

FLORIDA | Board of Pharmacy

Meeting Minutes

August 15-16, 2017

Embassy Suites Fort Lauderdale

1100 SE 17th Street

Ft Lauderdale, FL 33316

Contact Hotel: 954-315-1326



Mark Mikhael, PharmD
Chair

Jeenu Phillip, BPharm
Vice-Chair

C. Erica White
Executive Director

Tuesday, August 15, 2017 at 1:00 PM

Call to Order - The meeting was called to order by the Chair, Dr. Mikhael, at 1:01 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 Bisaillon
Debra Glass, BPharm
Jeffrey J. Mesaros, PharmD, JD
Gavin Meshad
Michele Weizer, PharmD

Attorneys

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

Board Staff:

C. Erica White, Executive Director
Savada Knight, Regulatory Supervisor
Jessica Hollingsworth, Government Analyst II

I. **Reports**

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

Discussion:

Dr. Mikhael recognized Dr. Weizer for attending the annual FSHP meeting, which Dr. Weizer gave a brief update on - noting the presentations and credit hours available and the large amount of people who attended. She also informed the board that the venue was changing for next year. Dr. Mikhael also recognized Dr. Alvarez for attending the FPA Meeting in Orlando, in which he gave a brief update and congratulated Dr. Fallon on receiving his 50th year certificate. Dr. Mikhael also mentioned that Dr. Mesaros spoke at the conference and recognized Dr. Alvarez for the award he received. Dr. Mikhael also gave a brief summary on the NABP District meeting, which took place in Louisville, Kentucky.

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

Discussion:

Ms. White recognized Jessica Hollingsworth, Government Analyst II for the Bureau of HCPR, for attending and assisting with the August board meeting and introduced Savada Knight as the new Regulatory Supervisor for the Board of Pharmacy, who will attend the meetings from now on.

1. Selection of Committee members under Section 465.186, FS

Mr. Philip provided a brief overview of the statute and the professions involved. He noted that this committee has not met for a long time and recommended that this committee reconvene. He further requested for 3 pharmacy members to be selected in anticipation of the committee reconvening.

A motion was made by Mikhael to appoint Mr. Philip as a committee member. Motion passed unanimously. A motion was made by Philip to appoint Dr. Weizer as a committee member. Motion passed unanimously. A motion was made by Mikhael to appoint Ms. Glass as a committee member. Motion passed unanimously.

Mr. Flynn suggested that the board work through their executive office and reach out to other boards that also need to appoint committee members.

2. EMS Drug Shortage Task Force

Dr. Weizer informed the board that she serves on the EMS Drug Shortage Task Force, which has been resurrected due to the current drug shortage. She explained the seriousness of the drug shortage problem and the role the task force plays in addressing this. The first meeting will be on August 29, 2017

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

Discussion:

Mr. Flynn referred the board to the rules report in the agenda. He further informed the board that the Annual Regulatory Plan must be filed before next board meeting.

A motion was made by Weizer to allow Mr. Flynn and Mr. Harris to work on the annual regulatory plan. Motion passed unanimously.

Mr. Flynn informed the board that the annual regulatory plan will include the updating of all applications and forms. Mr. Flynn and Mr. Harris will be working with the board staff in completing this.

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

Discussion:

Mr. Difiore gave the board a brief overview of the current state and measures of the

investigative services unit. The board members thanked Mr. Difiore and his staff for their assistance in keeping the Florida public safe.

II. General Business

A. Ratification Lists – A motion was made by 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. Nonresident Sterile Compounding
9. CE Providers
10. CE Courses
11. CE Individual Request (Approved)
12. CE Individual Request (Denied)

B. Approval of Minutes

1. April Full Board Minutes – A motion was made by Glass to approve pending the correction of changing Mr. Jeenu to Mr. Philip on pg. 10. Motion passed unanimously.
2. June Full Board Minutes – A motion was made by Mesaros to approve pending the addition of who made the motion on pg. 10, #8, and the outcome of the motion on pg. 10, #9. Motion passed unanimously.
3. June Rule Committee Minutes – A motion was made by Alvarez to approve. Motion passed unanimously.

C. Petitions for Declaratory Statement

1. Eric Dietrich, PS 40021, and the University of Florida College of Pharmacy; Reference: Section 465.003(13), FS and Rule 64B16-27.830(1), FAC, regarding whether clinical activities performed by a licensed Pharmacist in a physician's office within the framework of a Prescriber Care Plan are within the Scope of Practice for a Florida Pharmacist. - **PULLED**

D. Petitions for Rulemaking

1. Pacifico National, Inc., PH 16954 & PH 27532; Reference: Rule 64B16-28.608, FAC, regarding the amendment of six registered pharmacy technicians to one pharmacist (6:1) ratio to ten registered pharmacy technicians to one pharmacist (10:1) ratio. - Attorney,

Edwin Bayo, was present. Dr. Mesaros advised that this be discussed in the next rules committee due to the potential impact this rule change could have, in which everyone agreed. A motion was made by Mesaros to open the rule for development. Motion passed unanimously.

E. Petitions for Variance or Waiver

1. Richard W. Brady, PS 19057; Reference: Rule 64B16-26.1003 & 64B16-26.1021, FAC, regarding the waiver of the 24-hour consultant pharmacist CE requirement in rule 64B16-26.103, FAC. – A motion was made by Meshad to acknowledge that the hardship criteria have been met pending a letter of verification from a physician. Motion passed unanimously. A motion was made by Alvarez to amend the renewal fee to \$6 (\$5, ULA and \$1 renewal). Motion passed unanimously. A motion was made by Philip to amend the delinquent fee to \$1. Motion passed unanimously. Discussion ensued regarding the CE requirement. A motion was made by Mikhael to amend the 24-hour consultant pharmacist CE requirement to general hours. Motion passed unanimously.

III. Applications Requiring Board Review (2:33 p.m.)

A. Pharmacist Applications

1. Dobritch, Alan; 2201/49916 – Present and sworn in. A motion was made by Philip to approve the application. Motion passed unanimously.
2. Perez, Maritza; 2201/49436 – A motion was made by Philip to require an appearance. Motion passed unanimously.
3. Wyczesany, Piotr; 2201/50039 – A motion was made by Philip to vacate the previous motion to require an appearance. Motion passed unanimously. A motion was made by Philip to approve the application. Motion passed unanimously.

The meeting recessed at 2:45 p.m.

The meeting reconvened at 3:00 p.m.

B. Pharmacist Intern Applications

1. Rhoads, Ellamy; 2202/25890 – Present with Dr. Polles, Medical Director for PRN, and sworn in. A motion was made by Mikhael to approve the application. Motion passed unanimously.

C. Nuclear Pharmacist Applications

1. Nielson, Philip; 2204/472 – Present and sworn in. A motion was made by Weizer to approve the application after receiving the requested information on the record. Motion passed unanimously.

D. Registered Pharmacy Technician Applications

1. Jenkins, Michelle; 2208/75168 – A motion was made by Alvarez to deny due to failure to appear. Motion passed unanimously.

E. Pharmacy Permit Applications

1. Genoa, a QoI Healthcare Company, LLC; 2205/24861 – Present and sworn in. A motion was made by Mesaros to approve the application. Motion passed unanimously.
2. Brooksville Pharmaceuticals; 2205/24967 – Present with Attorney, Edwin Bayo, and sworn in. A motion was made by Mikhael to delegate approval of the application to the Chair of the Compounding Committee, Dr. Weizer, upon verifying completion of inspection. Motion passed unanimously.

F. Non-Resident Sterile Compounding Applications

1. Auro Pharmacies; 2210/259 – A motion was made by Weizer to deny due to ineligibility. Motion passed unanimously.

IV. Other Business

1. Presentation from Michael A. Moné, Cardinal Health/TelePharmacy

Mr. Moné, presenting as a representative for Cardinal Health, informed the board that presentation materials were provided to board staff for the agenda. Ms. White further informed the board that these materials were given to board staff who are no longer with the department. Mr. Moné will resend the materials at a later date but continued with his presentation. Mr. Moné gave a brief presentation on TelePharmacy, focusing on security and diversion. He explained the Indiana model as an example when discussing security cameras, monitoring supplies, qualifications for technicians, etc. Mr. Moné also informed the board that legislative materials he referred to for Section 465.003 (11)(A), F.S. can be found in the legislative committee agenda.

2. Presentation from Lindsay Brown, Troy Group Inc.

Mr. Brown, presenting as a representative for Troy Group, Inc., informed the board of his company's software solution to paper prescriptions, which is now used in 40 states. The solution solves the problem of pre-printed prescription paper theft, allowing prescription paper to be printed only as needed. Mr. Flynn informed Mr. Brown that rules regarding prescription pads fall outside of the Board of Pharmacy's purview. Ms. White will give Mr. Brown the correct contact to present his product to.

V. Committee Reports & Actions

1. August 2017 Compounding Committee - Michele Weizer, PharmD, Chair

A motion was made by Mesaros to accept the committee recommendation and close 64B16-27.797, F.A.C.. Motion passed unanimously.

A motion was made by Glass to accept the committee recommendation and approve the comments in the JAPC letter for Rule 64B16-28.802, F.A.C. Motion passed unanimously.

2. August 2017 Rules Committee - Jeffrey Mesaros, PharmD, JD, Chair

A motion was made by Mikhael to accept the committee recommendation and propose the suggested/updated language to subsection 1 and 2, and strike subsection 3 from Rule 64B16-27.100, FAC. Motion passed unanimously.

A motion was made Weizer to accept the committee recommendation and authorize a notice of change to correct the JAPC comments and authorize Mr. Harris to respond in writing to answer remaining questions for Rule 64B16-28.301 and Rule 64B16-28.501, FAC. Motion passed unanimously.

A motion was made by Mikhael to accept the committee recommendation and authorize a notice of change with the discussed updates to correct the JAPC comments and authorize Mr. Harris to respond in writing to answer remaining questions for Rule 64B16-28.608. Motion passed unanimously.

A motion was made by Glass to accept the committee recommendation and propose language to Rule 64B16-30.002, FAC to add a violation of this rule as a minor violation, which could be corrected through issuance of a notice of non-compliance. Motion passed unanimously

A motion was made by Philip to accept the committee recommendation and amend language regarding the removal of “on the premises” from Rule 64B16-27.410, FAC. Discussion ensued regarding the committee’s recommendation. Mr. Flynn advised the board not to remove this language without further research. The board agreed and Mr. Philip withdrew his motion.

VI. Public Comment

John Roccio, with CVS, informed the board that this is his last meeting. He thanked the board for their hard work and the board did the same for him.

The meeting recessed at 4:31 p.m.

Wednesday, August 16, 2017 at 9:00 AM

Call to Order - The meeting was reconvened by the Chair, Dr. Mikhael, at 9:01 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

Attorneys

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

Department of Health Counsel:
Christopher Jurich, Assistant General Counsel

Board Staff:

C. Erica White, Executive Director
Savada Knight, Regulatory Supervisor
Jessica Hollingsworth, Government Analyst II

Dr. Mikhael recognized Albert Garcia and Bob Parrado, who previously served on the Board of Pharmacy, for attending the meeting. He also recognized Dr. Polles from PRN, and Robert Difiore, Pharmaceutical Program Manager, and students in the audience for attending the meeting. Lastly, Dr. Mikhael and the rest of the board members congratulated Mr. Philip in being elected as representative for district 3 of the National Associates for Boards of Pharmacy and Ms. Glass in being elected as an alternate.

I. Committee Reports & Actions

1. August 2017 Legislative Committee - Jeenu Philip, BPharm, Chair

Mr. Philip gave an overview of the discussion that took place in the Legislative Committee meeting.

A motion was made by Philip to accept the committee recommendations and accept the proposed amended language for Section 456.0392, FS and to allow this language to be moved forward for legislation. Motion passed unanimously.

2. August 2017 Controlled Substances Committee - Gavin Meshad, Chair

Mr. Meshad gave an overview of the discussion that took place in the Controlled Substances Committee meeting.

II. Disciplinary Cases

A. Settlement Agreements

Recused Members: Jeenu Philip & Gavin Meshad

1. Whitt, James P.; PS 23825, Case #2016-27094, File #12920 (**\$507.25**) – A motion was made by Weizer to accept the settlement agreement. Motion passed unanimously.

Recused Members: Jeffrey J. Mesaros & Goar Alvarez

2. Gailey, Jennifer Taylor; PS 43764, Case #2016-30496, File #35515 – Present with Attorney, Robert Griscti, Dr. Polis from PRN, and sworn in. A motion was made by Philip to accept the settlement agreement with the oral amendment of decreasing the fine to \$2000, which should be paid with costs prior to termination of probation, and a required appearance to demonstrate compliance with probation. Motion passed unanimously. A motion was made by Philip to lift the suspension with the PRN evaluation that she is safe to practice. Motion passed unanimously.

B. Determination of Waivers

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 waived the right to a formal hearing (either by failing to respond at all or timely). 3). The Department asks that you adopt the findings of fact and conclusions of law as set forth in the Administrative Complaint and find that this constitutes a violation of the practice act.

Recused Members: Michele Weizer & Debra Glass

1. Lissmart Medical Supply, Inc.; PH 23040, Case # 2016-29820, File #15645 – A motion was made by Mikhael to impose revocation. Motion passed unanimously.
2. Kline, Bruce Robert; PS 46053, Case #2016-28462, File #37952 – Dr. Polles with PRN confirmed that Mr. Kline is currently non-compliant with PRN. A motion was made by

Philip to impose costs of \$86.77 and suspension until compliant with previous final order. Motion passed 5/6 with Mikhael in opposition. A motion was made by Philip to impose that costs to be payable upon reinstatement. Motion passed unanimously.

3. Lissmart Medical Supply, Inc.; PH 24199, Case #2016-29821, File #16857 – A motion was made by Philip to impose revocation. Motion passed unanimously.
4. Ortega, Lilette C.; RPT 62622, Case # 2016-29037, File #66821 – A motion was made by Philip to impose revocation. Motion passed unanimously.

Recused Members: Michele Weizer & Jeenu Philip

5. Hernandez-Chang, Frank M.; RPT 44337, Case # 2015-07317, File #46167 – A motion was made by Glass to impose revocation. Motion passed unanimously.

Recused Members: Michele Weizer & Leo “Lee” Fallon

6. Mercado-Sanchez, Oneida; PS 22956, Case #2013-05718, File #12096 – Mr. Flynn and Ms. White confirmed for the board that a notice of unavailability was received but no request for a continuance was received. A motion was made by Glass to impose revocation. Motion passed unanimously.

Recused Members: Michele Weizer & Jeenu Philip

7. Rodriguez, Jennifer Lee; RPT 63673, Case #2016-09842, File #66404 – A motion was made by Meshad to impose revocation. Motion passed unanimously.

Recused Members: Michele Weizer & Debra Glass

8. Brown, Kisswana; RPT 65794, Case #2017-00762, File #69028 – A motion was made by Alvarez to impose revocation. Motion passed unanimously.
9. Fernandez, Marlenis; RPT 48453, Case #2016-17827, File #50775 – A motion was made by Bisailon to impose revocation. Motion passed unanimously.

Recused Members: Jeenu Philip & Gavin Meshad

10. Fink, Brian; RPT 41021, Case #2017-03100, File #42581 – A motion was made by Weizer to impose revocation. Motion passed unanimously.

Recused Members: David Bisailon & Leo “Lee” Fallon

11. Parks, Toshiba Donta; RPT 36826, Case #2016-17175, File #37628 – A motion was made by Weizer to impose revocation. Motion passed unanimously.

C. Voluntary Relinquishments

No Recused Members - A motion was made by Glass to accept voluntary

relinquishments #1-4. Motion passed unanimously.

1. Girasol Pharmacy & Discount, Inc.; PH 28434, Case # 2017-01527, File #21785
2. My Pharmacy Discount Corp; PH 28466, Case #2017-00793, File #21840
3. Alvarado, Jasmine RPT 16266, Case # 2017-06716, File #11271
4. Menendez, Luis Francisco; RPT 60890, Case #2017-08907, File #64195.

Recused Members: Mark Mikhael & Debra Glass – A motion was made by Bisailon to accept voluntary relinquishment #5. Motion passed unanimously

5. Martin, Austin Chandler; RPT 51693, Case # 2015-28233, File #54130.

Recused Members: Jeffrey J. Mesaros & Goar Alvarez – A motion was made by Philip to accept voluntary relinquishments #6-8. Motion passed unanimously.

6. Gray, Alan David; PS 23115, Case #2016-23739, File #12248
7. City Pharmacy Corp; RPT 29006, Case #2017-00558, File #22260
8. Rodriguez, Lissette Natasha; RPT 59122, Case #2016-15689, File #61455

Recused Members: Jeenu Philip & Debra Glass – A motion was made by Weizer to accept voluntary relinquishment #9. Motion passed unanimously.

9. Klabe, Stephen Scott; PS 49293, Case #2016-16519, File #41693 (Case #2016-16521 – PULLED)

Recused Members: Michele Weizer & Debra Glass – A motion was made by Alvarez to accept voluntary relinquishment #10. Motion passed unanimously.

10. Calvo, Ileana; RPT 51465, Case #2016-17850, File #53828

Recused Members: Jeenu Philip & Gavin Meshad – A motion was made by Weizer to accept voluntary relinquishment #11. Motion passed unanimously.

11. Washington, Kevin Bruce; RPT 59175, Case #2016-30494, File #60278

D. Prosecution Services Report - Christopher Jurich, Assistant General Counsel

Mr. Jurich informed the board that a new attorney started, which will help with lowering the case-load. He continued with a brief update on the current caseload for the Prosecution Services Unit. A motion was made by Glass to allow PSU to continue to prosecute cases older than 1 year. Motion passed unanimously.

III. Licensure Issues

Break – 11:05 a.m. – 11:20 a.m.

A. Motion for Reconsideration

1. Sanders II, Dana Eugene; 2201/36147 – Dr. Weizer and Mr. Philip were recused. Present with Attorneys, George F. Indest III and Edwin Bayo, and sworn in. Mr. Sanders stated for the record that he agreed to waive the fees. A motion was made by Meshad to vacate the previous final order. Motion passed unanimously. Parties will work with PSU to determine a Settlement Agreement and the case will be brought back at a future meeting.

B. Petition for Termination of Probation

1. Friedman, Howard; 2201/16184 – A motion was made by Philip to accept the petition and terminate probation. Motion passed unanimously.
2. Wilson, Steven; 2201/6919 – Present with Attorney, Martin Dix, and sworn in. A motion was made by Weizer to accept the petition and terminate probation with completion of 12 hours of Laws and Rules by March 1, 2018. Motion passed unanimously

C. Petition to Lift Restriction & Request Payment Extension

1. Alonso, Richard; 2201/31017 – Present with Dr. Raymond Pomm, and sworn in. A motion was made by Meshad to grant a payment and 12-hour Laws & Rules CE course extension to February 24, 2018 and lift the restriction to work with medicinal drugs. Motion passed unanimously.

D. Petitions/Motions for Payment Extensions

1. Gonzalez, Marcial; 2201/10882 – Present and sworn in. A motion was made by Weizer to grant a payment, 8-hour ethics CE course, and 12-hour Laws & Rules CE course extension to the end of probation. Motion passed unanimously.
2. Professional Pharmacy & Compounding Services; 2205/20645 – Attorney, Edwin Bayo, was present. At the request of Mr. Bayo, the case was pulled.

E. Petition for Clarification on Probationary Terms

1. Bulfer, Brian; 2201/10804 – Present with Attorney, Edwin Bayo, and sworn in. A motion was made by Mesaros to accept Mr. Bulfer's appearance today as the required appearance for January and to terminate probation. Motion passed unanimously.

Public Comment:

Dr. Mikhael thanked Eric Alvarez, a past board member, for attending the board meeting.

Dr. Alvarez thanked the different committees for the work they have been doing.

Brian Conn, a Pharmacist Attorney, informed the board that PDMP is permanently funded through the last legislative session.

IV. Adjournment

The meeting adjourned at 12:47 p.m.