

FLORIDA | Board of Pharmacy

Draft Meeting Minutes

December 12-13, 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

Call to Order - The meeting was called to order by the Chair, Dr. Mikhael, at 1:30 p.m.

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

Board Members

Mark Mikhael, PharmD, Chair
Jeenu Philip, BPharm, Vice-Chair
David Bisailon
Jonathan Hickman, PharmD
Jeffrey J. Mesaros, PharmD, JD
Gavin Meshad
Richard Montgomery, BPharm
Blanca R. Rivera, RPh, CPh, MPharm, MBA
David Wright, BPharm

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

I. **Reports**

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

Discussion:

Dr. Mikhael thanked Dr. Weizer, Ms. Glass, and Dr. Alvarez for their commitment. Welcomed new members.

Dr. Mesaros provided an update on the Malta-gon meeting. Described Malta-gon – discussion of ratios, expansion of duties; discipline issues, inspection issues, and opioid crisis. Becomes a group discussion. Our state is working through medical cannabis. Tone was positive and inquisitive.

Mr. Philip provided an update on the ASPL (American Society of Pharmacy Law) meeting. ASPL provides the most robust content. Discussed compounding. We have been ahead of the curve in compounding. Healthcare law and ethical policy in big data use; did not really tie to the practice pharmacy. Privacy issues that come into play when talking about data. Discussed regulatory challenges and technical requirements. Another topic was anti-kickback. It is a top propriety for the Department of Justice. If you are not sure if something is a kick-back, you can reach out to the OIG for advice. Expanding scope of practice. Other government entities starting to leverage pharmacists more and more. Increase scope, you increase liability.

Mr. Montgomery provided an update on the ASHP meeting. Discussion around compounding. Mr. Flynn provided an update on the NABP Legal Counsel and Compliance Officer Forum. It was

invaluable for Mr. Flynn to attend and network with lawyers in other states with robust regulatory processes.

Dr. Mikhael – Provision allows past members to participate on the PCP. Ms. Glass and Dr. Weizer agreed to alternate months; one current, one past. Tripartite Committee has been broken; Ms. Glass has agreed to take over as Chair. Dr. Mesaros asked if Dr. Alvarez and Dr. Weizer can participate on the Tripartite committee? Dr. Mikhael asked Ms. White to reach out and see if they would like to serve on the Tripartite committee.

Elections and nominations for 2018. Dr. Mikhael nominated Mr. Philip for Chair. Motion made by Dr. Mikhael for Mr. Philip as Chair for 2018. Motion passed unanimously. Mr. Philip made motion for Dr. Mesaros to be Vice-Chair for 2018. Motion passed unanimously.

Dr. Mesaros shared that he participated on a panel discussion at Nova.

Dr. Mikhael shared that he spoke at the FMA Opioid Summit.

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

Discussion:

1. Delegation to Executive Order – Every year the Chair signs the delegations to the Executive Director. Information should be included related to policy & procedures for permits on every application; Rules committee working on amending to add; believes she has to be delegated authority to review this information. Mr. Harris read the rule. The Board must review the P&P and deny if does not comply; believes it is a delegable task to staff specifically the pharmacy consultant; needs standards for staff to review; we have a rule for controlled substance dispensing; suggestion – delegate standard with compliance with controlled substance dispensing rule. Motion made by Mr. Montgomery to delegate to board staff. Motion passed unanimously. Mr. Harris will take lead. Provided email address and encouraged members and public to email him suggestions.
2. 2018 Board of Pharmacy – Meeting Schedule
3. 2018 Board of Pharmacy – Proposed PCP Dates will be updated to add Ms. Glass and Dr. Weizer.

Break at 2:30 pm
Start 2:40 pm.

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

Discussion:

1. Monthly Rules Report – September 2017
Mr. Harris provided an update on the rules report. Will see more rules in the next 6-8 months.

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

Discussion:

Mr. Difiore presented current inspection numbers and proposed process map for recalls for outsourcing 503B facilities.

II. General Business

A. Ratification Lists – A motion was made by Mr. Meshad for ratification. 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

B. Approval of Minutes

1. October 2, 2017 – Rules Committee – A motion was made by Dr. Mesaros to approve. Motion passed unanimously.
2. October 3, 2017 – Controlled Substance Committee – A motion was made by Mr. Philip to approve. Motion passed unanimously.
3. October 3, 2017 – Legislative Committee – A motion was made by Mr. Bisailon to approve. Motion passed unanimously.
4. October 3-4, 2017 – Full Board – A motion was made by Mr. Bisailon to approve. Motion passed unanimously.

C. Request for Approval for AHCA Exemption

1. Felix Mitchell; 2201/34183 – Present and sworn in. Motion made by Mr. Bisailon to approve. Motion passed unanimously.

III. Applications Requiring Board Review

A. Pharmacist Applications

1. Maritza Perez; 2201/49436 – Present and sworn in. Dr. Mikhael made a motion to approve application by endorsement. Motion passed unanimously.
2. Sanjeev Seenath; 2201/51441 – Present and sworn in. Mr. Philip made a recommendation for a PRN evaluation. Dr. Mikhael made a motion to continue to the next board meeting. Motion passed unanimously. Applicant waived 90 days.
3. Samuel Shearer; 2201/51434 – Not present. Dr. Mesaros made a motion to require

appearance at the next two meetings with the understanding that the applicant will be contacted regarding the option of withdrawing or providing supporting documentation regarding the incident. Motion passed unanimously.

B. Pharmacy Permits

1. Costco Wholesale Corporation, Store #583; 2205/25077 – Dr. Mikhael made a motion to approve. Motion passed unanimously.
2. Biologics Inc.; 2205/25029 - Phyllis Smith and Attorney John Guard present and sworn in. Dr. Mikhael made a motion to approve. Motion passed unanimously.
3. Germaine Pharmacy, Inc. 2205/24833 – Scott Courtney and Attorney Mr. Bayo present and sworn in. Dr. Mikhael made motion to approve. Motion passed unanimously.

C. Non-Resident Sterile Compounding Applications

1. Imprimis Njof, LLC; 2210/277 – Brad Bingham and Proamod Sharma present and sworn in. Applicant requested continuance to obtain Department inspection. Motion made by Dr. Mesaros to delegate board member to review new inspection and issue license if approved. Motion passed unanimously. Applicant waived 90 days.

D. Registered Pharmacy Technician

1. Ebony Knight; 2208/77676 – Not present. Dr. Mikhael made a motion to deny. Motion passed unanimously.

IV. Presentations

1. **Presentation from Dorothy Brown, PharmD, MBA, Vaccines Field Medical Liaison, Vaccines Clinical and Medical Affairs, US, GKS – Florida – Cancelled.**

V. Committee Reports & Actions

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

Mr. Harris provided an update on the Rules report. Dr. Mesaros provided a brief overview of the discussion from the Rules Committee meeting (please see the Rules Committee Minutes).

- **Rule 64B16-28.141, F.A.C.** – Requirements for an Automated Pharmacy System in a Community Pharmacy
- **Rule 64B16-28.301, F.A.C. and Rule 64B16-28.303, F.A.C.**
Withdrawn. No discussion; no action by the Board.
- **Rule 64B16-27.410, F.A.C.** - Registered Pharmacy Technician to Pharmacist Ratio Committee voted to move forward with amended language that would incorporate changes to the ratios:
Ratio 3:1 for pharmacies engaging in sterile compounding.

Ratio 6:1 for dispensing pharmacies not engaged in sterile compounding.
Ratio 8:1 for non-dispensing pharmacies and dispensing pharmacies that have a segregated partition.

Included language that there would be no entities that would interfere with the setting of the ratio done by the prescription department manager or consultant of record.

Dr. Mikhael advised that he may vote no for this language, not because he is not in favor of it, but because he is in favor of an expansion of no ratio.

Motion made by Mr. Philip to move forward as described. Motion passed unanimously.

- **Rule 64B16—27.630, F.A.C. – Additional Immunizations or Vaccines Which May Be Administered**

The Committee voted to open 27.630 for development and in the event the adult immunization schedule is released adding SHINGRIX, then publish the proposed the rule immediately.

Motion made by Dr. Mikhael to move rule forward and to accept the recommendation from the Committee for the four questions as being “no.” Motion passed unanimously.

- **Rule 64B16-28.100, F.A.C., and Amendments to Pharmacy Permit Applications**

Dr. Mesaros provided a brief overview of the discussion from the Rules Committee meeting (please see the Rules Committee Minutes). Additional changes will be completed and a telephone conference scheduled to vote on the revised applications.

The meeting recessed at 5:22.

Start 5:36

2. December 2017 Compounding Committee

- Rule 64B16-27.1001, F.A.C. – Practice of Pharmacy – Will be responding back to JAPC.
- Rule Hearing – Rule 64B16-27.700, F.A.C. – Compounding of physicians is not under the purview of the Board of Pharmacy; it falls under the Board of Medicine as long as they are not dispensing.

3. December 2017 Controlled Substances Committee – Gavin Meshad, Chair

Moved to December 13, 2017. Working on embellishing Rule 64B16-27.831. Dr. Hickman will work with Mr. Flynn. Approve new draft of letter in support of legislation to combat opioid addiction. Motion made by Mr. Bisailon to approve letter. Motion passed unanimously.

4. December 2017 Legislative Committee – Jeenu Philip, BPharm, Chair

Section 465.0075, F.S. - Licensure by Endorsement

Mr. Philip provided a brief overview of the discussion from the Legislative Committee meeting (please see the Legislative Committee Minutes). The Committee recommended to strike the word “suspended” from 465.0075, F.S. and revise the language to read, “The Board may refuse to certify the Department to not issue a license by endorsement to any applicant whose license to practice pharmacy has been revoked...” Motion made by Mr. Bisailon to approve recommended language. Motion passed unanimously.

Section 465.009, F.S. - Continuing Professional Pharmaceutical Education.

Mr. Philip provided a brief overview of the discussion from the Legislative Committee meeting (please see the Legislative Committee Minutes). The Committee recommended the change in 465.009 for each pharmacist to complete a 3-hour continuing education course provided by the American Medical Association or ACPE on prescribing, ordering and interpreting laboratory tests and patient assessment as part of the renewal and to strike subsection "c." Mr. Philip also recommends striking subsection "b." Motion made by Dr. Mesaros. Dr. Hickman abstained from voting. Motion passed.

Section 465.014, F.S. - Pharmacy Technician

Mr. Philip provided a brief overview of the discussion from the Legislative Committee meeting (please see the Legislative Committee Minutes). The Committee recommended to add "or indirect as defined by the rule of the Board" and remove the line, "registered pursuant to this Section before January 1, 2001." Mr. Philip made a motion to table. Motion passed unanimously.

Section 465.026, F.S. - Filling of Certain Prescriptions

No discussion.

Bills Filed for the 2018 Legislative Session

Mr. Philip provided a brief overview of the discussion from the Legislative Committee meeting (please see the Legislative Committee Minutes). Mr. Jackson asked to pull out SB848/HB679. Dr. Mesaros asked to pull out HB351/SB534. Motion made by Mr. Bisailon to approve remaining bills.

HB351/SB534 – Dr. Mesaros commented that there should be consistency with the past to not get involved with regulating the billing and the contract. Mr. Montgomery commented that we should definitely have oversight of the PDM, because they have oversight of the pharmacist. Motion made by Dr. Hickman in favor of the Committee's recommendation. One opposed. Motion passes.

SB848/HB679 – Mr. Jackson reiterated the FPA's opposition of this legislation and his comments previously provided during the Committee meeting. Mr. Gonzalez also opposes this legislation and believes neutrality is a better position.

Dr. Mesaros made a motion to support. Mr. Meshad, Ms. Rivera, and Mr. Montgomery opposed. Vote is 5 to 3 in support. Motion passes.

Public Comment:

None.

Meeting adjourned at 7:02 p.m.

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 Philip, BPharm, Vice-Chair
David Bisailon
Jonathan Hickman, PharmD
Jeffrey J. Mesaros, PharmD, JD
Gavin Meshad
Richard Montgomery, BPharm
Blanca R. Rivera, RPh, CPh, MPharm, MBA
David Wright, BPharm

Attorneys

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

Department of Health Counsel:
Christopher Jurich, Assistant General Counsel
Raj Misra, Assistant General Counsel

Board Staff:

C. Erica White, Executive Director
Irene Lake, Program Operations Administrator

Dr. Mikhael made a recommendation for 2018 to roll committee meetings into the full board meeting.

Dr. Mikhael recognized guests Mr. Parrado and Dr. Pollus from PRN. Reminded attending students and licensees to sign-in for CE credits. Recognized students in the audience. Congratulated new chair, Mr. Philip and vice-chair, Dr. Mesaros.

VI. Disciplinary Cases

A. Settlement Agreements

Recused Members: Gavin Meshad & Jeenu Philip

Motion made by Mr. Bisailon to accept the settlement agreements. Motion passed unanimously.

1. Giriraj, LLC; PH26509; Case #2017-01890, File #19501 **(\$998.17)**
2. Beena Vishnubhai Patel, R.Ph.; PS49946; Case # 2017-01889, File #35305 **(\$987.25)**

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: None

1. Mariposa Pharmacy Discount, Inc.; PH28803, Case #2016-21196, File #22198 – Motion made by Mr. Bisailon to impose revocation. Motion passed unanimously. Department withdrew motion for cost.

Recused Members: Jeenu Philip

2. May D. Perez, RPT; RPT55452, Case #2016-22584, File #58349 – Present and sworn in. Motion made by Dr. Mikhael to dismiss. One opposed. Motion passes.

Recused Members: Jeffrey J. Mesaros & Gavin Meshad

3. Baizan Medical Equipment, Inc.; PH25507, Case #2016-13832, File #18370 – Motion made by Mr. Philip to impose revocation. Motion passed unanimously. Department withdrew motion for cost.

Recused Members: Jeenu Philip & Gavin Meshad

4. Tropical Pharmacy; PH23356, Case #2016-09214, File #15901 – Motion made by Mr. Bisailon to impose revocation. Motion passed unanimously. Department withdrew motion for cost.
5. Evelyn Miranda-Hankerson, RPT; RPT34280, Case #2016-07684, File #35128 – Motion made by Mr. Bisailon to impose revocation. Motion passed unanimously. Department withdrew motion for cost.

C. Voluntary Relinquishments

Recused Members: David Bisailon

1. Susy's Pharmacy; PH28182, Case #2017-01528, File #21491 – Motion made by Mr. Meshad to accept voluntary relinquishment. Motion passed unanimously.

Recused Members: Jeenu Philip

2. Lorraine Henninger, RPT; RPT75080, Case #2017-13014, File #79380 - Motion made by Mr. Meshad to accept voluntary relinquishment. Motion passed unanimously.

Recused Members: Mark Mikhael

- Ileana Morales, RPT; RPT56297, Case #2017-08099, File #56915 - Motion made by Mr. Meshad to accept voluntary relinquishment. Motion passed unanimously.

No Recused Members

- William Barrett, III, RPT; RPT72739, Case #2017-14104, File #77182 - Motion made by Mr. Meshad to accept voluntary relinquishment. Motion passed unanimously.

Recused Members: Gavin Meshad

- Jen-Chun Ho, R.Ph; PS 42218, Case #2012-08514, File #33636 – Motion made by Mr. Bisailon to accept voluntary relinquishment. Motion passed unanimously.

Recused Members: David Bisailon

- New Pharmacy Discount Corp; PH22651, Case #2016-25784, File #15193 – Motion made by Mr. Meshad to accept voluntary relinquishment. Motion passed unanimously.

Recused Members: Mark Mikhael

- Vital Rx, Inc; PH28210, Case #2017-10306 & Case #2015-24417, File #21089 - Motion made by Mr. Meshad to accept voluntary relinquishment. Motion passed unanimously.

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: David Bisailon

- Avellaneda Pharmacy & Discount, Inc., PH29946, Case #2017-01524, File #23482 – Withdrawn.

E. Prosecution Services Report – Christopher Jurich, Assistant General Counsel

Mr. Jurich provided a brief update on the current caseload for the Prosecution Services Unit. Motion made by Mr. Philip to allow PSU to continue to prosecute cases older than one year. Motion passed unanimously.

VII. Licensure Issues

A. Request to Maintain Pharmacy Permits while Hospital's License is Inactive

Mr. Flynn instructed the Board that they did not have the power and authority to answer this.

This should have come through either a Request for Declaratory Statement or Variance of Waiver to a rule. Responding could be considered a non-rule policy. No discussion or motion occurred.

1. Miami Medical Center; 2205/22959
2. Miami Medical Center; 2205/22956

B. Petition for Termination of Probation

1. Christina Buhrman; 2201/18576; Case #2015-06648 – Present with attorney Edwin Bayo and sworn in. Motion made by Dr. Mesaros to terminate probation. Motion passed unanimously.

C. Petition for Reinstatement

1. Jeffrey Butzin; 2201/46678; Case #2017-04270 – Present with Dr. Alexis Pollus with PRN and sworn in. Motion made by Mr. Bisailon to reinstate. Motion passed unanimously.
2. Rosemery Revilla; 2208/33064; Case #2013-18928 – Present and sworn in. Motion made by Mr. Bisailon to reinstate. Motion passed unanimously.

Break at 10:28 a.m.
Start 10:40 a.m.

Old/New Business:

Dr. Mesaros and Ms. White received an email from Nova regarding CE for DSN course. Ms. White will research.

Mr. Philip would like to see more active participation from deans and educators; make a recommendation to send a formal letter from the Board to invite them to the board meetings next year. Dr. Rivera asked about extending CEs. Mr. Harris discussed the provisions of 456.013(6), F.S. Discussion commenced on possibilities of changing the agenda order to allow participants more opportunities to receive CE credits. Motion made to delegate chair to send letter formally inviting deans of pharmacies to the Board meetings. Motion passed unanimously.

Public Comment:

Mr. Parrado continued discussions regarding CE day. It was important to see practitioners sanctioned and disciplined; some colleges made it a requirement of graduation; if going to offer 5 hours of CE, needs to be interesting. Dr. Mesaros commented that there is more opportunity of discussion around some of the cases. Further discussion and comments from several attendees regarding opportunities for students and licensees to learn from all parts of the Board meetings, not just the disciplinary portion.

Mr. Philip recognized and thanked Dr. Mikhael for his job this year as the Chair.

Adjourn: Motion made by Mr. Philip to adjourn. The meeting adjourned at 11:24 am.