

Draft Minutes

October 14, 2021

Hyatt Regency Orlando International Airport

9300 Jeff Fuqua Boulevard

Orlando, FL 32827

407-825-1234



Jonathan Hickman, PharmD
Chair

David Wright, BPharm
Vice-Chair

Jessica Sapp, Executive Director

**BOARD OF PHARMACY
GENERAL BUSINESS MEETING
DRAFT MINUTES
October 14, 2021
Hyatt Regency Orlando International Airport
9300 Jeff Fuqua Boulevard
Orlando, FL 32827
407-825-1234**

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

I. CALL TO ORDER/ROLL CALL

Call to Order - The meeting was called to order by Board Chair, Dr. Hickman, at 9:00 a.m. ET.

Those present during the meeting included the following:

MEMBERS PRESENT:

Jonathan Hickman, PharmD, Chair
David Wright, BPharm, Vice – Chair
Jeenu Philip, BPharm
Patty Ghazvini, PharmD, BCGP
Jeffrey J. Mesaros, PharmD, JD
Dorinda Segovia, PharmD
Gavin Meshad, Consumer Member
Maja Gift, BPharm, MHA, Cph

STAFF PRESENT:

Jessica Sapp, Executive Director
Traci Zeh, Program Administrator

BOARD COUNSEL:

David Flynn, Esq.
Senior Assistant Attorney General

COURT REPORTER:

Cindy Green
America Court Reporting
3213 Hargill Drive Orlando, FL 32806
Reportingorlando@aol.com
(407) 896-1813
Fax: (407) 896-1814

PROSECUTION ATTORNEY:

Matthew Witters, DOH Prosecution Services
Alejandro Camacho, DOH Prosecution Services

To accommodate individuals wishing to address the Board, the Board Chair may adjust the sequence of the agenda items. The meeting minutes reflect the actual sequence of the events rather than the original agenda order.

II. RULE HEARING

A. 64B16-28.830, F.A.C., Special - Closed System Pharmacy

The Florida Pharmacy Association requested a rule hearing on the proposed rule.

64B16-28.830 Special – Closed System Pharmacy.

(1) A Special – Closed System Pharmacy permit is a type of special pharmacy as provided for by section 465.0196, F.S., which dispenses medicinal drugs, utilizing closed delivery systems, to facilities where

prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, ALF's (Adult Congregate Living Facilities), ICF-IIDs (Intermediate Care Facilities – Developmentally Delayed, also known as ICF – Individuals with Intellectual Disabilities), or other custodial care facilities when defined by AHCA rules and which the Board may approve.

(2) A special – closed system pharmacy permittee shall maintain a policy and procedure manual including drug procurement, storage, handling, compounding, dispensing, record keeping and disposition, as well as procedures for preventing the dispensing of controlled substances based upon fraudulent prescriptions.

(3) A special – closed system pharmacy permittee shall provide twenty-four-hour emergency and on-call service.

(4) A special – closed system pharmacy permittee may dispense parenteral and enteral medications as provided by rule.

(5) A special – closed system pharmacy permittee shall be under the supervision of a prescription department manager who is responsible for maintaining all drug records, providing security of the prescription department and following other rules as relate to the practice of pharmacy. The prescription department manager of a closed system pharmacy shall not be the prescription department manager of any other pharmacy permit except when the permit is within the premises of a community pharmacy permit.

(6) The utilization of registered pharmacy interns and registered pharmacy technicians is as provided by rules 64B16-26.400, 64B16-27.4001, 64B16-27.410, and 64B16-27.420, F.A.C.

(7) A special – closed system pharmacy may dispense medicinal drugs for outpatient use to their employees, their employees' spouses, and their employees' dependents.

The Board approved the proposed language at the June 10, 2021 meeting.

TJ Morton, Esq. was present on behalf of the Florida Pharmacy Association and addressed the Board in opposition of the Rule.

Dr. Hickman reiterated the intent of the rule was to open access to employees of the pharmacy.

Mr. Flynn addressed the Board and communicated that per 465.003(11)(a), Florida Statutes, the proposed language may conflict with the statute as this would allow a special closed system pharmacy to act as a community pharmacy.

Motion: by Dr. Ghazvini to withdraw the proposed rule.

Second: by Dr. Segovia

Vote: Unanimous

III. DISCIPLINARY CASES - Jonathan Hickman, PharmD, Chair

A. SETTLEMENT AGREEMENT

- i. Paul DiPasquale, C.Ph., Case No. 2019-05968
(PCP – Mesaros & Mikhael)

This case was tabled to be heard at the December Meeting.

- ii. Paul DiPasquale, R.Ph., Case No. 2019-05992
(PCP – Mesaros & Mikhael)

This case was tabled to be heard at the December Meeting.

- iii. Charles Brumer, Case No. 2020-10025

(PCP – Weizer & Meshad)

The Respondent was present and represented by Joe Lumer, Esq.

Dr. Segovia recused herself from the case.

Mr. Camacho presented the case to the Board. The Respondent was charged with the following violation(s): **Count I:** Section 465.016(1)(e), F.S. (2019), through a violation of section 893.07(5)(b), F.S., **Count II and III:** Section 456.072(1)(k), F.S. (2019), through a violation of section 465.011(1)(b), F.S. by failing to maintain a complete and accurate record of controlled substances as the Respondent failed to report a significant theft or loss of controlled substances within 24 hours of discovery.

A Settlement Agreement was presented to the Board with the following terms:

- Appearance
- Fine of \$5,000.00 to be paid within ninety (90) days of the filing of the Final Order.
- Costs of \$8,869.85 to be paid within one hundred and eighty (180) days of the filing of the Final Order.
- Successful completion of a twelve (12) hour laws and rules course to be in addition to their hours required for renewal and to be completed within one (1) year of the filing of the Final Order.
- Probation for two (2) years to include:
 - Respondent cannot serve as a Prescription Department Manager (PDM)
 - Respondent cannot work at or for more than two pharmacies each quarter.
 - Submission of reports by the Respondent and his employer every three months.

After discussion, the following action was taken:

Motion: by Mr. Philip to accept the orally amended Settlement Agreement to include all terms with the amendment that the Respondent is permanently restricted from owning or serving as a Prescription Department Manager.

Second: by Mr. Wright

Vote: Unanimous

B. DETERMINATION OF WAIVER

- iii. Holiday CVS, L.L.C., Case No. 2020-39095
(PCP – Weizer & Meshad)

The Respondent was present represented by Edwin Bayo, Esq.

Mr. Witters presented the case to the Board. The Respondent was charged with the following violation(s): **Count I:** Section 465.023(1)(c), F.S. (2020), by violating Rule 64B16-28.110, F.A.C. **Count II:** 465.023(1)(c), by violating Rule 64B16-28.102(4), F.A.C. by failing to remove outdated medications from the active stock that was discovered during a routine inspection and for not operating under clean, uncrowded conditions with the presence of boxes and/or trash.

Motion: by Dr. Hickman to find the Administrative Complaint was properly served on Respondent and that Respondent failed to timely respond to the Administrative Complaint and has waived the right to request a hearing.

Second: by Mr. Wright

Vote: Unanimous

Motion: by Dr. Hickman to accept into evidence of the final investigative file.

Second: by Mr. Wright

Vote: Unanimous

Motion: by Dr. Hickman to adopt as its findings of fact, and conclusions of law as set forth in the Administrative Complaint

Second: by Mr. Wright

Vote: Unanimous

Motion: by Dr. Hickman to find the conclusions set forth in the Administrative Complaint constitutes a violation of the practice act.

Second: by Mr. Wright

The Department presented the following recommendation:

- Fine of \$1,000.00 to be paid within ninety (90) days of the of the filing of the Final Order.

After discussion, the following action was taken:

Motion: by Mr. Wright to accept the Departments recommendation.

Second: by Dr. Ghazvini

Vote: Unanimous

Motion: by Mr. Wright to impose the costs of \$2,051.51 to be paid within ninety (90) days of the of the filing of the Final Order.

Second: by Dr. Hickman

Vote: Unanimous

- i. Juanessa Jean Richardson-Welch, R.P.T., Case No. 2020-27548 (PCP – Montgomery & Ghazvini)

The Respondent was not present nor represented by Counsel.

Mr. Witters presented the case to the Board. The Respondent was charged with the following violation(s): **Count I:** Section 465.016(1)(a), F.S. (2009) **Count II:** Section 456.072(1)(h), F.S. (2016, 2018) by obtaining and renewing her license through misrepresentation and fraud.

Motion: by Mr. Philip to find the Administrative Complaint was properly served on Respondent and that Respondent failed to timely respond to the Administrative Complaint and has waived the right to request a hearing. To accept into evidence the final investigative file for the purposes of establishing a prima facie case for a violation of the Florida Statutes as charged in the Administrative Complaint. To adopt as its 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.

Second: by Mr. Wright

Vote: Unanimous

The Department presented the following recommendation:

- Revocation

After discussion, the following action was taken:

Motion: by Mr. Meshad to accept the Departments recommendation.

Second: by Mr. Philip

Vote: Unanimous

The Department withdrew their motion for costs.

- ii. Northern VA Compounders, P.H., Case No. 2020-36927
(PCP – Mikhael & Segovia)

The Respondent was present and represented by Bassem Girgis.

Mr. Witters presented the case to the Board. The Respondent was charged with the following violation(s): Section 456.072(1)(f) F.S. (2020) by being discipline by the Virginia Board for one of more violations that would constitute a violation of Florida Law.

Motion: by Mr. Wright to find the Administrative Complaint was properly served on Respondent and that Respondent failed to timely respond to the Administrative Complaint and has waived the right to request a hearing.

Second: by Mr. Meshad

Vote: Unanimous

Motion: by Mr. Wright to accept into evidence of the final investigative file.

Second: by Mr. Meshad

Vote: Unanimous

Motion: by Mr. Wright to adopt as its findings of fact, and conclusions of law as set forth in the Administrative Complaint

Second: by Mr. Meshad

Vote: Unanimous

The Respondent does not dispute issues of material facts.

Motion: by Mr. Wright to find the conclusions set forth in the Administrative Complaint constitutes a violation of the practice act.

Second: by Dr. Ghazvini

The Department presented the following recommendation:

- Fine of \$5,000.00 to be paid within one (1) year of the filing of the Final Order.
- Successful completion of a twelve (12) hour laws and rules course to be completed by the Pharmacist in Charge and to be completed within one (1) year of the filing of the Final Order.
- Probation for one (1) year until passing one (1) inspection at the Respondents cost.

After discussion, the following action was taken:

Motion: by Mr. Wright to accept the Departments recommendation.

Second: by Mr. Meshad

Vote: Unanimous

Motion: by Mr. Wright to impose the costs of \$109.85 to be paid within ninety (90) days of the filing of the Final Order.

Second: by Mr. Meshad

Vote: Unanimous

iv. Terence Kelvin Smith, Jr., R.Ph., Case No. 2020-30690
(PCP – Weizer & Hickman)

The Respondent was not present nor represented by Counsel.

Mr. Witters presented the case to the Board. The Respondent was charged with the following violation(s): Section 465.016(1)(e), F.S. (2020), through a violation of Section 893.13(6)(a), F.S. by unlawfully possessing cocaine, a Schedule II controlled substance.

Motion: by Mr. Philip to find the Administrative Complaint was properly served on Respondent and that Respondent failed to timely respond to the Administrative Complaint and has waived the right to request a hearing. To accept into evidence the final investigative file for the purposes of establishing a prima facie case for a violation of the Florida Statutes as charged in the Administrative Complaint. To adopt as its 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.

Second: by Dr. Ghazvini

Vote: Unanimous

The Department presented the following recommendation:

- Revocation

After discussion, the following action was taken:

Motion: by Dr. Ghazvini to accept the Departments recommendation.

Second: by Mr. Philip

Vote: Unanimous

The Department withdrew their motion for costs.

v. Terence Kelvin Smith, Jr., R.Ph., Case No. 2020-13453

(PCP – Meshad & Wright)

The Respondent was not present nor represented by Counsel.

Mr. Witters presented the case to the Board. The Respondent was charged with the following violation(s): Section 456.072(1)(x), F.S. (2020) by failing to report to the Board within 30 days after being convicted of one count resisting an officer without violence and one count leaving the scene of a crash involving damage in Volusia County.

Motion: by Mr. Philip to find the Administrative Complaint was properly served on Respondent and that Respondent failed to timely respond to the Administrative Complaint and has waived the right to request a hearing. To accept into evidence the final investigative file for the purposes of establishing a prima facie case for a violation of the Florida Statutes as charged in the Administrative Complaint. To adopt as its 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.

Second: by Dr. Ghazvini

Vote: Unanimous

The Department presented the following recommendation:

- Revocation

After discussion, the following action was taken:

Motion: by Dr. Ghazvini to accept the Departments recommendation.

Second: by Mr. Philip

Vote: Unanimous

C. INFORMAL

- i. Deepak Aggarwal, R.Ph., Case No. 2021-00687
(PCP – Weizer & Gift)

The Respondent was not present nor represented by Counsel.

Mr. Camacho presented the case to the Board. The Respondent was charged with the following violation(s): **Count I:** Section 456.072(1)(k), F.S. (2020), by violating Section 465.022(11)(a), F.S. (2020), by failing to ensure compliance with Rule 64B16-28.110, F.A.C. **Count II:** Section 456.072(1)(k) by violating Section 465.022(11)(a) by failing to ensure compliance with Section 499.007(3), F.S. (2020) **Count III:** Section 456.072(1)(k) by violating section 465.022(11)(a) by failing to ensure compliance with Rule 64B16-28.140(3)(d), F.A.C. by failing to perform statutory or legal obligations as the prescription department manager for Coastal Pharmacy as during a routine inspection expired medications on active stock shelves, one of more bottles of medication with no label and/or drug name and a certified daily log not maintained was discovered.

Motion: by Mr. Philip to find that the Respondent was properly served, and the matter was appropriately before the Board as an informal hearing, to accept the investigative report into evidence, and adopt the findings of fact as set forth in the Administrative Complaint and to adopt the conclusions of law as set forth in the Administrative Complaint

Second: by Dr. Ghazvini
Vote: Unanimous

Motion: by Mr. Philip to find by clear and convincing evidence that this constitutes a violation of the Practice Act.

Second: by Dr. Ghazvini
Vote: Unanimous

The Department presented the following recommendation:

- Suspension until the Respondent appears before the Board. The Board reserves the jurisdiction to impose additional discipline.

After discussion, the following action was taken:

Motion: by Dr. Hickman to accept the Departments recommendation.
Second: by Dr. Ghazvini
Vote: Unanimous

Motion: by Dr. Hickman to impose the costs of \$545.85 payable within one (1) year of the reinstatement of the license.
Second: by Dr. Ghazvini
Vote: Unanimous

- ii. Coastal Pharmacy, LLC, Case No. 2021-00309
(PCP – Weizer & Gift)

The Respondent was not present nor represented by Counsel.

Mr. Camacho presented the case to the Board. The Respondent was charged with the following violation(s): **Count I:** Section 465.023(1)(c), F.S. (2020), by failing to comply with Rule 64B16-28.110, F.A.C. **Count II:** Section 465.023(1)(c), F.S., by violating section 499.007(3), F.S. (2020) **Count III:** Section 465.023(1)(c), F.S., by failing to comply with Rule 64B16-28.140(3)(d), F.A.C., by failing to remove outdated medications, by failing to accurate label medications, and by failing to maintain a daily log since approximately September 2020.

Motion: by Dr. Hickman to find that the Respondent was properly served, and the matter was appropriately before the Board as an informal hearing, to accept the investigative report into evidence, and adopt the findings of fact as set forth in the Administrative Complaint and to adopt the conclusions of law as set forth in the Administrative Complaint and find by clear and convincing evidence that this constitutes a violation of the Practice Act.

Second: by Mr. Meshad
Vote: Unanimous

The Department presented the following recommendation:

- Fine of \$2,000.00 to be paid within one (1) year of the filing of the Final Order.
- Probation for one (1) year to include two (2) biannual inspections at the Respondents cost.

After discussion, the following action was taken:

Motion: by Dr. Hickman to accept the Departments recommendation.

Second: by Mr. Meshad

Vote: Unanimous

Motion: by Mr. Philip to impose the costs of \$546.54 payable within one (1) year of the filing of the Final Order.

Second: by Dr. Hickman

Vote: Unanimous

D. VOLUNTARY RELINQUISHMENT

- i. Jessica Brosnick Silva, R.P.T., Case No. 2019-38905
(PCP – Montgomery & Mesaros)

Motion: by Dr. Hickman to accept the voluntary relinquishment.

Second: by Dr. Ghazvini

Vote: Unanimous

E. Prosecution Services Report – Alejandro Camacho

Mr. Camacho presented the prosecution services case report to the Board and explained the current caseload is at 254 cases, from 277.

Motion: by Mr. Philip to allow prosecution to continue prosecuting cases older than one year.

Second: by Mr. Wright

Vote: Unanimous

IV. APPLICATIONS FOR REVIEW – Jeenu Philip, BPharm

A. Pharmacists

- i. Kelsey Echelbarger

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

The applicant applied for a pharmacist license and answered yes to the discipline history questions on her application.

After further discussion the Board took the following action:

Motion: by Dr. Hickman to approve the application.

Second: by Mr. Wright

Vote: Unanimous

- ii. James Pawlowski

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

The applicant applied for a pharmacist license and answered yes to the discipline history questions on his application.

After further discussion the Board took the following action:

Motion: by Mr. Wright to approve the application.

Second: by Dr. Ghazvini

Vote: Unanimous

B. Registered Pharmacy Technician

- i. Valencia Woods

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

The applicant applied for a registered pharmacy technician license and answered yes to the criminal history questions on her application.

After further discussion the Board took the following action:

Motion: by Mr. Philip to approve the application.

Second: by Mr. Wright

Vote: Unanimous

C. Pharmacy Permits

- i. Doctors Parenteral & Enteral Pharmacy

This application was pulled from the agenda.

D. Initial Course Applications

- i. Application for Initial Test and Treat Certification Course

The Board of Pharmacy received an Initial Test and Treat Certification Course Provider Application from Nova Southeastern University College of Pharmacy Section 465.1895(2)(b) requires this application be reviewed and approved by the Board of Pharmacy, in consultation with the Boards of Medicine and Osteopathic Medicine. The Joint Rules Committee voted to approve the application during the October 1, 2021 meeting. The application and minutes from the Joint Committee Meeting was provided for Full Board review.

After further discussion the Board took the following action:

Motion: by Dr. Hickman to approve the application.

Second: by Dr. Segovia

Vote: Unanimous

V. PETITION FOR VARIANCE OR WAIVER

- A.** Integrated Medical Supplies, LLC, 64B16-27.797, F.A.C., The Standards of Practice for Compounding Sterile Products and 64B16-28.802, F.A.C., Special Sterile Compounding Permits for Pharmacies and Outsourcing Facilities

The petitioner was present and represented by Martin Dix, Esq.

Integrated Medical Supplies, LLC submitted a petition seeking a variance from the requirement

that the Petitioner utilize the December 1, 2013 edition of the USP as it relates to low-risk compounding and instead wished to rely on the version of USP 797 published on June 1, 2019. The 2019 version of USP 797 changes the requirements for immediate use of compounding. If the variance was to be granted the Petitioner would not need to obtain a special sterile compounding pharmacy permit to provide immediate use sterile products for clinical study protocols.

The petitioner withdrew their petition.

VI. PETITION FOR DECLARATORY STATEMENT

A. Corie Hawks

The petitioner was not present nor represented by Counsel.

The petitioner requested the Board's clarification of office use compounding as identified in Rule 64B16-27.700 and how the regulation may substantially affect veterinarians.

Motion: by Dr. Mesaros to deny the petition as Ms. Hawks is not a licensed pharmacist and therefore has no legal standing.

Second: by Mr. Wright

Vote: Unanimous

VII. REPORTS – Jonathan Hickman, PharmD, Chair

A. Board Chair

Dr. Hickman provided an overview of the District 3 meeting he attended.

B. Executive Director's Report – Jessica Sapp, Executive Director

i. Pharmacy Processing Numbers

Ms. Sapp provided an overview of the current processing numbers.

ii. Staff Recognition

This was provided for informational purposes.

iii. 2022 Legislation

Ms. Sapp provided an overview of the bills that have currently been filed for the 2022 legislation.

C. Board Counsel Report – David Flynn, Senior Assistant Attorney General

iv. Rules Status Report

Ms. Flynn provided the Board with a summary of the current rules report.

D. Committee Report

i. Rules Committee – Jeffery J. Mesaros, PharmD, JD

a. Rules Committee Update

i. 64B16-27.420, F.A.C., Pharmacy Technician – Delegable and Non-Delegable Tasks

During the August 25, 2021 Rules Committee meeting, the Committee reviewed a request from Sr. Director of Pharmacy Affairs for CVS Health, Lauren Paul, PharmD, MS., and proposed the Board discuss 64B16-27.420, F.A.C., to allow technicians to transfer prescriptions verbally. During the discussion Mr. Flynn addressed the Committee regarding 465.026, Florida Statutes, Filling of Certain Prescriptions, and stated the authority lies with the pharmacist. He recommended the Committee place this discussion on the October agenda to allow time to research the statutory authority for rule change. This was placed on the agenda for further discussion.

This will be placed on a future Rules Committee Meeting for further discussion.

b. Compounding Committee Update

Dr. Segovia provided an overview of the October 13, 2021 Committee Meeting.

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

Mr. Difiore provided a brief update on the inspection results as of October 2021.

As of October 2021 - Non-Sterile Pharmacy inspections currently at 2,325 inspections completed; Sterile Compounding Pharmacy inspections currently at 211 inspections completed.

VIII. NEW BUSINESS – Rich Montgomery, BPharm, MBA, Chair

A. Ratification of Issued Licenses/Certificates

- i. Pharmacist (licensure) – 487
- ii. Pharmacist (exam eligibility) – 476
- iii. Pharmacist Intern – 482
- iv. Consultant Pharmacist – 43
- v. Nuclear Pharmacist - 2
- vi. Pharmacy/Facilities – 67
- vii. Registered Pharmacy Technician – 1,225
- viii. Registered Pharmacy Technician Training Program – 23
- ix. Nonresident Sterile Compound – 2
- x. Approved CE Courses – 30
- xi. Individual Pharmacist Request for Approval of CE – 3

Motion: by Dr. Mesaros to accept the ratification lists.

Second: by Mr. Philip

Vote: Unanimous

IX. OLD BUSINESS – Rich Montgomery, BPharm, MBA, Chair

A. Review and Approval of Meeting Minutes

- i. August 25, 2021 White and Brown Bagging Workgroup Meeting Minutes
- ii. August 25, 2021 General Business Meeting Minutes
- iii. August 25, 2021 Rules Committee Meeting Minutes

- iv. August 26, 2021 General Business Meeting Minutes
- v. October 1, 2021 Joint Rules Committee Meeting Minutes

Motion: by Dr. Mesaros to accept the meeting minutes.

Second: by Mr. Meshad

Vote: Unanimous

X. FOR YOUR INFORMATION

A. Unlicensed Activity Presentation

Mr. Chilo Cases, Unlicensed Activity Liaison, provided a ULA presentation to the Board.

B. Florida Prescription Drug Monitoring Program Monthly Report

This was provided for informational purposes.

XI. ADJOURNMENT

There being no further business the meeting adjourned at 2:00 p.m.