Section 120.57(1), Florida Statutes, and Chapter 458, Florida Statutes.

2. The conclusions of law set forth in the Recommended Order are approved and adopted and incorporated herein by reference.

#### PENALTY

Upon a complete review of the record in this case, the Board determines that the penalty recommended by the

Administrative Law Judge be ACCEPTED. WHEREFORE, IT IS HEREBY ORDERED AND ADJUDGED:

1. Respondent shall pay an administrative fine in the amount of \$1,000.00 to the Board within 30 days from the date the Final Order is filed. Said fine shall be paid by money order or cashier's check.

2. Respondent shall be placed on probation for a period of **one year** subject to the following terms and conditions:

a. Respondent shall appear before the Board's Probation Committee at the first meeting after said probation commences, at the last meeting of the Probation Committee preceding termination of probation, and at such other times requested by the Committee. Respondent shall be noticed by Board staff of the date, time and place of the Board's Probation Committee whereat Respondent's appearance is required. Failure of the Respondent to appear as requested or directed shall be considered a violation of the terms of probation, and shall subject the Respondent to disciplinary action.

b. Respondent shall not practice except under the indirect supervision of a **BOARD CERTIFIED** hematologist, oncologist, or internal medicine physician who is trained or experienced in stem cell therapies, and fully licensed under Chapter 458 to be approved by the Board's Probation Committee. Absent provision for and compliance with the terms regarding temporary approval

of a monitoring physician set forth below, Respondent shall cease practice and not practice until the Probationer's Committee approves a monitoring physician. Respondent shall have the monitoring physician present at the first probation appearance before the Probation Committee. Prior to approval of the monitoring physician by the committee, the Respondent shall provide to the monitoring physician a copy of the Administrative Complaint and Final Order filed in this case. A failure of the Respondent or the monitoring physician to appear at the scheduled probation meeting shall constitute a violation of the Board's Final Order. Prior to the approval of the monitoring physician by the Committee, Respondent shall submit to the committee a current curriculum vitae and description of the current practice of the proposed monitoring physician. Said materials shall be received in the Board office no later than fourteen days before the Respondent's first scheduled probation appearance. The attached definition of a monitoring physician is incorporated herein. The responsibilities of a monitoring physician shall include:

(1) Submit quarterly reports, in affidavit form, which shall include:

- A. Brief statement of why physician is on probation.
- B. Description of probationer's practice.

C. Brief statement of probationer's compliance with terms of probation.

D. Brief description of probationer's relationship with monitoring physician.

E. Detail any problems which may have arisen with probationer.

(2) Be available for consultation with Respondent whenever necessary, at a frequency of at least once per month.

(3) Review 100% of Respondent's patient records for all patients treated with stem cell therapy.

(4) Report to the Board any violations by the probationer of Chapter 456 and 458, Florida Statutes, and the rules promulgated pursuant thereto.

c. In view of the need for ongoing and continuous monitoring or supervision, Respondent shall also submit the curriculum vitae and name of an alternate supervising/monitoring physician who shall be approved by Probation Committee. Such physician shall be licensed pursuant to Chapter 458, Florida Statutes, and shall have the same duties and responsibilities as specified for Respondent's monitoring/supervising physician during those periods of time which Respondent's monitoring/supervising physician is temporarily unable to provide supervision. Prior to practicing under the indirect supervision of the alternate monitoring physician or the direct

supervision of the alternate supervising physician, Respondent shall so advise the Board in writing. Respondent shall further advise the Board in writing of the period of time during which Respondent shall practice under the supervision of the alternate monitoring/supervising physician. Respondent shall not practice unless Respondent is under the supervision of either the approved supervising/monitoring physician or the approved alternate.

d. CONTINUITY OF PRACTICE.

(1) TOLLING PROVISIONS. In the event the Respondent leaves the State of Florida for a period of 30 days or more or otherwise does not or may not engage in the active practice of medicine in the State of Florida, then certain provisions of the requirements in the Final Order shall be tolled and shall remain in a tolled status until Respondent returns to the active practice of medicine in the State of Florida. **Respondent shall notify the Compliance Officer 10 days prior to his/her return to practice in the State of Florida.** Unless otherwise set forth in the Final Order, the following requirements and only the following requirements shall be tolled until the Respondent returns to active practice:

(A) The time period of probation shall be tolled.

(B) The provisions regarding supervision whether direct or indirect by the monitor/supervisor, and required reports from the monitor/supervisor shall be tolled.

(2) ACTIVE PRACTICE. In the event that Respondent leaves the active practice of medicine for a period of one year or more, the Respondent may be required to appear before the Board and demonstrate the ability to practice medicine with reasonable skill and safety to patients prior to resuming the practice of medicine in the State of Florida

RULING ON MOTION TO ASSESS COSTS

The Board reviewed the Petitioner's Motion to Assess Costs and voted to bifurcate the ruling on the Motion to Assess Costs. The Motion to Assess Costs will be considered by the Board at a future meeting.

**(NOTE: SEE RULE 64B8-8.0011, FLORIDA ADMINISTRATIVE CODE. UNLESS OTHERWISE SPECIFIED BY FINAL ORDER, THE RULE SETS FORTH THE REQUIREMENTS FOR PERFORMANCE OF ALL PENALTIES CONTAINED IN THIS FINAL ORDER.)**

DONE AND ORDERED this 23<sup>rd</sup> day of August,  
2017.

BOARD OF MEDICINE

Claudia Kemp  
Claudia Kemp, J.D., Executive Director  
For Magdalena Averhoff, M.D., Chair



NOTICE OF RIGHT TO JUDICIAL REVIEW

A PARTY WHO IS ADVERSELY AFFECTED BY THIS FINAL ORDER IS ENTITLED TO JUDICIAL REVIEW PURSUANT TO SECTION 120.68, FLORIDA STATUTES. REVIEW PROCEEDINGS ARE GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. SUCH PROCEEDINGS ARE COMMENCED BY FILING ONE COPY OF A NOTICE OF APPEAL WITH THE AGENCY CLERK OF THE DEPARTMENT OF HEALTH AND A SECOND COPY, ACCOMPANIED BY FILING FEES PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEAL, FIRST DISTRICT, OR WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES. THE NOTICE OF APPEAL MUST BE FILED WITHIN THIRTY (30) DAYS OF RENDITION OF THE ORDER TO BE REVIEWED.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by U.S. Mail to DOUGLAS M. BURKS, M.D., 1151 Shire Street, Nokomis, Florida 34275; to Christopher Schulte, Esquire, Weekley, Schulte, Valdes, LLC, Suite 100, 1635 North Tampa Street, Tampa, Florida 33602; to J. Lawrence Johnston, Administrative Law Judge, Division of Administrative Hearings, The DeSoto Building, 1230 Apalachee Parkway, Tallahassee, Florida 32399-3060; by email to Allison Dudley, Assistant General Counsel, Department of Health, at [Allison.Dudley@flhealth.gov](mailto:Allison.Dudley@flhealth.gov); and by email to Edward A. Tellechea, Chief Assistant Attorney General, at [Ed.Tellechea@myfloridalegal.com](mailto:Ed.Tellechea@myfloridalegal.com) this 24<sup>th</sup> day of August, 2017.

Amy L. Canawry  
Deputy Agency Clerk