

**FLORIDA** | Board of Pharmacy

# Draft Meeting Minutes

**February 6 - 7, 2018**

Hilton University of Florida Conference Center

1714 SW 34<sup>th</sup> Street

Gainesville, FL 31607

Contact Hotel: (352) 371-3600



**Jeenu Phillip, BPharm**  
Chair

**Jeffrey Mesaros, PharmD, JD**  
Vice-Chair

**C. Erica White, MBA, JD**  
Executive Director

**Tuesday, February 6, 2018, 10:00 a.m.**

**BOARD MEMBERS:** Present

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

**BOARD STAFF:** Present

C. Erica White, MBA, JD - Executive Director  
Adrienne Rodgers, JD, Bureau Chief

**BOARD COUNSEL:** Present

David Flynn, Assistant Attorney General  
Lawrence Harris, Assistant Attorney General

**Excused absences:**

Gavin Meshad, Consumer Member

**Tab 1. Reports:**

**A. Chair's Report** – Jeenu Philip, BPharm - Chair

Discussion:

Chair announced the following committee appointments:

Chair made the following committee assignments:

- Rules Committee: Dr. Mesaros as Chair, Mr. Bisailon, Dr. Hickman, Mr. Phillip, Ms. Rivera.
- Compounding Committee: Dr. Mikhael as Chair, Ms. Rivera, Mr. Montgomery and Mr. Wright.
- Legislative Committee: Mr. Phillip as Chair, Dr. Hickman, Dr. Mikael and Mr. Wright
- Controlled Substance Committee: Mr. Meshad as Chair, Mr. Bisailon, Dr. Mesaros, Mr. Montgomery and Mr. Phillip.
  - Tripartite committee: Ms. Glass will continue to review CE courses.
  - Probable Cause Panel: Dr. Mikhael, Dr. Weiser and Ms. Glass.

Chair made the following meeting announcements:

NABP meeting: May 5-8, 2018 in Denver, CO.

District 3 meeting: August 12-14, 2018 in Asheville, NC.

MALTAGON meeting: October 12 thru 14, 2018 in Kansas City, MO.

ASPL November 1-4, 2018, in Hilton Head, SC will be attended by Mr. Flynn.

NABHP meeting: March 16-19, 2018 in Nashville, TN.

Annual MQA Chair/vice chair meeting: April 23, 2018 in Tallahassee, FL.

FPA annual meeting is July 12-15, 2018, in Bonita Springs, FL. Dr. Hickman to attend; his alternate is Mr. Wright.

FSHP meeting: August 3-5, 2018, in Orlando, FL will be attended by Mr. Montgomery, with Ms. Rivera as alternate. Dr. Hickman will be attending for business. Dr. Mikhael is scheduled to make a presentation.

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

A) First Quarter Budget - Mr. Philip, Budget Liaison

No discussion.

B) NABP – The NABP Executive Committee approved that the Pharmacist Assessment for Remediation Evaluation (PARE) Assessment will no longer be administered effective January 31, 2018. It is recommended that the safe return to practice be dealt by completion of additional education. No one had used this solution in some time. Board Counsel recommended changes to rule to strike through this exam.

Discussion:

Board was advised that the Rules Committee will address this. Mr. Harris recommended that the requirement be deleted from rules.

Ms. White presented at the FHP Regulatory and Law Conference.

**C. Attorney General's Report** - David Flynn and Lawrence Harris, Assistant Attorneys General

A) Five rules are open and one, rule 64B16-27.700, F.S., on the definition of compounding, became effective on January 28, 2018. Of the five open rules, two have letters from JAPC that have been addressed by board counsel.

Mr. Harris presented the Monthly Rules Report as of January 2018 – Rule 27.410, FAC, is in the 21-day comment period. As related to rule 64B16-27.630, FAC, the CDC published its update on February 5, 2018; this rule will be submitted for publication and will begin the 21-day comment period.

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

Discussion:

Mr. DiFiore gave the following information on inspections:

- FY 2017-2018 to date – 5549 inspections scheduled and 3715 or 67% completed.
- Started with 513 completed 318 for a 62% reduction.
- Five out of state inspections were completed. Most are in good compliance; some required submission of a corrective action plan.
- CGMP training - FDA chose one Florida DOH inspector to train; the department now has 4 senior pharmacists can do these inspections.
- Inspections are commenced in 30-60 days from referral.

**Tab 2. – Business**

**A. Ratification of Issued Licenses/Certificates**

Discussion:

	License/Certificate	Client	Number
1.	Pharmacist (Licensure)	2201	88
2.	Pharmacist (Exam Eligibility)	2201	81
3.	Pharmacist Interns	2202	65
4.	Consultant Pharmacist	2203	22
5.	Pharmacy/Facilities	2205	71
6.	Registered Pharmacy Technicians	2208	561
7.	Registered Pharmacy Technician Training Programs	2209	16
8.	Nonresident Sterile Compounding	2210	1
9.	CE Providers Approved	-	2
10.	CE Courses Approved	-	19

Action taken: Licenses 1 through 10 ratified unanimously.

### **B. Review and approval of minutes**

1. January 12, 2018 - Rules Committee  
Action taken: approved unanimously.
2. December 11, 2017 - Rules Committee – typographical error on page 7, second paragraph, last word – should be Meningococcal. Action taken: approved unanimously with this amendment.
3. December 11, 2017 - Legislative Committee - Action taken: approved unanimously.
4. December 12, 2017 - Compounding Committee – Action taken: approved unanimously
5. December 12, 2017 - Controlled Substance Committee – Dr. Meshad and Mr. Phillip were on the call, add Mr. Bisailon as being on the call. Action taken: approved unanimously with this amendment.
6. December 12-13, 2017 - Full Board Meeting – Action taken: approved unanimously.

### **TAB 3. “COMMITTEE” DISCUSSIONS CONDUCTED AT THIS MEETING BY THE FULL BOARD**

#### **1. Rules – presented by Dr. Mesaros**

A.) Rule 64B16-27.831, F.A.C., regarding standards of practice for filling controlled substances prescriptions; electronic prescribing; and mandatory continuing education. Proposed language adds to rule 64B16-27.831, subparagraphs (f) and (g) on proper disposal of controlled substances and protocols for addressing and resolving problems recognized during drug utilization review.

#### Discussion:

The focus of the changes is around the content of the continuing education (CE) course, leaving the majority of the rule intact and not requiring additional hours. In particular, counseling and opioid information are being added to the CE content and the rule will update the biennium required for completing the courses.

Concerns were expressed that parenthesis (h) may not take counseling far enough due to naïve patients who need counseling, and adding the word “mandatory” was discussed.

The statutory requirement calling the professional judgment of the pharmacist into play may be a barrier to creating a mandatory rule for counseling. The alternative, suggested by counsel, was to require that all pharmacists have a policy on when counseling will be mandatory. If this was done, the rule could be amended in a 3-step process. Step one is to get counseling in the rule, step 3 is to have it added to requirements for policy and procedures. The patient counseling rule may be the better avenue to have the mandatory language.

Motion by Dr. Mikhael to accept changes to (h) as presented for pharmacist initiated counseling for patients with opioid prescriptions and add mandatory counseling, with second by Ms. Rivera. Action taken: Approved unanimously.

Mr. Flynn recommended a change to (g)4, regarding naloxone standing orders to include language regarding “section 381.887, F.S., and State Surgeon General’s statewide standing order for naloxone.”

Motion by Dr. Mikhael, with second by Mr. Bisailon. Action taken: approved unanimously.

SERC – Motion no adverse fiscal impact by Dr. Mikhael, second by Mr. Bisailon. Action taken: approved unanimously.

SERC – Motion that the change to this rule does not create a minor violation made by Dr. Mikhael with second by Dr. Hickman. Action taken: approved unanimously.

Board members directed board staff to place on the rule changes on the board website, and send message to distribution list and providers.

Board members questioned how credit could be not be given to those who took the course before the change if the rule changed in mid-renewal cycle. Mr. Brian Kahn asked that the board consider approving satisfaction of the mandatory requirement for those who took the course before the effective date of the rule.

Mr. Flynn advised that an affected party could apply for variance/waiver. He also suggested that the board put beginning and end dates in the rule.

Dr. Mikhael moved to add a sentence at the end of the rule that any licensee who completed the validation of prescription for controlled substance course between October 1, 2017 through [effective date of the rule] shall receive credit for the course with second by Dr. Hickman. Action taken: approved unanimously.

SERC – motion no adverse fiscal impact by Mr. Bisailon with second by Mr. Wright. Action taken: approved unanimously.

#### **Break at 11:27 AM; resumed at 11:39 AM**

B.) Rule 64B16-28.830, F.A.C., regarding special – closed system pharmacies. Proposed language adds ICF-IID and its definition; and requires procedures for preventing dispensing of controlled substances based on fraudulent prescriptions.

#### Discussion:

Mr. Harris stated that one purpose of the proposed language is to bring the rule into present nomenclature for Intermediate Care Facilities – Developmentally Delayed (ICF-IIDs), for individuals with intellectual disabilities. Rule 64B16-27.410, F.A.C., can also be updated.

Motion to accept language as reflected by Dr. Mikhael with second by Mr. Bisailon. Action taken: approved unanimously.

SERC – Motion no adverse fiscal impact by Mr. Phillip with second by Mr. Bisailon. Action taken: approved unanimously.

SERC – Motion no adverse fiscal impact five-year fiscal impact by Mr. Phillip with second by Mr. Bisailon. Action taken: approved unanimously.

Motion that the change to this rule does not create a minor violation by Dr. Mikhael with a second by Dr. Hickman. Action taken: approved unanimously.

C.) Rule 64B16-28.501, F.A.C., regarding institutional permits; consultant pharmacist of record (COR); initial designation; and changes to the designated consultant. Adds language regarding fingerprint retention and tracking designated consultant or Pharmacy Department Manager (PDM).

#### Discussion:

Mr. Harris gave the background on changes made since the January 12, 2018, Rules Committee meeting and board counsel's subsequent recommendations. If the underlying permit is a community

permit, then the manager of a sterile compounding facility is a PDM. If the underlying permit is an institutional or special ALF permit, then the manager of a sterile compounding facility is a Consultant Pharmacist of Record (COR). Both this rule and the PDM rule need to be changed. It was recommended that the term "PDM" be eliminated from the rule since it does not apply to institutional settings; add "institutional" before "sterile compounding." Mr. Harris will continue to work on the exact language for both the institutional and community rules.

Motion by Mr. Bisailon to approve the language with the verbal amendment recommended today.  
Second by Mr. Phillip. Action taken: approved as verbally amended.  
SERC – Motion no adverse fiscal impact by Mr. Bisailon with second by Ms. Rivera. Action taken: approved unanimously.

Motion by Mr. Bisailon that violation of this rule this is not a minor violation with second by Dr. Hickman. No vote taken.

Board members discussed that there may be a delay when there is a change of Consultant of Record and gives 10-day window to notify of the change.

Motion that the change to this rule does not create a minor violation by Mr. Phillip with second by Mr. Bisailon. Action taken: approved unanimously.

D.) Rule 64B16-27.450, F.A.C., regarding prescription department managers. Adds language regarding requirements that applications for a Special Sterile Compounding Permit require the pharmacist in charge to be designated as either the PDM or a consultant pharmacist of record; and fingerprint retention and tracking designated consultant or PDM.

Discussion:

Mr. Harris gave the background on changes to the language approved at the January 12, 2018, Rules Committee meeting, and board counsel's recommendations.

Same types of changes as those made in rule 64B16-28.501, F.A.C., will be made.

Motion by Dr. Hickman with second by Mr. Phillip. Action taken: approved unanimously  
SERC - Motion by Mr. Montgomery that there is no adverse fiscal impact with second by Mr. Bisailon.  
Action taken: approved unanimously.  
SERC – Motion by Dr. Hickman that there is no adverse 5-year fiscal impact, with second by Mr. Bisailon. Action taken: approved unanimously.  
Motion that the change to this rule does not create a minor violation by Mr. Bisailon with a second by Dr. Hickman. Action taken: approved unanimously.

E.) Rule 64B16-28.100. F.A.C., regarding pharmacy permits applications and permitting. Adds language regarding fingerprint retention. In addition, applications for community, institutional, nuclear, special pharmacies and Internet pharmacies, change in PDM and change in consultant pharmacist are captured for review by the board.

Discussion:

Mr. Harris gave the background on changes made to the language approved at the January 12, 2018, Rules Committee meeting and board counsel's subsequent recommendations. Mr. Harris recommends: deleting language duplicative of other rules; adding/changing language that is not clear; making language consistent between applications. An exception for pharmacies that already hold a special permit was also amended.

Rule 64B16-28.100, F.A.C., discussed as to the community, institutional, nuclear, Internet, change in Pharmacy Department Manager and change in Consultant Pharmacist of Record forms.

Motion by Mr. Bisailon to approve the language in these forms with the verbal amendments recommended today with second by Mr. Phillip. Action taken: approved unanimously.

Special pharmacy permit:

Board members discussed several issues of concern regarding this permit. The language is very old and may have been significantly amended since its initial promulgation.

Motion by Mr. Phillip to approve the applications as shown in the record but continue discussions with second by Mr. Bisailon. Action taken: approved unanimously.

Special sterile compounding permit:

Board members determined that this form should be sent to the Compounding Committee for further discussion and recommendations. The issues to be discussed by committee members included:

Should the application ask if the applicant received an FDA Form 483 warning letter?

Should this question be a yes/no?

Should this require attachment of the letter?

Should the letter be accompanied by photographs, etc.?

Should the matter of a failed inspection with a CAP correcting the matters come before the board?

Motion by Dr. Mikhael to amend as recommended with second by Dr. Hickman. Action taken: approved unanimously.

Review questions 34, 35, 36 on the application form for the purpose of moving the standard to CETA CGA00.3

Review question 28 regarding the products and should it be bulk or something else?

Review the entire application for updating to current standards.

Motion by Mr. Bisailon to move forward with application as presented but move it to the Compounding Committee for further review, second by Dr. Mikhael. Action taken: approved unanimously.

SERC - Motion by Dr. Mikhael that there is no adverse fiscal impact with second by Ms. Rivera. Action taken: approved unanimously.

Motion by Mr. Phillip that violation of the rule is a minor violation with a second by Dr. Mikhael. Action taken: approved unanimously.

The board members discussed that if a JAPC letter was received, they could set a special telephone conference to respond to any JAPC changes or questions.

F) Rule 64B16-26.351 – delegation of authority pharmacy technician training program approval. Rule must include a date certain on the approval. This rule will be updated each year to determine if there are significant changes that need to be considered by the board

Motion by Dr. Mikhael to update the rule with second by Mr. Phillip. Action taken: approved unanimously.

SERC - Motion by Mr. Bisailon that there is no adverse fiscal impact with second by Mr. Phillip.  
Action taken: approved unanimously.

Motion that the change to this rule does not create a minor violation by Mr. Phillip with a second by Dr. Mikhael. Action taken: approved unanimously.

G) Rule 26.200, FAC, regarding the examination rule that designates the Pharmacist Assessment for Remediation Evaluation (PARE) Assessment to assess current clinical competency. The examination is no longer being offered. Question was posed as to whether this could be used in discipline cases. Mr. Flynn informed the board that this had only been used one time since 1975.

Motion to strike subparagraph (2) by Mr. Phillip with second by Mr. Wright. Action taken: approved unanimously.

SERC - Motion by Mr. Phillip that there is no adverse fiscal impact with second by Bisailon. Action taken: approved.

Audience comment period:

Mr. Lance Leider of the Health Law Firm representing pharmacies and pharmacy owners asked for the board to consider draft rules that he sent to Mr. Flynn. Mr. Flynn recommended deferral to committee since more research is needed.

**1:30 pm Lunch break meeting resumed at 2:39 pm**

**2. Compounding** – presented by Dr. Mikhael

A) Rule 64B16-27.1001, F.A.C., regarding the practice of pharmacy. Presented for discussion of subparagraph (2)(b) on the requirement that the pharmacist mix “extemporaneous compounding” or be physically present.

Discussion:

Mr. Flynn stated that Mr. Montgomery worked with him on a response to JAPC concerns, explaining that there is no delegation down to a technician. Based on discussion, Mr. Flynn stated that he could break this rule into 2 rules, but anticipates that there will be federal legislation that may clarify.

Dr. Mikhael asked the board members to get comments to Mr. Flynn before the next meeting; identifying key questions and that a telephonic workshop could be held for the compounding committee so that clean copy can be presented to the full board at the April meeting.

**3. Controlled Substances** – presented by Dr. Hickman

Discussion:

Dr. Hickman reported on the subgroup for educational needs of using controlled substances. There were 6 modules reviewed: scope of the epidemic (compare and contrast Florida with national statistics); risk and complications from use; controlled substance pharmacology and pharmacokinetics; practical examples of acute pain management; acute pain management strategies; patient education. Would not be enough time in a 3-hour course to cover chronic pain, so concentrated on acute. Topics of interest were using e-force, who is the audience for courses.

#### 4. **Legislation** - presented by Mr. Philip

- HB 21 was amended by the Health Policy Committee. The board's concern has to do with the term "medically necessary treatment," limits for prescribing opioids for acute pain in certain circumstances, and the mandate to consult the PDMP for every dispensation of every schedule II thru V drug. The board members were also concerned about how the PDMP consult would be verified and still provide HIPPA protection. Mr. Kahn suggested that the board write a statement containing wording of the changes that they want to see addressed. Motion by Dr. Hickman with second by Mr. Bisailon to send message of concerns to the legislature.
- HB 351 drug pricing transparency. The board remains in support.
- HB 431/ SB 524 treatment of influenza was killed in committee this morning.
- HB 679 telepharmacy needs a clear grant of authority left to the board on some areas. The board remains in support.
- HB 1047 is the Department of Health bill.
- HB 1099 provides that advanced birth centers will be considered a modified class II pharmacy.
- HB 1047 and 1099 was given a motion to support by Mr. Bisailon with a second by Dr. Hickman. Action taken: approved unanimously.
- Dr. Mikhael asked about the HB513 which provides that dialysate can be sent to the patient's home. Mr. Dalim stated that the reason for the legislation was because of the bulk of this item for home dialysis. The change has been on the legislative agenda before but has never passed. The bill appears to be aligning terms and calling it distribution. This is already an exception for manufacturers.
- Expansion of technician roles  
The board members discussed looking at the changes to pharmacist roles and the cost benefit analysis of expanding the role of a pharmacy technician, as well as the benefit to patients. The question was raised to whether the board wants to expand pharmacy technician duties and free up pharmacist time, or increase the number of pharmacy technicians that a pharmacist can supervise. The board members discussed what safety measures would need to be in place to ensure a pharmacy technician could safely perform tasks assigned to them, freeing up the pharmacist to perform the expanded duties and improve patient outcomes.

The board members determined that expansion needs a separate subcommittee to look at the educational requirements, etc. Dr. Mesaros volunteered to gather data from other states on this issue.

Motion to adjourn by Mr. Bisailon second by Ms. Rivera approved at 4:47pm.

**Wednesday, February 7, 2018, 9:00 a.m.**

**BOARD MEMBERS:**

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

**BOARD STAFF:**

C. Erica White, MBA, JD - Executive Director  
Adrienne Rodgers, JD, Bureau Chief

**DEPARTMENT OF HEALTH COUNSEL:**

Matthew Witters, Assistant General Counsel

**BOARD COUNSEL:**

David Flynn, Assistant Attorney General

**Excused absences:**

Gavin Meshad, Consumer member

Called to order at 9:01 AM

**TAB 4: PETITIONS FOR VARIANCE OR WAIVER**

David Flynn, board counsel, gave overview of the variance/waiver authority of the board. With respect to variance/waiver, Mr. Flynn informed the board of the burden that the petitioner must carry before the board can grant a variance/waiver.

3. Lakeview Pharmacy file # 19974 Petitioner was not present and was not represented by counsel. The petition had been withdrawn.
2. Moffitt Cancer Center file # not provided. Petitioner was represented and was not represented by counsel.

Petition to permanently waive rule 64B16-27.797, FAC, as the using the PhaSeal closed system transfer device since a study confirmed it works to provide a mechanical barrier to the entry of contaminants into sterile solutions up to 168 hours. Moffitt requested the authority to use leftover drugs for subsequent patient admixtures from SDVs. Moffitt would continue to keep leftover solutions at 2-8 degrees Celsius and utilize the drugs within 6 hours or less depending on the manufacturer's data. Permit number is missing.

**Discussion:**

Mr. Flynn asked if there was an open investigation or discipline case and was informed that the DOH inspector advised Moffitt to seek a variance/waiver at this time and the inspector has not filed a complaint.

Representative gave an overview of the request and stated that the request stemmed from drug shortages and benefiting patients without delay and without compromising sterility of the drugs. Petitioner had validated studies in its own environment but had not been tested through independent laboratory. Feels this is a permanent practice and not just during shortages periods. Petitioner indicated that 3 out of 11 U.S. cancer centers use this system. Hardship is the drug shortage and fiscal impact of not being able to bill for waste.

The board members discussed the issues of broad approval if this petition is granted, sterility of the drugs after opening, immunocompromise of patients by the storage, safety as compared to 797 standards, appropriate staff training for its use. The lack of independent study, and use of the device for other than its marketed use as a containment device was also expressed.

The board found that granting this variance was a valuable change to the rule and not granting the petition will shut down Moffitt's Cancer Center current process. The board recognized that variances to 797 have been granted by the board before today.

Motion, as amended, by Dr. Mikhael finding hardship and that the variance used by Moffitt's Cancer Center meets the underlying purpose of the statute; variance/waiver to the granted for a 12-month timeframe, extending storage under the description provided by Petitioner to 6-hours according to 797 standards; specifying the particular product currently used by the Petitioner; and requiring independent study and report be provided to the board within 120-days. Seconded by Dr. Mesaros. Action taken: approved with one opposed.

Mr. Flynn stated Petitioner must produce permit number(s) so that the variance/waiver can be completed.

1. All Med Pharmacy file # 23673. A representative for Petitioner was not present and Petitioner was not represented by counsel.

Petitioner requested a temporary waiver from rule 64B16-28.1081, FAC, and modify its hours of operation during the pendency of a sale of its business from 40-hours to 15-hours. Petition did not reference the information required under s. 120.542(5), F.S., which requires the petitioner to name the rule from which a variance or waiver is requested, the type of action requested, the specific facts that would justify a waiver or variance for the petitioner, and the reason why the variance or the waiver requested would serve the purposes of the underlying statute.

Discussion:

Hardship is not being able to meet needs of clients due to being unable to remain open for 40-hours.

The board members discussed whether this type of request should be revisited through rulemaking. It was determined that the rule had already been revised once and that further reduction would not meet the prescription needs of the public.

Motion by Mr. Wright, seconded by Mr. Bisailon to deny petition. Action taken: approved unanimously.

4. Plantation General Partnership file # \_\_\_\_\_. Petitioner was represented and was not represented by counsel.

Petitioner requested a waiver from rule 64B16-28.141, FAC, stating that its patient autofill meets all requirements except to being located adjacent to the pharmacy. The patient autofill will be located near the Emergency Room with 24/7 security. The autofill would only open during regular pharmacy hours. Petitioner had received similar approval for its Jacksonville hospital, which is 800-feet away from the pharmacy location.

Petitioner's representatives spoke to the technology involved.

Discussion:

The board members discussed whether all other requirements of meeting with pharmacist apply; where the board is in rulemaking on automated systems; availability of controlled substances; and how the earlier approval is working.

Motion by Dr. Mikhael to grant the petition for an 800-foot distance from the pharmacy without controlled substances; all other requirements of rule must be met. Seconded by Dr. Hickman. Action taken: approved unanimously.

Break taken at 10:49 AM; resumed at 11:07 AM

Petition for variance/waiver not on the agenda found at Bates 231:

Eric L. Harris, President of Pharm-Tech Technical Institute was present and not represented by counsel.

Pharmacy technologist program was approved by Council for Independent Education (CIE) in April 2017. Petitioner requested variance/waiver to continue the program since rule 64B16-26.351, FAC, requires a technical program have approval of CIE before April 1, 2107. Petitioner's application to the Board of Pharmacy did not meet the deadline and, therefore, required approval of the board. CIE granted contingent approval based on approval of the Board of Pharmacy, and gave a 90-day window to go before the board.

Mr. Lawrence Harris noticed the petition in Florida Administrative Laws, Code, Register (FAR) but the notice was not filed 14 days prior to the board meeting as required by law. Petitioner had been noticed of the board meeting today and drove up from south Florida. Mr. Harris believed there was good cause to hear the matter at the board meeting today, and stated that if the board was inclined to act favorably, the proposed action can become final once the time for comment ends. There were no comments to date and the matter had 10-days left to run.

Mr. Philip moved to approve once the 14-day period concludes if there are no comments. Second by Mr. Bisailon. Action taken: approved unanimously.

## **TAB 5: APPLICATIONS REQUIRING BOARD REVIEW**

### **A. Pharmacist Applications – Montgomery presenting**

1. Sanjeev Seenath file # 51441 Applicant was present and was not represented by counsel. Dr. Brown of PRN also appeared OBO applicant.

**Mr. Seenath was arrested on March 3, 2017 for criminal mischief and aggravated battery with a deadly weapon. Case was transferred to misdemeanor court for a lesser charge of public affray. He entered a plea of nolo contendere and adjudication was withheld on 6/27/2017. Mr. Seenath had to submit to random alcohol checks and substance abuse evaluation and any recommended follow-up treatment.**

Discussion:

Mr. Flynn informed the board that the criminal matter was in abeyance conditioned upon the applicant leaving the United States for a period of 10-years, and which time the criminal action would be dropped. Mr. Flynn added that if the board acted to grant the license at this meeting, then there the board would have no authority to rescind the license if the applicant failed to meet the terms of the criminal judgment. Mr. Flynn recommended the application be held in abeyance until Georgia criminal case is completed, then the applicant must appear before the board for a decision on granting or otherwise treating the application for license.

Motion by Dr. Mikhael to withhold a decision until the criminal charges in Georgia are settled; Applicant must report to board once the criminal matter is finalized. Seconded by Dr. Hickman. Action taken: withhold determination.

### **B. Registered Pharmacy Technician**

1. Elise Bowman file # 80173. Applicant was present and was not represented by counsel.

**Applicant submitted a Registered Pharmacy Technician Application with Health History. Applicant answered "yes" to Health history questions, "In the last five years, have you been admitted or referred to a hospital, facility or impaired practitioner program for treatment of a diagnosed mental disorder or impairment?"**

Discussion:

Applicant is under regular treatment with her physician every one to three months. She was last hospitalized in June 2016. She currently teaches others how to live with the diagnosis.

Motion by Dr. Mikhael to approve. Second by Dr. Hickman. Action taken: approved unanimously.

2. Felicia Bradley file # 80506 Applicant was not present and was not represented by counsel.

**Applicant submitted a Registered Pharmacy Technician Application with criminal history. Applicant answered "yes" to criminal history question, "Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest, to a crime in any jurisdiction other than a minor traffic offense?"**

Discussion:

The board members discussed whether the applicant should be at the board meeting to respond to concerns of the board.

Motion to continue to appear at one of the next two meetings. Second by Dr. Hickman. Action taken: approved with Mr. Phillip opposed.

3. Edite Cindy Olcine file # 82441 Applicant was not present and was not represented by counsel.

**Applicant submitted a Registered Pharmacy Technician Application with criminal history. Applicant answered "yes" to criminal history question, "Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest, to a crime in any jurisdiction other than a minor traffic offense?"**

Discussion:

The board members discussed whether the applicant should be at the board meeting to respond to concerns of the board.

Motion by Dr. Hickman to continue to appear at one of the next two meetings. Second by Dr. Mikhael. Action taken: approved unanimously.

## C. Pharmacy Permits

1. New Vitalis, LLC. A representative for Applicant was present and Applicant was not represented by counsel.

Affiliate Michael Kellihan, PharmD, answered "yes" to criminal history question, "Has the applicant, or any officer, member or partner ever been convicted of a felony, misdemeanor, excluding minor traffic convictions?" Conviction was mail fraud, mail laundering, forfeiture, & tax evasion in 1999.

### Discussion:

Dr. Kellihan was not present. Applicant's representative presented the information. Board members asked what business the applicant would do in Florida and were told that it would provide non-sterile and sterile hormone replacement therapy to persons with homes in Florida who are patients of clinics through which they have contracts. They may also pursue contracts with clinics in Florida.

Motion by Mr. Phillip. Seconded by Mr. Bisailon. Action taken: approved unanimously.

2. Downing Labs, LLC. A representative for Applicant was present and Applicant was not represented by counsel.

Applicant submitted a Non-Resident Sterile Compounding application and supporting documents on March 24, 2017. The inspection report is dated March 2016 from the State of Texas. The inspection is a partial inspection that does not address USP 797 compliance. Additionally, this inspection is also not within the six month period prior to submitting the application.

Board staff determined that inspection does not meet statutory criteria. Applicant asked to have full board review.

### Discussion:

Applicant currently does sterile compounding in Florida. Applicant has a consent decree with FDA from 2015, which requires that the company meet 797 criteria, and has 2 quarterly reports so far, but still has 11 areas of compliance to complete. Applicant had asked for Florida inspector to come out.

Mr. Flynn informed the board that a decision must be made today but an approval could not be entered until an inspection was completed and reviewed by the board. The applicant could also be allowed to withdraw and reapply with a clean inspection.

Motion by Dr. Mikhael to allow withdrawal of the application. Seconded by Dr. Hickman. Action taken: approved unanimously.

## TAB 6. DISCIPLINARY CASES

### A. SETTLEMENT AGREEMENTS

SA-02 Centro Dr Dignostico Y. Tratamiento, Inc 2016-24512 Members recused: Dr. Mikhael  
Alleged: that Respondent violated s. 465.023(1)(c), F.S., by rule 64B16-27.797(1)(a), FAC

On or about August 29, 2016, the Department conducted a sterile compounding inspection of Respondent and found one or more deficiencies relating low and medium-risk sterile compounding.

Settlement terms recommended by the department with oral amendment to extend time to pay one year:

1. Appearance
2. \$3000 fine payable within 90 days
3. Costs limited to \$2,570.27 payable within 90 days
4. 1 year probation with the following terms:
  - a. Semi-annual inspections at Respondent's cost;
  - b. Corrective action plan submitted within 90 days;
  - c. Reappearance within last 3 months of probation

Costs: \$1,722.88.

Motion by Dr. Hickman to approve. Second by Dr. Mesaros. Action taken: approved unanimously

SA-03 Babak Haghgou 2016-24514 Members recused: Dr. Mikhael  
Alleged: Respondent violated s. 465.022(11)(a), F.S. (2016) by rule 64B16-27.797(1)(a), FAC

At all times material to the Administrative Complaint, Respondent was the prescription department manager of record for Centro De Diagnostico Y Tratamiento, Inc., a special sterile compounding pharmacy located in Sanford, Florida. On or about August 29, 2016, the Department conducted a sterile compounding inspection of the pharmacy and found one or more deficiencies relating low and medium-risk sterile compounding.

Settlement terms recommended by the department with oral amendment to extend time to pay one year:

1. Appearance
2. \$3000 fine payable within 90 days
3. Costs limited to \$2053.55 payable within 90 days
4. CEs – 50 hours of Essential Elements of Compounded Sterile Preparations

Costs: \$1,162.56

Motion by Dr. Hickman to approve. Second by Dr. Mesaros. Action taken: approved unanimously.

SA-01 Jerrett C. Pigott 2017-09030 Members recused: Mr. Bisaillon  
Respondent was present and was not represented by counsel.  
Alleged: that Respondent violated s. 465.016(1)(g), F.S. (2016)

On or about February 3, 2017, the Respondent dispensed lorazepam oral concentrate 2mg/mL bearing a label for loratadine 5mg/5mL syrup to patient A.B. when patient A.B. had a prescription for loratadine.

Settlement terms recommended by the department:

1. Appearance
2. \$1000 fine payable within 30 days
3. Costs limited to \$2,657.27 payable within 90 days
4. CEs – 8 hours Medication Errors, 12 hours Laws and Rules

Costs \$1,744.48

Discussion:

Board members requested information on how the pharmacy safety procedures had changed since this incident and made recommendations to the Respondent for further improvement.

Motion by Mr. Phillip to reject the proposed settlement agreement and counter by removing the fine but keeping all other terms of the proposed settlement agreement. Mr. Witters advised that removing the fine would make this a non-reportable offense. The department had no objection. Mr. Flynn advised the board that there are aspects to discipline, punishment being only one of them.

Second by Dr. Mesaros. Action taken: approved unanimously. Respondent accepted the counter offer.

The board discussed whether options may be available at the probable cause stage when finding that the punishment aspect of the disciplinary process may not be applicable but that education and remediation aspects are most important.

## **TAB 7: LICENSURE ISSUES**

### **B. Petition for Payment Extension**

1. Austin Conner 2016-05067

Petitioner was present and was not represented by counsel.

Petitioner petitioned for extension of time to pay fines and costs. Ordered to pay by December 2018. \$1500 paid, leaving extension to remainder of costs and fines. Had been out of work due to hurricanes but is working now. He can pay in increments.

Motion by Dr. Mikhael to grant 18-month extension of time to pay remaining fines and costs. Second by Mr. Bisailon. Action taken: approved 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.*

DOW-01 Karissa Lynn Bono, RPT 2016-25734 Members recused: Dr. Mikael

Respondent was not present and was not represented by counsel.

Alleged: Respondent violated s. 456.072(1)(x), F.S. (2014) by failing to report plea of nolo contendere to one count of possession of a controlled substance, a felony in violation of s. 893.13(1)(a)1, F.S., and s. 465.072(1)9c, F.S., by entering a plea of nolo contendere to one count of possession of a controlled substance, a felony in violation of s. 893.13(1)(a)1, F.S., and one count of grand theft in violation of s. 812.014(2)(c)1, F.S., crimes which relate to the practice of pharmacy. Also alleged is violation of s. 465.016(1)(e), F.S., by entering a plea of nolo contendere to possession of a controlled substance in violation of s. 893.13(6)(a), F.S. Respondent was served by publication.

Recommendation of the department is revocation. Costs: \$730.40 (withdrawn)

Motion by Mr. Bisailon to accept the recommendation of the department. Second by Dr. Mesaros. Action taken: approved unanimously

DOW 02 Nereida Alina Montejo, RPT 2016-17952 - Tabled to the April 2018 meeting

### **C. VOLUNTARY RELINQUISHMENTS (VR)**

VR-01 Dino Ajlino 2017-15108

Member recused: Mr. Meshad

Respondent was not present and was not represented by counsel.

Motion by Dr. Mesaros to accept VR with second by Dr. Wright. Action taken: accepted unanimously.

VR-03 Grant B. Satterlee 2017-04713; VR-04 Grant B. Satterlee 2017-04729; VR-05  
Grant B. Satterlee 2017-04716; VR-06 Grant B. Satterlee 2017-04732  
Members recused: Dr. Mesaros & Mr. Bisailon

Respondent was not present and was not represented by counsel.

Motion by Dr. Mikhael to accept VR with second by Dr. Hickman. Action taken: approve unanimously

VR-02 Home Care Pharmacy of Palm Coast 2015-31480

Members recused: Mr. Philip

Respondent was not present and was not represented by counsel.

Motion by Mr. Wright to accept VR with second by Dr. Hickman. Action taken: approved unanimously.

#### **D. HEARINGS NOT INVOLVING ISSUES OF DISPUTED MATERIAL FACTS**

*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.*

I-01 Joseph Corgan 2015-31479 Members recused: Mr. Philip

Respondent was present and was represented by counsel.

Alleged: Respondent violated s. 456.072(1)(k), F.S., by a violation of s. 465.022(11)(a), F.S. by filing to ensure the permittee's compliance with rule 64B16-27.797(1)(a), FAC.

At all times material to the Administrative Complaint, Respondent was the prescription department manager of record for Home Care Pharmacy of Palm Coast, Inc., a permitted special sterile compounding pharmacy located in Palm Coast, Florida. On or about October 28, 2015, and May 1, 2017, the Department conducted sterile compounding inspections of Home Care Pharmacy and found one or more deficiencies relating to sterile compounding.

Mr. Corgan presented mitigating circumstances for consideration of the board. In 2015, was missing information at the time of the inspection by presented the missing information at a later time. In 2017, inspector came in on a Monday but pharmacy only did sterile compounding twice a week with the assistance of someone in addition to the regular staff technician. This individual kept all of the information necessary to comply with the inspection and so it was not available at the time of the inspection. Respondent did have the information, just not at the time of the inspection. The company he uses for fungal containment is 797 compliant.

Mr. Flynn raised the question of whether this was a dispute of material facts or whether the presentation was being made for the purpose of presenting mitigating circumstances. He recommended that a settlement agreement be drafted and presented to the board. Respondent's counsel agreed to discuss settlement and bring it back to the board.

Oral settlement agreement presented to the board by Mr. Witters:

Fine: \$4,000 and costs: \$1,131.05, each payable in one year from the date of the entry of the order;

Practice restriction: Respondent will not own, operate, or practice pharmacy within a sterile compounding pharmacy in Florida until he appears before the board to demonstrate competency, at a minimum to be a completion of the UF 50-hour sterile compounding course.

There are no issues with Respondent's community pharmacy permit.

Motion by Mr. Mikael to accept the recommendations of counsel, seconded Mr. Bisailon. Action taken: approved unanimously.

### **E. PROSECUTION SERVICES REPORT**

Discussion:

Mr. Witters provided an update on the current caseload for the Prosecution Services Unit. A motion was made by Dr. Mikael with second by Dr. Mesaros to allow PSU to continue to prosecute cases older than one year. Motion passed unanimously.

#### **TAB 7. LICENSURE ISSUES**

##### **A. Petition for Termination of Probation**

1. Holiday CVS, LLC d/b/a/ CVS Pharmacy # 05195 2012-02055
2. Holiday CVS, LLC d/b/a/ CVS Pharmacy # 00219 2012-02032

Sharif Helim, CVS District Leader, represented the Petitioner. Petitioner was represented by counsel. Recused: Dr. Mesaros

Compliance officer determination of current status as to 2012-02055:

**Completed:**

- \$10,000.00 Fine; \$1,000.00 Costs; Paid 01/29/2016
- CE's = Laws and Rules and Ethics; Completed 06/19/2017

**Outstanding Requirements:**

- Probation
- Quarterly Inspections
- Controlled Substance

Compliance officer determination of current status as to 2012-02032:

**Completed:**

- \$10,000.00 Fine; \$1,000.00 Costs; Paid 01/08/2016
- CE's = Laws and Rules and Ethics; Completed 06/14/2017

**Outstanding Requirements:**

- Probation
- Quarterly Inspections
- Controlled Substance

Discussion:

Mr. Bayo represented that the inspections for both cases were completed. The most recent inspection was on Dec. 29, 2017, and there were no deficiencies in the previous quarterly inspections.

Motion by Mr. Wright, seconded by Mr. Bisailon to terminate probation. Action taken: approve unanimously.

3. Richard Alonso, Jr. 2012-06981  
Petitioner was present with Dr. Pomm.

**Compliance determination of current status:**

**Completed:**

- PRN Evaluation
- Fine = \$1,000.00; Paid August 29, 2013
- Costs = \$5,000.00; Paid November 17, 2017
- Practice Restriction: shall not have access to any medicinal drugs during probation  
(Lifted 09/27/2017)

**Outstanding Requirements:**

- Probation
- Quarterly Reports (current)
- Practice Restriction: shall not serve as a Prescription Department Manager during the first 2 years of probation
- Practice Restriction: shall not work at or for more than 2 pharmacies during each quarter of the probationary period unless prior written Board approval
- Final Appearance

**Order Denying Modification of Final Order was filed 10/31/2016**

- Modification of the Final Order is Denied
- All terms of probation remain as originally entered

**Discussion:**

Board members discussed timeframe for probation and requirements for probation have been met. Respondent stated the terms of the settlement agreement allowed him to grow and improve.

Motion by Dr. Mikael to terminate probation with second by Mr. Bisailon. Action taken: approve unanimously.

**B. Petition for Payment Extension – (PRESENTED EARLIER IN THE AGENDA)**

**C. Petition to Lift Restriction**

1. Douglas Neil Kassan 2006-42732

Petitioner was present and was not represented by counsel.

**Compliance determination of current status:**

**Completed:**

- Suspension = Lifted 05/19/2010
- Costs = \$2,366.96; Completed 07/18/2008
- CE= Completed 04/23/2008 & 07/09/2008
- Evaluation
- Quarterly Reports; Current

**Outstanding Requirements:**

- Probation
- Quarterly Reports
- Semi-Annual Inspections
- Practice Restriction

**Discussion:**

Petitioner requested the 2 pharmacy practice restriction be lifted. All other terms have been met and probation will continue for 18-months. PRN contract is complete.

Petitioner will seek work through a temp agency and possibly permanent positions.

Motion by Mr. Phillip to remove the restriction, seconded by Dr. Mikael. Action taken: approves unanimously.

**Open forum:**

Dr. Mikael requested that rule 64B16-27.797, FAC, regarding closed containment devices be put on the next agenda.

**Motion to adjourn meeting.**

Motion by Dr. Hickman to adjourn with second by Ms. Rivera. Action taken: approved unanimously