

FLORIDA | Board of Pharmacy

Draft Meeting Minutes

February 5-6, 2019

Four Points by Sheraton Tallahassee

316 W. Tennessee Street

Tallahassee, FL 32301

Contact Hotel: 850-422-0071



Jeffrey Mesaros, PharmD, JD
Chair

Richard Montgomery, BPharm, MBA
Vice-Chair

Jennifer Wenhold, MSW
Acting Executive Director

Florida Board of Pharmacy Meeting Agenda
February 5-6, 2019
Tallahassee, FL

Participants in these public meetings should be aware that these proceedings are being recorded and that an audio file of the meetings will be posted to the board's website.

Board Members:

Jeffrey J. Mesaros, PharmD, JD, Chair (Orlando)
Richard Montgomery, BPharm, MBA, Vice-Chair (Orlando)
Jeenu Philip, BPharm, (Jacksonville)
David Wright, BPharm (Ft. Pierce)
David Bisailon, Consumer Member (Bradenton)
Jonathan Hickman, PharmD (Tallahassee)
Mark Mikhael, PharmD (Orlando)
Gavin Meshad, Consumer Member (Sarasota)
Blanca R. Rivera, MPharm, MBA (Miami)

Attorneys:

David Flynn, Senior Assistant Attorney General
Lawrence Harris, Senior Assistant Attorney General
Matthew Witters, Assistant General Counsel

Board Staff:

Jennifer Wenhold, MSW, Acting Executive Director
Eric Pottschmidt, MBA, Program Operations Administrator
Amber Greene, Program Operations Administrator
Jessica Hollingsworth, Government Analyst II

Tuesday, February 5, 2019 at 1:30 PM

Call to Order - The meeting was called to order by Board Chair, Dr. Mesaros, at 1:31 p.m.

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

Board Members:

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

Absent:

David Bisailon, Consumer Member - Excused

I. **Reports – Jeffrey J. Mesaros, PharmD, JD, Chair**

A. Chair's Report – Jeffrey J. Mesaros, PharmD, JD, Chair

1. Committee Assignments

Dr. Mesaros provided updates regarding the National Association of Boards of Pharmacy (NABP), which included the following:

- NABP requested information from board staff and attorneys related to certain surveys, which is being addressed.
- NABP offered for board staff to attend education and training on NABP processes. Dr. Mesaros is working with the Executive Director to see if openings are still available.
- NABP requested volunteers to work on the MPJE rule writing process in mid-March. Dr. Mesaros acknowledged that Debra Glass has assisted numerous times and recommended that she attend again. He requested for one more board member to attend, at which Mr. Philip volunteered.

A motion was made by Mikhael to volunteer Debra Glass and Jeenu Philip to attend the MPJE rule writing process with NABP. Motion passed unanimously.

Dr. Mesaros requested three volunteers for the formulary committee, per s. 465.186, F.S., which requires participants from the Boards of Medicine, Osteopathic Medicine, and Pharmacy. He added that the date and location is not yet known. Dr. Mesaros volunteered as the Chair. Dr. Hickman, Mr. Philip, and Mr. Wright also volunteered to attend. Mr. Philip clarified that the list of medicinal drugs to be reviewed by the committee is in Rule 64B16-27.220, F.A.C, which was last updated in 2007. Dr. Mesaros informed the public that if they had any material to provide for the formulary to review, it would be helpful.

Mr. Philip brought up statute reference to OTC items approved by Florida Medicaid and how it would be helpful to include in rule, so pharmacists may dispense those items without requiring a prescription. Ms. Rivera stated that she was one of the members when the committee originally formed and recalled pharmacists being uncomfortable with the uncertainty of where liability would fall if pharmacists were to dispense those items without a prescription. She suggested that if this were to happen, any information on changes should be disseminated to pharmacies and continuing education related to dispensing without a physician prescription should be created.

B. Executive Director's Report – Jennifer Wenhold, MSW, Acting Executive Director

1. Annual Delegations

Ms. Wenhold provided a brief overview of the changes made to the 2019 delegations, which included formatting to match other board delegations and additional delegations to the Executive Director that were previously missing. She requested for the board to ratify the document presented.

A motion was made by Mikhael to ratify the 2019 Pharmacy Delegation of Authority. Motion passed unanimously.

2. Health History Questions

Ms. Wenhold provided a brief explanation of the proposed health history questions that the department is working to standardize for all board applications. She added that the corresponding rules and applications will be updated with the health history questions for the April agenda, which the board will be asked to vote on.

3. 2019 Legislation Bills

Ms. Wenhold provided a brief overview on the following legislation bills:

- A. HB 287 / SB 488 - Drug Safety - requiring the addition of a warning sticker to specified opioids and requiring pharmacies to offer for sale prescription lock boxes.

Mr. Montgomery and Mr. Wright expressed concern for how the warning sticker could make it easier to divert drugs. Mr. Wright suggested asking Rebecca Poston if there has been a trend on prescriptions in states that have done this, which Ms. Wenhold confirmed could be done. Dr. Mesaros raised concern with

lock boxes being required in pharmacies that don't dispense, which would be an unnecessary impact. Dr. Mikhael encouraged not taking a position on this bill.

A motion was made by Mikhael to remain neutral on HB 287 and SB 488. Motion passed unanimously.

- B. HB 111 / SB 300 - Testing for and Treatment of Influenza & Streptococcus - authorizing pharmacists to test for and treat influenza and streptococcus under protocol with a supervising physician.

Ms. Wenhold reminded the board that this bill requires rulemaking within 90 days of becoming law, which could be problematic due to the timeframe in which it takes to update a rule. Mr. Harris agreed with the timeframe posing an issue and suggested multiple options for addressing the bill. Discussion ensued on the best method for taking future action on the bill. It was agreed that a conference call would be scheduled when the bill looks like it is about to pass.

A motion was made by Mikhael to support HB 111 and SB 300. Motion passed unanimously.

- C. HB 271 - Prescribed Drug Services and Audits - prohibiting attorneys from engaging in misleading advertisement related to medicinal drugs and providing requirements for pharmacy contracts and auditing entities.

Michael Jackson, CEO and Vice-President of the Florida Pharmacy Association, informed the board that this bill is of interest to the pharmacy profession due to statutory language dealing with pharmacy audits. He asked the board to discuss and support the bill.

Mr. Philip requested clarification on who would enforce the items listed in the audit. Dr. Hickman and Ms. Wenhold answered that it likely falls under the Office of Insurance Regulation. Mr. Philip expressed concern for the process related to enforcement not being clear in the bill. Dr. Mesaros also pointed out that the discipline process for attorney violations related to misleading advertisements is also unclear. Mr. Jackson said the enforcement aspect has been an ongoing discussion and suggested the board also review SB 650 as a comparative bill.

Mr. Wright suggested that the board review the bill prior to voting in support. He agreed with Mr. Jackson that any help with fair auditing practices is needed. Dr. Hickman raised concern with adding a law requiring what type of business deal pharmacies and PDMs must have with each other. Dr. Mesaros agreed with Dr. Hickman's concerns. Mr. Montgomery recalled a comment made on misleading advertising that makes people stop taking medication, which could be dangerous.

Ms. Rivera asked Mr. Jackson about whether this bill will increase audits in pharmacies and the benefits in doing so. Mr. Jackson answered that pharmacies don't fear audits and that they will always be necessary. He added that this bill makes the audit process fairer. Mr. Jackson informed the board that FPA believes auditing standards should apply across the board for all pharmacy types.

Gary Daylen, representative for Daylen Florida Society of Health System Pharmacists, referred to another piece of legislation on collaborative practice related to the consultant pharmacist license. He informed the board that the bill reworks the education component of the consultant pharmacist license and that FMA is now in support. He added that the bill should be out soon and requested the board's support. Dr. Mesaros answered that the board will review the bill when it is available.

Dr. Mesaros suggested reviewing HB 271 and discussing it later. Ms. Wenhold informed the board that board staff will schedule a conference call for this within the next couple of weeks.

- D. HB 59 / SB 104 - Prescription Drug Donation Repository Program - creating the Prescription Drug Donation Repository Program within the Department of Health to facilitate prescription drug donations.

Mr. Montgomery recommended that the board vote in favor of this bill due to the money wasted on the disposal of drugs and the potential benefit for patients in need. Dr. Hickman raised concern about the logistics of donating drugs and ensuring they're safe, including determining what is dispensed and how things are returned to stock.

A motion was made by Montgomery to support HB 59 and SB 104. Motion passed with Hickman in opposition.

- E. HB 491 - Controlled Substance Prescribing - changing the definition of acute pain to exclude pain related to sickle-cell anemia to limit opioid prescriptions for acute pain.

Informational Item – no discussion.

- F. HB 383 / SB 448 - Advanced Birth Centers - amending the definitions of "Institutional Pharmacy" and "Modified Class II Institutional Pharmacy" to include reference to advanced birth centers

Informational Item – no discussion.

- G. HB 451 - Non-Opioid Directives - requiring the department to establish a form for patients to execute a voluntary non-opioid directive that the patient may not be prescribed, ordered, or administered an opioid drug listed as a Schedule II controlled substance; providing specific circumstances under which the directive may be revoked or contradicted.

A motion was made by Montgomery to remain neutral on HB 451. Motion passed unanimously.

- H. SB 706 - Institutional Pharmacies - allowing an institutional formulary system to be used in a Class I institutional pharmacy; requiring specific policies and procedures for Class I institutional pharmacies that use the institutional formulary

system.

Mr. Harris provided a brief summary on the bill. Mr. Wright expressed concern with medical marijuana prescribed to patients in nursing homes and the burden on families due to nursing homes not having the ability to dispense. He informed the board that this should be something to consider during rule-making.

Dr. Mesaros proposed a recurring conference call during legislative session to stay current on bill updates. Ms. Wenhold agreed that a call would also be helpful for board staff.

4. 2020 Board Meetings

Ms. Wenhold informed the board of the request from the department's meeting planning team to schedule board meeting dates in 2020 so meeting sites may be procured. She presented a list of possible meeting dates for the board to review and approve.

Ms. Rivera requested whether the board can meet in Miami. Ms. Wenhold answered that the request will be submitted. Ms. Wenhold further explained the process for securing board meeting locations and the difficulty with hotels in South Florida due to room rates. Board members suggested finding meeting locations other than hotels, such as schools, which Ms. Wenhold confirmed was possible if parking and space isn't an issue. She added that this is something the next Executive Director can address.

Mr. Daylen pointed out that the proposed December date conflicts with ASHP mid-year meeting.

Mr. Harris asked the board to ensure dates don't change once the schedule is set, due to possible conflicts with board counsel in which Mr. Harris or Mr. Flynn cannot attend the board meeting.

The 2020 meeting dates were tabled for the April meeting.

C. Attorney General's Report – *David Flynn, Senior Assistant Attorney General*

1. January 2019 Rules Report

Due to Mr. Flynn's absence, Mr. Harris provided a brief overview of the January 2019 Rules Report.

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

Mr. Difiore provided a brief update on the second quarter inspection results as of January 31, 2019. He also announced the newest member of their team, Swaniece Grubb, a senior pharmacist who will attend the April meeting.

Dr. Mikhael requested an update on inspections related to sterile compounding pharmacies

complying with the revised USP Ch. 795, 797, and 800 proposals that will be in effect at the end of the year. Mr. Difiore responded that inspectors are looking forward to it and that most pharmacies are already working towards compliance with the revised USP Ch. 800 proposal.

II. General Business – Jeffrey J. Mesaros, PharmD, JD, Chair

A. Ratification of Issued Licenses / Certificates

A motion was made by Hickman to ratify the licenses presented. Motion passed unanimously.

1. Pharmacist (Licensure) – 142
2. Pharmacist (Exam Eligibility) – 2,305
3. Pharmacist Interns – 112
4. Consultant Pharmacist – 31
5. Pharmacy / Facilities – 96
6. Registered Pharmacy Technicians – 1,056
7. Registered Pharmacy Technician Training Program – 20
8. Nonresident Sterile Compounding – 5
9. Approved CE Providers – 0
10. Approved CE Courses – 20

B. Review and Approval of Minutes

1. December 11, 2018 Tripartite Committee Minutes

A motion was made by Philip to approve the minutes as written. Motion passed unanimously.

2. December 11, 2018 Rules Committee Minutes

Mr. Philip reminded board staff reach out to schools regarding the consistent reporting of pharmacy interns no longer enrolled in school, per pg. 5 of the minutes.

A motion was made by Philip to approve the minutes as written. Motion passed unanimously.

3. December 11-12, 2018 Board Meeting Minutes

A motion was made by Philip to approve the minutes as written. Motion passed unanimously.

4. December 27, 2018 Board Meeting Minutes

Mr. Philip pointed out that clarification was needed regarding the extended deadline for the CEs required for students. Ms. Rivera added that technicians and consultants

also had an extended deadline, which was not clear in the minutes.

A motion was made by Wright to approve the minutes as written, pending the above amendments. Motion passed unanimously.

Break: 2:56 p.m. – 3:19 p.m.

III. Presentations – Jeffrey J. Mesaros, PharmD, JD, Chair

A. Loretta Boesing, Patient Advocate

Ms. Boesing thanked the board for allowing her to speak on behalf of the patients she represents. She informed the board that as a physician hospital contractor and health insurance agent, she learned that patients don't have many options for insurance plans. She further informed the board that most plans force patients to use mail-order pharmacy, which has put her son's life at risk. The following concerns were raised about mail-order pharmacy:

- Patients share more information and ask more questions to a pharmacist face-to-face than over the phone or via a tv screen
- Prescriptions experience extreme temperatures, such as freezing due to ice packs or melting due to heat in delivery trucks and mailboxes, causing medications to not work
- Patients may not receive prescriptions timely
- Medications may be lost, stolen, or left in unsafe areas where children can reach them

Ms. Boesing shared her personal story of trying mail-order pharmacy for her son, which caused her son's transplant to be rejected. She added that when she tried to obtain medication through an alternative method, she was told by CVS Caremark that mail-order was the only method under full coverage, so she filed a complaint with the US Department of Labor which responded that even though forcing mail-order pharmacy is unethical, it is not illegal.

Ms. Boesing asked why temperatures are on the label if they do not matter and why mail-order pharmacy is held to a different standard than independent and hospital pharmacies. She stated that patients should have the option to receive medication the safest way possible and business should be earned, not forced. Ms. Boesing concluded that the pharmacy business should be about patients and not profits.

Mr. Wright agreed that it is the board's duty to protect patients and suggested discussing possible rule changes. Mr. Meshad recommended for this topic to be discussed in a future committee. Mr. Harris clarified that these complaints fall under Ch. 499, F.S. - Drugs; Devices; Cosmetics; Household Products, which is implemented by the Florida Department of Business and Professional Regulation (DBPR). Mr. Harris stated that the board has authority in disciplining pharmacists or permit holders but very little jurisdiction over mandatory conditions for drugs being delivered.

Dr. Mikhael and Mr. Meshad agreed that since they don't have a full understanding of the process or the issues involved, the board would need to hear from subject matter experts to move forward effectively. Mr. Wright agreed that mail-order is necessary but there should be guidelines to keep it safe. Ms. Rivera suggested assessing the definition of dispensing and whether it ends at giving drugs to delivery trucks or giving it to the patient. Dr. Mikhael volunteered to assist if a subcommittee is created. Mr. Wright echoed the request to join the subcommittee. Dr. Mesaros thanked Ms. Boesing for presenting to the board and suggested the board and Mr. Harris research jurisdiction prior to forming a committee.

B. The Florida Pharmacy Association – Rule 64B16-27.4001, FAC

Mr. Jackson and Attorney, T.J. Morton, requested that the board reconsider the rule change from last December, which redefines direct supervision. He provided written comments to the board outlining FPA's concern with the rule, which he summarized. The comments raised concern that the definition of direct supervision was expanded to allow pharmacists to not be in the same location if they use technology to provide personal assistance, direction, and approval required to meet the standard of practice for delegated tasks.

Mr. Jackson stated that he interpreted this as a pharmacy having the ability to contain numerous technicians if there is one pharmacist on sight to supervise six technicians and remote pharmacists available via technology to supervise the rest. Mr. Morton added that they do not believe the board has been granted authority to define direct supervision and it has been commonly understood that direct supervision implies being on the same premises. He referred to multiple statutes that he believed provided context on what direct supervision means.

Dr. Mikhael asked if the FPA has concern with the ratio or with technicians working from home. Mr. Jackson clarified that concern lies with the rule itself and their stance on technicians working from home depends on the tasks they are delegated. Discussion ensued regarding interpretation of the new rule language. Mr. Meshad asked Mr. Harris if there is too much ambiguity in the new rule. Mr. Harris answered that neither he nor Mr. Flynn would advocate for the board to pass a rule that they feel is not defensible or aligned with statute, but that it never hurts to re-review rules if concern is raised from outside parties.

Mr. Philip reminded the board of the petition from PetMeds regarding the opportunity to explore this option. He explained that this rule has huge benefits for technicians, creating opportunity for advancement. He added that the board needs to consider the positive side of the rule instead of the "what if" scenarios. He concluded that he is comfortable with the way the rule was written. Mr. Harris agreed that this rule assisted the petitioner economically.

Dr. Hickman stated that specific examples from the FPA regarding why the rule does not work or recommendations for better language is needed before the board should reconsider. Mr. Jackson reiterated his example of one pharmacist on sight to supervise six technicians and remote pharmacists available via technology to supervise the rest, which could be a limitless number.

Mr. Wright stated that the rule may not be clear from an enforcement perspective,

specifically how an inspector would know whether technicians over the limit are being supervised remotely. Mr. Meshad agreed and added that there is uncertainty regarding whether the pharmacist is actively supervising or at home.

Dr. Mikhael asked Mr. Harris if any public comments or challenges were received before the rule was changed, which Mr. Harris answered there was not. Dr. Mikhael echoed Mr. Philip that the board did its due process and followed the appropriate guidelines, making him comfortable with where the language stands. Ms. Rivera stated that she feels they should entrust those who take advantage of this rule and hopes that whoever does sets their own standards as to where their employees should be working.

Ms. Julie Berger, a technician educator, stated that the ambiguity on the discussed issues and delegated tasks is what makes pharmacists uncomfortable. She requested clarification on whether research was conducted on why technicians call in sick, so it can be addressed rather than having technicians work from home. Mr. Montgomery answered that it was due to socioeconomic issues such as childcare, transportation, sick family, etc.

Dr. Mikhael stated that the rule doesn't address technician duties, meaning pharmacies shouldn't expect technicians to do anything different from what they already do in the pharmacy so additional training shouldn't be required. Ms. Berger countered that there is a difference due to a technician having on-the-job training in a pharmacy and the ability to turn to a pharmacist as opposed to working from home. Dr. Hickman disagreed and stated that a technician can ask questions through multiple mediums from home and if they aren't comfortable working in that capacity, then they should work in the pharmacy. He added that rules updated by the board are never done with the intent of watering down the level of care and that the same expectation is required for all avenues in which health care is provided.

Mr. Jackson reiterated that he thinks a hole has been found in the rule and encouraged the board to reconsider. Mr. Montgomery suggested that the board review the rule again and only open it if they find concrete evidence suggesting they need to. Dr. Mikhael stated that he did not support re-opening the rule. Mr. Meshad agreed with Mr. Montgomery and pointed out that it is rare when outside parties request for rules to be reconsidered and the board has an obligation to do their due diligence and re-review when asked.

Mr. Harris informed the board and FPA that they have the option to file a petition to initiate rule making, which would identify the reason for their concern and possible solutions. He also proposed the option of opening the rule for development today and scheduling it for further hearings. Mr. Jackson said the FPA plans to bring possible solutions to the board.

A motion was made by Mikhael to reject the request to open Rule 64B16-27.4001, F.A.C., with an understanding that the FPA will bring forth specific concerns and proposed language. Motion passed with Wright and Meshad in opposition.

Mr. Jackson thanked the board for allowing the FPA to share their concerns and stated that the association will determine what their next step should be.

Break: 5:27 p.m. - 5:38 p.m.

Dr. Hickman was excused from the remainder of the meeting.

IV. Petition for Declaratory Statement – Jeffrey J. Mesaros, PharmD, JD, Chair

A. PharMerica & AscribeRx America, LLC

Reference: Section 465.0235, F.S., and Rule 64B16-28.607, F.A.C., regarding whether automated pharmacy systems may be placed in assisted living facilities.

Mr. Edwin Bayo, Attorney, was present. Mr. Harris agreed with Mr. Bayo that automated pharmacies may be placed in assisted living facilities and proposed that instead of issuing a declaratory statement, the board open the rule for development to incorporate the statutory reference into rule.

A motion was made by Wright to find that the declaratory statement is not necessary and to open Rule 64B16-28.607, FAC, for development to propose the addition of the statutory term for Ch. 429 and to explore revisions to correct emergency box situation. Motion passed unanimously.

A motion was made by Mikhael to acknowledge that the proposed language adding chapter 429 will not have an adverse impact on small business or increase costs to any entity including the government in excess of \$200,00 in one year. Motion passed unanimously. A motion was made by Mikhael to acknowledge that this rule would likely not increase cost to any entity in excess of \$1,000,000 within five years after implementation of the rule. Motion passed unanimously. A motion was made by Mikhael to acknowledge that any section of this rule is not designated as a minor violation. Motion passed unanimously.

The petition was withdrawn by Mr. Bayo.

B. Health First, Inc

Reference: Rules 64B16-27.830 and 64B16-27.810, F.A.C., regarding whether penicillin skin testing may be performed by Health First hospital pharmacists.

Martin Dix, Attorney, was present with Mike Sanchez, Residency Director for Health First, Inc. Dr. Mark Mikhael recused himself due his vendor relationship with Health First.

Mr. Harris stated that he was in favor of the declaratory statement but cautioned the board that they need to ensure the declaratory statement is granted in this instance only.

A motion was made by Wright to approve the Petition for Declaratory Statement. Motion passed unanimously.

A motion was made by Mesaros to move committee reports to Wednesday, February 6, 2019. Motion passed unanimously.

The meeting recessed at 6:03 p.m.

Wednesday, February 6, 2019 at 9:00 a.m.

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

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

Board Members:

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

Absent:

David Bisailon, Consumer Member – Excused

V. **Committee Reports – Jeffrey J. Mesaros, PharmD, JD, Chair**

A. Compounding Committee – Mark Mikhael, PharmD

Dr. Mikhael provided a brief overview of the Compounding Committee held on Monday, February 4, 2019, which included discussion on Rule 64B16-27.797, F.A.C. He informed the board that a five- to six-member panel will be formed to conduct a workshop, which will be scheduled sometime in March to collaborate on new language. He asked for volunteers to contact Jennifer Wenhold or Amber Greene with the board office.

B. Rules Committee – Jeffrey J. Mesaros, PharmD, JD, Chair

Dr. Mesaros provided a brief overview of the Rules Committee held on Tuesday, February 5, 2019, which included discussion on automation related to Rule 64B16-28.141, F.A.C., which will continue in future meetings. He also briefed the board on the committee's discussion regarding pharmacy technicians, specifically on ratios, education, and assigned duties. He informed the board that they will continue to gather information for a better understanding of what technicians do in other states to later discuss elevating the role of technicians. He encouraged everyone to forward any material to the board office that they think will be helpful.

C. Committee Assignments – Jeffrey J. Mesaros, PharmD, JD, Chair

Dr. Mesaros informed the board that during session, recurring conference calls are scheduled to discuss legislation impacting pharmacy, so the board can provide feedback of their position on the bills. He reminded the board of the legislation bills discussed yesterday

during the Executive Director's report. He asked the board to review their calendars, so a conference call can be scheduled within the next few weeks to discuss pending legislation. Mr. Montgomery asked board staff if they can notify the board when bills are updated. Ms. Wenhold confirmed that they can. Dr. Mesaros agreed that this would be beneficial, so everyone isn't tracking different things or different versions of bills.

*****Settlement Agreement 5 was heard out of order*****

5. FIS's Care Pharmacy; Case #2018-20032
Recused: Michele Weizer & Richard Montgomery

The respondent was present and sworn in by the court reporter and was represented by counsel, Nathan Diamond.

Mr. Jurich presented the case to board. The respondent was charged with the following violation: 456.072(1)(kk), F.S. (2018), by being terminated from the state Medicaid program. A Settlement Agreement was presented to the Board with the following terms:

- Appearance by the respondent's representative
- \$10,000 administrative fine payable within 12 months.
- \$415.94 in costs payable within 90 days

A motion was made by Philip to accept the proposed settlement agreement. Motion passed unanimously.

*****Informal Hearing 3 was heard out of order*****

3. James W. Huff; Case #2017-09344
Recused: Michele Weizer & David Bisailon

The respondent was present and sworn in by the court reporter and was represented by counsel, Suzanne Hurley.

Mr. Jurich presented the case to board. The respondent was charged with the following violation: 456.072(1)(c), F.S. (2016), by entering a plea of nolo contendere to fourteen (14) counts of possession of material depicting sexual conduct by a child, a third-degree felony in violation of section 827.071(5), F.S. (2016). The department presented the following recommendation:

- Revocation

A motion was made by Mikhael to accept the department's recommendation. Motion failed with Philip, Rivera, Meshad, and Wright in opposition.

Discussion ensued regarding appropriate discipline for the respondent. The department requested that if the board does not agree with revocation, that they place a permanent restriction from working in an establishment that is accessible to children.

Break: 10:25 a.m. – 10:41 a.m.

Mr. Harris informed the board that if they choose to impose discipline less than revocation and impose a PRN evaluation to determine further discipline, they will be unable to impose revocation for this case in the future.

A motion was made by Meshad to accept the department's recommendation for revocation. Motion passed with Philip and Rivera in opposition.

VI. Applications Requiring Board Review – Jonathan Hickman, PharmD

A. Pharmacists

1. Peter Lee; 2201/53370

The applicant was present and sworn in by the court reporter.

Mr. Lee disclosed prior discipline history from 2010 in the state of Maine, and multiple criminal history offenses ranging from 2004 to 2011.

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

2. Timothy David; 2201/52044

Mr. David originally applied by endorsement in April 2018, which was denied at the October 2018 board meeting due to failure to disclose discipline imposed by the State of Oregon. Mr. David submitted a new endorsement application disclosing the imposed discipline.

A motion was made by Montgomery to approve the application. Motion passed unanimously.

3. Elveera Valieva; 2201/53463

Ms. Valieva disclosed prior discipline history from 2018 in the state of Washington. Mr. Philip expressed concern with granting a license due to the applicant serving probation in the state of Washington. The board agreed that they would be more comfortable granting licensure once probation is lifted.

A motion was made by Philip to deny the application due to discipline in another state with the opportunity for the applicant to withdraw their application within 14 days of the order. Motion passed unanimously.

B. Pharmacy Permits

1. Bruce Derby, (Beach Pharmacy LLC); 2205/25993

The applicant was present and sworn in by the court reporter. The applicant was

represented by counsel, Edwin Bayo.

The application reflects the current PDM as Bruce Derby, who had two instances of prior discipline history from 1991 and 1995 in the state of Florida.

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

Break: 11:20 a.m. – 11:27 a.m.

VII. Disciplinary Cases – Jeffrey J. Mesaros, PharmD, JD, Chair

C. Settlement Agreements (Appearance Required)

A motion was made by Hickman to accept settlement agreements 1 and 3. Motion passed unanimously.

1. Carl D. Acquaviva D/B/A Acquaviva's LTC Pharmacy; Case #2018-07105
Recused: Michele Weizer & Debra Glass

The respondent was charged with the following violations: Count 1: 465.023(1)(c), F.S. (2015-2017), by and through a violation of Section 893.07(1)(a), F.S. (2015-2017), by failing to complete one or more biennial controlled substance inventories following the last completed inventory on October 26, 2016; Count II: section 465.023(1)(c), F.S., by and through a violation of Rule 64B16-28.108(6)(b)9, F.A.C., by dispensing a customized patient medication package with a label bearing a beyond use date of one year. A settlement agreement was presented to the board with the following terms:

- Appearance
- \$1,500 administrative fine payable within 90 days
- \$1,033.69 in costs payable within 90 days
- Probation- One(1) year with conditions

2. Meena C. Kukreja; Case #2018-08596
Recused: Gavin Meshad & Debra Glass

The respondent was present and sworn in by the court reporter and was represented by counsel, Edwin Bayo.

The respondent was charged with the following violation: 456.072(1)(k), F.S. (2017), by and through a violation of Rule 64B16-28.110, F.A.C., by dispensing irbesartan 150 mg to a patient with an expiration date which had been reached, October 2017, on one or more prescription bottles. A settlement agreement was presented to the board with the following terms:

- Appearance
- \$1,000 administrative fine payable within 90 days
- \$1,701.12 in costs payable within 90 days

A motion was made by Philip to accept the proposed settlement agreement. Motion passed unanimously.

3. Denise Traficante; Case # 2018-14506
Recused: Michele Weizer & Mark Mikhael

The respondent was charged with the following violation: 465.016(1)(g), F.S. (2017), by dispensing buprenorphine 8mg tablets to patient instead of the prescribed buprenorphine 2mg tablets. A settlement agreement was presented to the board with the following terms:

- Appearance
- \$500.00 administrative fine payable within 90 days
- \$721.94 in costs payable within 90 days
- Complete 8 hours of continuing education in Prevention of Medical errors

4. Starcia Lucretia Moore; Case #2017-14903 - *This case was withdrawn by PSU*
Recused: Jeenu Philip & Mark Mikhael

D. 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.

1. Gisela Delasnieves Alvarez; Case #2017-21165
Recused: Michele Weizer & Mark Mikhael

Ms. Phillips presented the case to board. The respondent was charged with the following violation: 456.072(1)(k), F.S. (2018), by defaulting on a student loan issued or guaranteed by the state or Federal Government. The department presented the following recommendation:

- Costs of \$830.89 to be paid within 90 days of reinstatement
- Fine of \$1,027.18 to be paid within 90 days of reinstatement
- Suspension until new payment terms are agreed upon with the Florida Department of Education followed by probation for the remainder of the respondent's student loan

A motion was made by Philip to accept the department's recommendation. Motion passed unanimously.

2. Jesus Albert Sanchez; Case #2017-12995
Recused: Michele Weizer & Jeffrey Mesaros

Richard Montgomery, Vice-Chair, chaired this portion of the meeting due to Jeffery Mesaros, Chair, being recused.

Ms. Phillips presented the case to board. The respondent was charged with the following violation: 456.072(1)(II), F.S. (2017), by entering a plea of guilty to one count of conspiracy to commit health care fraud and section 456.072(1)(x), F.S. (2017), by failing to report, to the board, in writing, within 30 days of entering the plea. The department presented the following recommendation:

- Revocation

A motion was made by Philip to accept the department's recommendation for revocation. Motion passed unanimously.

PSU withdrew their motion for costs.

3. Lillian Marie Neese; Case #2018-01226
Recused: Debra Glass & David Wright

Ms. Phillips presented the case to board. The respondent was charged with the following violation: 465.016(1)(e), F.S. (2017), by and through a violation of section 893.13(7)(a)9, F.S. (2017), by acquiring or attempting to acquire one or more tablets of Alprazolam 2mg, a controlled substance, from CVS, by placing a bottle of Alprazolam 2mg in her pocket. The department presented the following recommendation:

- Costs of \$938.03 to be paid within 90 days of reinstatement
- Suspension until respondent appears before the board and demonstrates they are safe to practice their profession with reasonable skill and safety to include a mental and physical evaluation by PRN, determining that the respondent is safe to practice their profession with reasonable skill and safety
- Probation for two years upon reinstatement, concurrent with PRN monitoring if applicable
- That the board reserve the right to impose reasonable conditions of reinstatement at the time the respondent appears before the board to demonstrate present ability to engage in the safe practice of their profession

Mr. Philip suggested amending the department's recommendation for two years of probation to allowing the board to decide the period of probation based on the PRN evaluation.

A motion was made by Philip to accept the department's amended recommendation. Motion passed unanimously.

A motion was made by Hickman to accept the department's motion for costs. Motion passed unanimously.

4. Orlando Ayala; Case #2018-08217
Recused: Michele Weizer & Mark Mikhael

Ms. Phillip presented the case to board. The respondent was charged with the following violation: 456.072(1)(aa), F.S. (2017), by testing positive on an employer-

ordered drug screen. The department presented the following recommendation:

- Costs of \$768.38 to be paid within 90 days of reinstatement
- Fine of \$500.00 to be paid within 90 days of reinstatement
- Suspension until respondent appears before the board and demonstrates they are safe to practice their profession with reasonable skill and safety to include a mental and physical evaluation by PRN, determining that the respondent is safe to practice their profession with reasonable skill and safety
- That the board reserve the right to impose reasonable conditions of reinstatement at the time the respondent appears before the board to demonstrate present ability to engage in the safe practice of their profession

A motion was made by Philip to accept the department's recommendation. Motion passed unanimously.

A motion was made by Phillip to accept the department's motion for costs. Motion passed unanimously.

5. Rishi Ramdial; Case #2018-13305
Recused: Michele Weizer & Blanca Rivera

Mr. Jurich presented the case to board. The respondent was charged with the following violations: Count I: 465.016(1)(e), F.S., by violating Chapter 893.13(6)(a), F.S., and/or Chapter 893.13(7)(a)9, F.S. (2017), by possessing, acquiring, attempting to acquire and obtain hydromorphone, zolpidem, oxycodone, fentanyl, oxycodone-acetaminophen, hydrocodone- acetaminophen, and alprazolam by misrepresentation, fraud, forgery, deception and/or subterfuge; Count II: section 465.016(1)(r), F.S. (2017), by employing a trick or scheme related to his profession by using his profession as a registered pharmacy technician to divert hydromorphone, zolpidem, oxycodone, fentanyl, oxycodone-acetaminophen, hydrocodone- acetaminophen, and alprazolam from his employer. The department presented the following recommendation due to aggravating factors:

- Revocation

A motion was made by Wright to accept the department's recommendation for revocation. Motion passed unanimously.

PSU withdrew their motion for costs.

E. Voluntary Relinquishments

1. Angela Denise Clark; Case #2018-17375
Recused: None

Probable cause was waived in this case.

A motion was made by Mikhael to accept voluntary relinquishment. Motion passed unanimously.

2. Annia Marrero; Case #2017-22314
Recused: Mark Mikhael & Jeenu Philip

A motion was made by Wright to accept voluntary relinquishment. Motion passed unanimously.

3. Michelle Green; Case #2017-19121
Recused: Mark Mikhael & Jeenu Philip

A motion was made by Wright to accept voluntary relinquishment. Motion passed unanimously.

4. Yara Suarez; Case #2017-13007
Recused: Debra Glass & David Wright

A motion was made by Meshad to accept voluntary relinquishment. Motion passed unanimously.

5. Star Pharmacy, Inc.; Case #2018-23533
Recused: None

Probable cause was waived in this case.

A motion was made by Mikhael to accept voluntary relinquishment. Motion passed unanimously.

6. Jares Investments Global, Inc.; Case #2018-17374
Recused: None

Probable cause was waived in this case.

A motion was made by Mikhael to accept voluntary relinquishment. Motion passed unanimously.

F. 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 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.

1. Carlos Juan Mazariegos; Case #2017-07272
Recused: Michele Weizer & Richard Montgomery

The respondent was present and sworn in by the court reporter and was represented by Counsel, Ben Curtis.

Mr. Jurich presented the case to board. The respondent was charged with the following violations: Count 1: 456.072(1)(II), F.S. (2016), by entering a plea of guilty to defraud the United States, a crime which relates to health fraud; Count II: 456.072(1)(c), F.S. (2016), by entering a plea of guilty to conspiracy to defraud the United States; Count III: 456.072(1)(x), F.S., by failing to report, to the board. The department presented the following recommendation:

- Revocation

A motion was made by Wright to accept the department's recommendation for revocation. Motion passed unanimously.

PSU withdrew their motion for costs.

2. Anh Kim Le; Case # 2018-08597
Recused: Debra Glass & David Wright

The Respondent was present and sworn in by the court reporter.

Ms. Phillip presented the case to board. The respondent was charged with the following violation: 456.016(1)(g), F.S., by dispensing Lisinopril 20mg to a patient instead of the prescribed Lipitor 20mg. The department presented the following recommendation:

- Fine of \$250.00 to be paid within 90 days
- Complete 8 hours of continuing education in medication errors within 1 year

A motion was made by Philip to dismiss the case. Motion passed unanimously.

G. Motion for Reconsideration

Tashima Cheree Kenny; Case # 2016-17809

Mr. Jurich presented the case to board. This case was presented to the board as a Voluntary Relinquishment during the December 2018 board meeting. However, the respondent's license was previously revoked by an order of the board.

A motion was made by Philip to accept the reconsideration request to vacate the previous order and accept the voluntary relinquishment. Motion passed unanimously.

H. Prosecution Services Report – Matthew Witters, Assistant General Counsel

Mr. Jurich presented the prosecution services case report to the board. He also informed the board that they are now fully staffed and introduced Veve Monfort, who started in August, and Cynthia Shaw, who started in September.

A motion was made by Mikhael to allow PSU to continue prosecuting cases older than one year. Motion passed unanimously.

Ms. Rivera asked Mr. Jurich why there are cases from 2012. Mr. Jurich explained that cases stay open for many reasons, including being stuck in litigation, being inherited from other attorneys, or containing a lot of evidence that must be reviewed.

VIII. Licensure Issues

A. Request for Repeal

Ryan Whiting; RPT 44932, Case #2015-01647

Mr. Whiting filed a request for the board to repeal the revocation imposed on his license on April 25, 2016.

A motion was made by Rivera to deny request for repeal. Motion passed unanimously.

B. Request for Exemption

Gary Kazim; PS 38103

The Respondent was present and sworn in by the court reporter.

A motion was made by Mikhael to accept the request for exemption. Motion passed unanimously.

New Business - Jennifer Wenhold

Rule 64B16-26.103, F.A.C.

- (1) Individual Requests for Continuing Education Credit
 - a. DH/MQA/PH112
- (2) Individual Requests for Continuing Education Credit for Volunteers
 - b. DH/MQA/PH1170

Ms. Wenhold informed the board that staff have been working with Mr. Flynn on the two forms, which the board will see at the April meeting.

IX. Public Comment

Dr. Garcia thanked the board for giving FAMU students the opportunity to attend the board

meeting. She acknowledged that it makes an impact on students to see the various actions of the board. She also spoke on behalf of Julie Berger and supported the board in working with her on technician-related rules. She added that many pharmacists would like to see the board vote in favor of legislation that keeps pharmacists in communities.

Mr. Montgomery recalled a declaratory statement petitioned by Moffitt. He reminded the board that Moffitt was supposed to come back and after speaking with their director. He added that they should be ready to present by the next meeting. Mr. Montgomery also asked if something could be done about the 90-day issue with HB 111 and SB 300. Ms. Wenhold answered that the bill analysis is the appropriate time to inform the legislature of issues and she will ensure the 90-day issue is included.

Ms. Rivera recognized the FAMU and UF students sitting in the audience.

Ms. Wenhold stated that it has been a pleasure serving as the Executive Director for the Board of Pharmacy meeting and thanked the board for their patience and for assisting her with questions. The board also thanked her for her hard work.

X. Adjournment

The meeting adjourned at 12:55 p.m.