

FLORIDA | Board of Pharmacy

Meeting Minutes

October 3-4, 2017

Rosen Plaza Hotel

9700 International Drive

Orlando, FL 32819

Contact Hotel: 407-996-9700



Mark Mikhael, PharmD
Chair

Jeenu Phillip, BPharm
Vice-Chair

C. Erica White
Executive Director

Tuesday, October 3, 2017 at 1:00 PM

Call to Order - The meeting was called to order by the Chair, Dr. Mikhael, at 3:00 p.m.

Roll Call - Those present during the meeting included the following:

Board Members

Mark Mikhael, PharmD, Chair
Jeenu Phillip, BPharm, Vice-Chair
Goar Alvarez, PharmD
David Bisailon
Debra Glass, BPharm
Jeffrey J. Mesaros, PharmD, JD
Gavin Meshad
Michele Weizer, PharmD
Blanca R. Rivera, RPh, CPh, MPharm, MBA

Attorneys

Board Counsel:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Board Staff:

C. Erica White, Executive Director
Irene Lake, Program Operations Administrator
Jessica Hollingsworth, Government Analyst II

I. **Reports**

A. Chair's Report - Mark Mikhael, PharmD, Chair

Discussion:

Dr. Mikhael began the meeting by thanking the committees for their input during discussion in the October committees and for all their hard work. Ms. Blanca Rivera was recognized and welcomed as the newest member of the board of Pharmacy. Those who presented in the October committees, previous board members who attended, Robert Difiore with Investigative Services, Dr. Polles with PRN, and students in the audience were also recognized.

Dr. Mikhael invited Ms. Rivera to join the Compounding and Legislative committees, which she accepted.

Dr. Mikhael recognized the Governor and the Department of Health in their efforts of emergency preparedness after hurricane Irma.

Dr. Mikhael informed the board that he attended the District III meeting in Louisville, Kentucky. He suggested the revival of Budgetary Committee to build in necessary annual meetings during the allocation of the 2018. It was recommended that the following meetings be included in the budget:

- National Association of Boards of Pharmacy (NABP) Annual Meeting
- NABP District III Meeting
- MALTA-GON Meeting
- Florida Pharmacy Association (FPA) National Convention
- Florida Society of Health System Pharmacists (FSHP) State Convention
- American Society for Pharmacy Law (ASPL) Annual Meeting (in which board attorney will attend)
- FDA Intergovernmental Meeting on Compounding
- American Public Health Association (APHA) Annual Meeting
- American Society of Health System Pharmacists (ASHP) Summer Meeting

A motion was made by Dr. Mikhael to enclose the above meetings with the 2018 budget. Motion passed unanimously.

Dr. Mikhael thanked Dr. Weizer for allowing him to present on her behalf and use her slides at the FPA Meeting. He informed the board that the December meeting will begin on Monday at 9 a.m. and asked committee chairs to contact Ms. White if they would like to have a meeting

B. Executive Director's Report – C. Erica White, Executive Director

Discussion:

Ms. White introduced Ms. Irene Lake as the new Program Operations Administrator for the Florida Board of Pharmacy.

1. 2018 Board of Pharmacy Meetings

Ms. White informed the board that the August dates chosen for 2018 conflict with the NABP District III Meeting and requested for the board to choose different dates.

A motion was made by Dr. Weizer to add an extra day to all 2018 meetings and move the August meeting dates to August 6-8, 2018. Motion passed unanimously.

C. Attorney General's Report - David Flynn, Assistant Attorney General

Discussion:

1. Annual Regulatory Plan 2017 – 2018

Mr. Flynn provided an update on the annual regulatory plan, which was filed. He informed the board that applications are in the process of being updated, which is taking time due to the work involved.

2. Monthly Rules Report – September 2017

Mr. Harris gave a brief overview on the September 2017 Rules report. He agreed with Mr. Flynn that the applications will take time and has been in contact with their JAPC attorney on moving the applications forward expeditiously once approved by the board.

D. Investigative Services Report – Robert Difiore, Pharmaceutical Program Manager

Discussion:

Mr. Difiore provided a brief update on the first quarter inspection results.

II. General Business

A. Ratification Lists – A motion was made by Dr. Weizer to approve the following list of ratifications. Motion passed unanimously.

1. Pharmacist (Licensure)
2. Pharmacist (Exam Eligibility)
3. Pharmacist Interns
4. Consultant Pharmacist
5. Nuclear Pharmacist
6. Pharmacy/Facilities
7. Registered Pharmacy Technicians
8. Registered Pharmacy Technician Training Program
9. Nonresident Sterile Compounding
10. CE Providers
11. CE Courses
12. CE Individual Request (Approved)

B. Approval of Minutes

1. August 14, 2017 - Compounding Committee – A motion was made by Dr. Weizer to approve. Motion passed unanimously.
2. August 14, 2017 - Rules Committee – A motion was made by Mr. Bisailon to approve. Motion passed unanimously.
3. August 15, 2017 - Controlled Substance Committee – A motion was made by Dr. Alvarez to approve. Motion passed unanimously.
4. August 15, 2017 - Legislative Committee – A motion was made by Dr. Mesaros to approve pending the change of the statute number from 456 to 465 in both the first paragraph and fourth paragraph on page 3. Motion passed unanimously.
5. August 15-16, 2017 - Full Board Meeting – A motion was made by Dr. Alvarez to approve pending the change of Dr. Fallon's recognition from 5 to 50 years on page 2. Motion passed unanimously.

6. August 25, 2017 - Tripartite Committee Meeting – A motion was made by Dr. Alvarez to approve. Motion passed unanimously.

C. Petitions for Variance or Waiver

1. Elizabeth Niemyjski, 2208/79541; Reference: Rule 64B16-26.351(4), FAC, regarding the waiver of the six-month time-limit in which a Pharmacy Technician Training Program must contain a minimum of one-hundred and sixty (160) hours of training. A motion was made by Dr. Weizer to grant the variance and waiver. Motion passed unanimously.

III. Applications Requiring Board Review

A. Pharmacist Applications

1. Douglas Cammann; 2201/49743 – Present and sworn in. A motion was made by Mr. Philip to approve. Motion passed unanimously.
2. Catherine MacCasland; 2201/51282 – Present with Dr. Polles from PRN and sworn in. A motion was made by Mr. Meshad to approve. Motion passed unanimously.

3. Michael Petrilli; 2201/50147 – Present and sworn in. Mr. Petrilli requested to withdraw his application.

The board agreed that if Mr. Petrilli submits an application by examination, they would have no objection to the application being approved by board staff. Mr. Petrilli was instructed to provide a note with his new application to serve as a reminder.

A motion was made by Dr. Mesaros to accept the request for withdrawal. Motion passed unanimously.

4. Brendan Ricklefs; 2201/50937 – Present and sworn in. Mr. Ricklefs requested to withdraw his application.

The board agreed that if Mr. Ricklefs submits an application by examination, they would have no objection to the application being approved by board staff. Mr. Ricklefs was instructed to provide a note with his new application to serve as a reminder.

A motion was made by Dr. Mesaros to accept the request for withdrawal. Motion passed unanimously.

5. Sanjeev Seenath; 2201/51441 – Discussion ensued regarding concern over the applicant's criminal history and its possible relation to health history. A consensus was reached that the board would feel more comfortable making a decision if the applicant had a PRN evaluation. Board staff agreed to contact the applicant and advise they obtain a PRN evaluation before appearing to help the board with their decision.

A motion was made by Mr. Meshad to require an appearance. Motion passed unanimously.

6. Advit Shah; 2201/51381 – Present with Attorney, Edwin Bayo, and sworn in. Due to the unique situation of Mr. Shah reaching out to the board office on whether his hours were sufficient and the board office incorrectly confirming in addition to his work history, the board agreed to accept the application.

A motion was made by Mr. Philip to approve. Motion passed unanimously.

Break: 5:25 p.m. – 5:35 p.m.

B. Registered Pharmacy Technician Applications

1. Ebony Knight; 2208/77676 – A motion was made by Dr. Mesaros to extend Ms. Knight's required appearance to December. Motion passed unanimously.
2. Nikhil Mani; 2208/76616 – A motion was made by Mr. Philip to deny with the opportunity to withdraw within 5 business days. Motion passed unanimously.
3. Paige Marie Slocum; 2208/78409 – A motion was made by Mr. Philip to approve. Motion passed unanimously.

C. Non-Resident Sterile Compounding Applications

1. Advanced Pharma, Inc.; 2210/283 – **Continued to 10/4/2017**

IV. CE Applications Requiring Board Review

A. Individual Continuing Education Applications

1. Ali Dalili; General Credit – **PULLED**
2. Minh-Tri Duong; General Credit – **PULLED**
3. Dixie Murphy; General Credit – **PULLED**
4. Sheldon J. Rich; General Credit – **PULLED**
5. Uyen Sokol; Live Credit – A motion was made by Mesaros to approve. Motion passed unanimously.
6. Fred Werner; General Credit – **PULLED**

B. Provider Continuing Education Applications

1. CEULAB; Course #20-586471 – **PULLED**
2. Florida Pharmacy Association; Course #20-615792 – **PULLED**

V. Presentations

1. Presentation from Rick Hillbom, MBA, MS, RPh, FACHE, Associate Director of Strategic Alliances - Pharmacy Technician Training Board

Mr. Hillbom gave a PowerPoint presentation on national trends for the regulatory oversight of Pharmacy Technicians, which included a wealth of Pharmacy technician information, including PTCB updates, the Pharmacy Technician Stakeholder Consensus Conference, and technician statistics.

Dr. Weizer asked if the requirements were going to incur additional costs for technicians and if the CEs were going to be incorporated into the current requirements. Mr. Hillbom could not recall but guessed it would be part of the requirements and the exam would be more expensive. Dr. Weizer asked if the 30,000 technicians working in the field were surveyed for the breakout, to clarify why compounding questions were removed from the exam. Mr. Hillbom explained that technicians from retail pharmacies gave pushback on these questions since they don't participate in sterile compounding.

Ms. Glass asked if the program is diversified enough to accommodate technicians working in all settings. Mr. Hillbom answered that they are working to address all roles.

VI. Committee Reports & Actions – Continued to 10/4/2017

1. October 2017 Rules Committee - Jeffrey Mesaros, PharmD, JD, Chair

2. October 2017 Controlled Substances Committee – Gavin Meshad, Chair

3. October 2017 Legislative Committee – Jeenu Philip, BPharm, Chair

Public Comment:

Dr. Gary Daylen, a member of FSHP, informed that board of a resolution that passed in the FSHP Annual meeting on advocating for a Pharmacy Technician to be added as a temporary member to the board of Pharmacy. He was uncertain as to how aggressive FSHP would be in moving forward with this but asked the Legislative Committee to look at that concept. Mr. Philip said he would add this as an agenda topic to the December meeting.

Michael Jackson, Executive Vice-President and CEO of the Florida Pharmacy Association, expressed his surprise in seeing FPA on the agenda for continuing education. Mr. Jackson asked if CE Broker was notified that CEs were extended to the end of October. Ms. White informed Mr. Jackson that she would reach out to CE Broker.

The meeting recessed at 5:45 p.m.

Wednesday, October 4, 2017 at 9:00 AM

Call to Order - The meeting was reconvened by the Chair, Dr. Mikhael, at 9:00 a.m.

Roll Call - Those present during the meeting included the following:

Board Members

Mark Mikhael, PharmD, Chair
Jeenu Phillip, BPharm, Vice-Chair
Goar Alvarez, PharmD
David Bisailon
Debra Glass, BPharm
Jeffrey J. Mesaros, PharmD, JD
Gavin Meshad
Michele Weizer, PharmD
Blanca R. Rivera, RPh, CPh, MPharm, MBA

Attorneys

Board Counsel:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Department of Health Counsel:
Matthew Witters, Assistant General Counsel

Board Staff:

C. Erica White, Executive Director
Irene Lake, Program Operations Administrator
Jessica Hollingsworth, Government Analyst II

Dr. Mikhael recognized previous board members who were in the audience, PRN, Robert Difiore, students in the audience, and the board members who contributed morning snacks for the board. Tom Cuomo reminded Dr. Mikhael that October is National Pharmacist month.

Non-Resident Sterile Compounding Applications

Advanced Pharma, Inc.; 2210/283 – Alejandro Barboza and Samantha Madison were present and sworn in. The application did not include a current inspection in compliance with statutory standards for Florida. Advanced Pharma, Inc. requested a continuance on their application so an inspection can be requested at their expense and completed, giving the board all necessary materials to rule on the application. A motion was made by Dr. Weizer to accept the request. Motion passed unanimously.

Committee Reports & Actions

1. October 2017 Rules Committee - Jeffrey Mesaros, PharmD, JD, Chair

Dr. Mesaros provided a brief overview of the discussion from the Rules Committee meeting (please see October 2017 Rules Committee Minutes), which included a motion to change the ratio from 6:1 to 8:1 under Rule 64B16-27.410(6), FAC.

Dr. Mesaros requested volunteers to review permit application updates. The following applications were assigned:

- Dr. Weizer will review the special sterile compounding pharmacy permit application.
- Mr. Philip will review the community pharmacy permit application.
- Dr. Rivera will review the institutional permit application.
- Dr. Alvarez will review the special pharmacy permit application.
- Dr. Weizer will review the nuclear pharmacy permit application.
- Dr. Mesaros will review the internet pharmacy permit application.

2. October 2017 Controlled Substances Committee – Gavin Meshad, Chair

Mr. Meshad provided a brief overview of the discussion from the Controlled Substances Committee meeting (please see the October 2017 Controlled Substances Committee Minutes), which included a motion to open Rule 64B16-27.831, FAC. for development. Dr. Mikhael will submit the list of recommendations to board staff to send to the board members.

3. October 2017 Legislative Committee – Jeenu Philip, BPharm, Chair

Mr. Philip provided a brief overview of the discussion from the Legislative Committee meeting (please see the Legislative Committee Minutes), which included a motion to propose the suggested language to Section 465.021, FS., pending legislative changes.

VII. Presentations

1. Presentation from Jennifer M. Hoppe, MPH, Senior Associate Director, State and External Relations, and Margherita Labson, Executive Director for the Home Care Accreditation - The Joint Commission (re: approval to conduct inspections for nonresident sterile compounding pharmacies).

Ms. Hoppe thanked the board for accepting the Joint Commission's request to discuss the approval of their Medical Compounding Certification program and Home Care Accreditation program in lieu of conducting state inspections for special sterile compounding permits and non-resident sterile compounding permits. She continued to present information on both programs. Ms. Labson explained the difference between accreditation and certification. Ms. Hoppe and Ms. Labson ended their presentation by answering questions from the board.

Mr. Flynn informed the board that they do not have the statutory authority to approve this request for non-resident sterile compounding permits and that because a complete application was not submitted, the board cannot take action at this time. Dr. Weizer stated that the board cannot make changes to rule when standards are not set.

Dr. Mikhael asked Dr. Weizer if the Compounding Committee had looked at the NABP multi-pharmacy inspection blueprint to crosswalk our inspection. Dr. Weizer responded that the Committee has only looked at it, but not crosswalked it. Mr. Flynn added that our checklist exceeds other checklists; it would be NABP getting up to the Department's standards.

VIII. Disciplinary Cases

A. Settlement Agreements

Recused Members: Gavin Meshad & Jeffrey J. Mesaros

1. Jeffrey Kenneth Butzin, R.Ph.; PSI 28785, Case #2017-04270, File #16527 (**\$3,106.20**) – Present with Attorney, Alfredo Zamora, and sworn in. Dr. Weizer pointed out that the settlement agreement lists the discipline incorrectly and clarified that it should specify a board-approved 12-hour CE course in laws and rules, and a board-approved 8-hour CE course in ethics. She further clarified that under the terms of probation, the manager-quarterly report needs to include evidence of a controlled substance audit which includes 5 controlled substances - 2 high-volume, 2 low-volume, and 1 random drug of choice. The respondent stated for the record that all drugs were stolen for personal consumption only.

A motion was made by Dr. Weizer to accept the orally amended settlement agreement. Motion passed unanimously.

Recused Members: Michele Weizer & David Bisailon

2. Kohlls Pharmacy & Homecare; NSC 63, Case # 2017-06087, File #7 (**\$372.70**) – A motion was made by Mr. Philip to accept the settlement agreement. Motion passed unanimously.

B. Determination of Waivers

The board, as appropriate, accepted unanimously the following motions: 1) The Department asks that you find that the Respondent was properly served and waived the right to a formal hearing (either by failing to respond at all or timely). 2). The Department asks that you accept the investigative report into evidence for the purpose of imposing a penalty. 3). The Department asks that you adopt the findings of fact as set forth in the Administrative Complaint. 4) The Department asks that you adopt the conclusions of law as set forth in the Administrative Complaint and find that this constitutes a violation of the practice act.

Recused Members: Debra Glass & Michele Weizer

1. Angelina Gonzalez; RPT 43541, Case #2017-01058, File #45365 – A motion was made by Mr. Philip to impose revocation. Motion passed unanimously.
2. Withdrawn
3. Michael Joseph Duran; RPT 47104, Case #2016-28719, File #48765 – A motion was made by Mr. Philip to impose revocation. Motion passed unanimously.

Recused Members: Jeffrey J. Mesaros & Gavin Meshad

4. Joseph Rivera; RPT 50769, Case #2016-14358, File #53303 – A motion was made by Ms. Glass to impose revocation. Motion passed unanimously.

Recused Members: Michele Weizer & Jeenu Philip

5. Dana Eugene Sanders, II, R.Ph.; PS 44052, Case #2015-23026, File #36147 – Present with Attorney, Edwin Bayo, and sworn in. A motion was made by Dr. Mesaros to impose a fine of \$10,000 to be paid within 24 months, 1 year of probation, a board approved 12-hour CE course in laws and rules, and a board approved 8-hour CE course in ethics, in which the 20 hours cannot be used towards renewal. Motion passed 7/8 with Dr. Mikhael in opposition. Motion was made by Ms. Glass to impose costs of \$1,372.83 to pay within 60 days. Motion passed unanimously.

C. Voluntary Relinquishments

Recused Members: Jeffrey J. Mesaros & David Bisailon - A motion was made by Mr. Meshad to accept voluntary relinquishments #1-2. Motion passed unanimously.

1. Michael O. Ayotunde, C.Ph.; PU 4996, Case #2016-17772, File #3736
2. Michael O. Ayotunde, R.Ph.; PS 31437, Case #2016-17764, File #20448

No Recused Members - A motion was made by Mr. Meshad to accept voluntary relinquishment #3. Motion passed unanimously.

3. Jodi Anne Ralston; RPT 30611, Case #2017-06000, File #31404

D. Informals

The board, as appropriate, accepted unanimously the following motions: 1). The Department asks that you accept the investigative report into evidence for the purpose of imposing a penalty. 2). The Department asks that you find that the Respondent was properly served and requested an informal hearing. 3). The Department asks that you adopt the findings of fact as set forth in the Administrative Complaint. 4) The Department asks that you adopt the conclusions of law as set forth in the Administrative Complaint and find that this constitutes a violation of the practice act.

Recused Members: Mark Mikhael & Jeenu Philip

1. William T. Walker, R.Ph., PS 27392, Case #2017-07769, File #16428 – A motion was made by Dr. Weizer to impose revocation. Motion passed unanimously.

Recused Members: Jeffrey J. Mesaros & David Bisailon

2. Fernando Noboa; RPT 63255, Case #2017-03496, File #66482 – A motion was made by Ms. Glass to impose revocation. Motion passed unanimously.

Break: 11:44 a.m. – 11:59 a.m.

E. Prosecution Services Report - Matthew Witters, Assistant General Counsel

Mr. Witters provided a brief update on the current caseload for the Prosecution Services Unit. A motion was made by Ms. Glass to allow PSU to continue to prosecute cases older than one year. Motion passed unanimously.

IX. Licensure Issues

A. Petition for Termination of Probation

1. Jillian Boyett; 2201/29509 – Present with Dr. Polles from PRN, and sworn in. Mr. Philip recused himself. A motion was made by Dr. Weizer to terminate probation upon successful completion of the PRN contract. Motion passed unanimously.
2. Michael Kenney; 2201/22782 – Present with Dr. Polles from PRN, and sworn in. A motion was made by Mr. Meshad to terminate probation effective immediately. Motion passed unanimously.
3. Veronica Taran; 2201/31046 – **PULLED**
4. Pharmacy Doctors Enterprises, Inc. – **PULLED**

B. Petitions/Motions for Payment Extensions

1. Julia Thompkins; 2208/17515 – Present with Dr. Polles from PRN, and sworn in. A motion was made by Dr. Mesaros to vacate costs. Motion passed unanimously.

Public Comment:

Verender Gail Brown, a Pharmacy Technician Educator, thanked the board for taking the time to explain the discipline process to her students.

X. Adjournment

The meeting adjourned at 12:21 p.m.