

Draft Minutes

June 9-10, 2021

Holiday Inn Orlando Disney Springs

1805 Hotel Plaza Boulevard

Lake Buena Vista, FL 32830

(407) 828-8888



Jonathan Hickman, PharmD
Chair

David Wright, BPharm
Vice-Chair

Jessica Sapp, Executive Director

**BOARD OF PHARMACY
GENERAL BUSINESS MEETING
DRAFT MINUTES
June 9-10, 2021
Holiday Inn Orlando Disney Springs
1805 Hotel Plaza Boulevard
Lake Buena Vista, FL 32830
(407) 828-8888**

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.

WEDNESDAY, JUNE 9, 2021 at 1:30 p.m. ET

I. CALL TO ORDER/ROLL CALL

Call to Order - The meeting was called to order by Board Chair, Dr. Hickman, at 1:30 p.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

STAFF PRESENT:

Jessica Sapp, Executive Director
Traci Zeh, Program Administrator

BOARD COUNSEL:

David Flynn, Esq.
Senior Assistant Attorney General
Christopher Dierlam, Esq.
Assistant Attorney General

ABSENT MEMBERS:

Maja Gift, BPharm, MHA, Cph

COURT REPORTER:

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

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. APPLICATIONS FOR REVIEW – Jeenu Philip, BPharm

A. Pharmacists

- i. Edward Olszewski

The applicant was not present nor represented by Counsel.

Mr. Olszewski submitted a request to table his application to a future meeting.

Motion: by Dr. Hickman to ratify the required appearance of Mr. Olszewski and require him to appear at the August meeting.

Second: by Dr. Ghazvini

Vote: Unanimous

ii. Kaitlin Kennedy

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

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

After further discussion the Board took the following action:

Motion: by Dr. Mesaros to approve to the application.

Second: by Dr. Hickman

Vote: Unanimous

B. Registered Pharmacy Technician

i. Rodney Nicolas

The applicant was not present nor represented by Counsel.

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

Mr. Nicolas failed to appear at the April 15, 2021 Board meeting; therefore, his application was placed on the June agenda for final review.

Motion: by Dr. Hickman to deny to the application due to failure to appear and prior criminal history being related to the practice of pharmacy.

Second: by Mr. Meshad

Vote: Unanimous

ii. Kelly Pascal

The applicant was not present nor represented by Counsel.

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

Ms. Pascal failed to appear at the April 15, 2021 Board meeting; therefore, her application was placed on the June agenda for final review.

Ms. Pascal submitted a request to withdraw her application.

Motion: by Dr. Hickman to approve the request to withdraw the application.

Second: by Dr. Segovia
Vote: Unanimous

iii. Renika Redding

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. Wright to approve to the application.
Second: by Dr. Mesaros
Vote: Unanimous

C. Pharmacy Permits

i. Sanford Investment Ventures, Inc.

The applicant was present and represented by Christopher Perseo, Pharmacy Managing Member. Mr. Perseo was sworn in by the court report.

The applicant submitted an application for a non-resident pharmacy permit application and has answered yes to the discipline history questions on the application.

After further discussion the Board took the following action:

Motion: by Dr. Hickman to accept the application.
Second: by Dr. Segovia
Vote: Unanimous

ii. East Tremont Pharmacy, LLC

The applicant was present and represented Jacob Jamron, Pharmacy Managing Member. Mr. Jamron was sworn in by the court report.

The applicant submitted an application for a non-resident pharmacy permit application and has answered yes to the discipline history questions on the application.

After further discussion the Board took the following action:

Motion: by Dr. Ghazvini to deny the application due to prior discipline and the denial of licensure in another state due to the falsification of documentation submitted.
The motion was not seconded.
Motion failed.

Motion: by Dr. Hickman to accept the application
Second: by Mr. Meshad
Vote: 6/1. Dr. Ghazvini opposed.

iii. Guardian Pharmacy

The applicant was present and represented by Martin Dix, Esq. and sworn in by the court reporter.

The applicant submitted an application for a community pharmacy permit application and has answered yes to the discipline history questions on the application.

Guardian Pharmacy currently holds Special Closed System Pharmacy and a Sterile Compounding Pharmacy. The Sterile Compounding Pharmacy entered into a Final Order on May 3, 2021 and is currently on probation.

After further discussion the Board took the following action:

Motion: by Dr. Hickman to accept the application.

Second: by Mr. Philip

Vote: Unanimous

III. PETITION FOR VARIANCE OR WAIVER

A. Maria Garcia, 64B16-26.300, F.A.C., Consultant Pharmacist Licensure

Pursuant to Rule 64B16-26.300(3)(b), F.A.C., Successfully complete a consultant pharmacist course of no fewer than twenty (20) hours approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and covers the subject matter set forth in Rule 64B16-26.301, F.A.C. The course shall be instructionally designed to include a cognitive test on which the applicant must score a passing grade for certification of successful completion of the course.

Effective December 20, 2020 the required continuing education course was amended from 12 hours to a 20-hour course. Ms. Garcia has completed an approved 16-hour continuing education course and is requesting a waiver of the rule to allow her to complete an additional 4 hours of consultant pharmacist continuing education to get to a total of 20 hours instead of one 20-hour course.

B. Yael El-Gad, 64B16-26.300, F.A.C., Consultant Pharmacist Licensure

Pursuant to Rule 64B16-26.300(3)(b), F.A.C., Successfully complete a consultant pharmacist course of no fewer than twenty (20) hours approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and covers the subject matter set forth in Rule 64B16-26.301, F.A.C. The course shall be instructionally designed to include a cognitive test on which the applicant must score a passing grade for certification of successful completion of the course.

Effective December 20, 2020 the required continuing education course was amended from 12 hours to a 20-hour course. Ms. El-Gad has completed an approved 16-hour continuing education course and is requesting a waiver of the rule to allow her to complete an additional 4 hours of consultant pharmacist continuing education to get to a total of 20 hours instead of one 20-hour course.

C. Christina Somorin, 64B16-26.300, F.A.C., Consultant Pharmacist Licensure

Pursuant to Rule 64B16-26.300(3)(b), F.A.C., Successfully complete a consultant pharmacist course of no fewer than twenty (20) hours approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and covers the subject matter set forth in Rule 64B16-26.301, F.A.C. The course shall be instructionally designed to include a cognitive test on which the applicant must score a passing grade for certification of successful completion of the course.

Effective December 20, 2020 the required continuing education course was amended from 12 hours to a 20-hour course. Ms. Somorin has completed an approved 16-hour continuing education course and is requesting a waiver of the rule to allow her to complete an additional 4 hours of consultant pharmacist continuing education to get to a total of 20 hours instead of one 20-hour course.

Motion: by Mr. Wright to grant petitions A-C.

Second: by Dr. Segovia

Vote: Unanimous

D. Lee Allison Boris, 64B16-26.300, F.A.C., Consultant Pharmacist Licensure

Pursuant to Rule 64B16-26.300(3)(b), F.A.C., Successfully complete a consultant pharmacist course of no fewer than twenty (20) hours approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and covers the subject matter set forth in Rule 64B16-26.301, F.A.C. The course shall be instructionally designed to include a cognitive test on which the applicant must score a passing grade for certification of successful completion of the course.

Effective December 20, 2020 the required continuing education course was amended from 12 hours to a 20-hour course. Ms. Boris has completed an approved 16-hour continuing education course and is requesting a waiver of the rule and allow the 16-hour class accepted to meet the requirement.

Motion: by Mr. Wright to partially grant the petition contingent upon Ms. Boris completing 4 additional hours to get to a total of 20 hours.

Second: by Dr. Mesaros

Vote: Unanimous

IV. ADJOURNMENT

There being no further business, the meeting adjourned at 3:15 p.m. ET.

THURSDAY, JUNE 10, 2021 at 9:00 a.m. ET

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

STAFF PRESENT:

Jessica Sapp, Executive Director

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

Traci Zeh, Program Administrator

BOARD COUNSEL:

David Flynn, Esq.
Senior Assistant Attorney General
Christopher Dierlam, Esq.
Assistant Attorney General

ABSENT MEMBERS:

Maja Gift, BPharm, MHA, Cph

COURT REPORTER:

Jane Heneghan
America Court Reporting
3213 Hargill Drive
Orlando, FL 32806
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(407) 896-1813
Fax: (407) 896-1814

II. DISCIPLINARY CASES - Jonathan Hickman, PharmD, Chair

A. SETTLEMENT AGREEMENT

- i. Guillermo Salas, R.Ph., Case No. 2019-10611
(PCP – Weizer & Mesaros)
(PCP – Wright & Meshad)

This case was tabled to be presented at the August meeting.

- ii. 904 Prospect Pharmacy, Inc., Case No. 2020-02816
(PCP – Weizer & Hickman)

Mr. Camacho presented the case to the Board. The Respondent was charged with the following violation(s): Section 456.072(1)(f), F.S. (2019) by having a license revoked suspended or acted upon in another jurisdiction for submitting fraudulent or inaccurate inspection report during the initial application process.

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

- Appearance
- Reprimand
- Fine of \$2,000.00 to be paid within ninety (90) days of the filing of the Final Order
- Costs of \$2,447.49 to be paid within ninety (90) 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 to be completed by the Prescription Department Manager (PDM) and to be completed within one (1) year of the filing of the Final Order.

Motion: by Dr. Segovia to accept the settlement agreement.

Second: by Mr. Philip

Vote: Unanimous

B. DETERMINATION OF WAIVER

- i. Vital Life Institute, LLC, Case No. 2019-12924
(PCP – Weizer & 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): **Count I:** Section 456.072(1)(j) F.S., (2018) **Count II:** Section 465.023(1)(c), F.S. (2018) through rule 64B16-28.140(4)(d) and (i), F.A.C., by aiding, assisting, procuring, employing, or advising any unlicensed person or entity to practice a profession and violating records maintained in a data processing records by having an employee that was neither a pharmacist nor registered pharmacy technician compounding drugs failing to maintain records of compounded drugs including patient signatures.

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. Meshad

Vote: Unanimous

The Department presented the following recommendation:

- Probation for two (2) years to include semi-annual inspections at the Respondents cost.
- Fine of \$5,000.00 to be paid within ninety (90) days of the filing of the Final Order.

After discussion, the following action was taken:

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

Second: by Dr. Ghazvini

Vote: Unanimous

Motion: by Mr. Meshad to impose the costs of \$480.65 payable within six (6) months of the reinstatement of the license.

Second: by Dr. Mesaros

Vote: Unanimous

- ii. Taylor L. Corley, R.P.T., Case No. 2020-31097
(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): **Count I:** 465.016(1)(e), F.S. **Count II:** 456.072(1)(m), F.S. by unlawfully possessing a controlled substance and making a deceptive, untrue, or fraudulent representation related to the

pharmacy of a profession by diverting buprenorphine at the Respondents place of employment.

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. Meshad

Vote: Unanimous

The Department presented the following recommendation:

- Revocation

After discussion, the following action was taken:

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

Second: by Mr. Meshad

Vote: Unanimous

The Department withdrew their motion for costs.

C. INFORMAL

- i. Yadelmis Marzabal, R.P.T., Case No. 2020-23967
(PCP – Montgomery & Philip)

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 456.072(1)(II), F.S. (2019) **Count II:** Section 456.072(1)(x), F.S. (2019) **Count III:** Section 456.072(1)(kk), F.S. (2019) by entering a plea of guilt to one count conspiracy to commit health care fraud and wire fraud, a felony violation of Title 18, U.S.C. Section 1349.

Motion: by Mr. Meshad 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 Dr. Ghazvini

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. Wright
Vote: Unanimous

The Department withdrew their motion for costs.

ii. Joseph M. Spellman, R.Ph., Case No. 2018-10771
(PCP – Glass & Philip)

The Respondent was present and represented by Edwin Bayo, Esq. The respondent was sworn in by the court report.

Dr. Segovia recused herself due to professional association that would prevent her from ruling an unbiased opinion in the case.

Dr. William Jacobs, Associate Medical Director, Professional Resources Network (PRN) was present and addressed the Board.

Mr. Camacho presented the case to the Board. The Respondent was charged with the following violation(s): Section 456.072(1)(v), F.S. (2017) by engaging or attempting to engage in sexual misconduct.

Motion: by Mr. Wright to find that the Respondent was properly served, and the matter was appropriately before the Board as an informal hearing.
Second: by Dr. Ghazvini
Vote: Unanimous

Motion: by Mr. Wright to accept the investigative report into evidence.
Second: by Dr. Mesaros
Vote: Unanimous

Motion: by Mr. Wright and adopt the findings of fact as set forth in the Administrative Complaint.
Second: by Dr. Ghazvini
Vote: Unanimous

Motion: by Mr. Wright 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:

- Revocation
- Fine of \$10,000.00 to be paid within two (2) years of the filing of the Final Order.

After discussion, the following action was taken:

Motion: by Mr. Meshad to impose the following penalties.

- Revocation

Second: by Dr. Ghazvini
Vote: Unanimous

The Department withdrew their motion for costs.

- iii. Joseph M. Spellman, R.Ph., Case No. 2020-29513
(PCP – Weizer & Mesaros)

The Respondent was present and represented by Edwin Bayo, Esq. The respondent was sworn in by the court report.

Dr. Segovia recused herself due to professional association that would prevent her from ruling an unbiased opinion in the case.

Mr. Camacho presented the case to the Board. The Respondent was charged with the following violation(s): **Count I:** Section 456.072(1)(v), F.S. (2018) **Count II:** Section 465.016(1)(q), F.S. (2018) by engaging or attempting to engage in sexual misconduct and using or releasing patient records improperly.

Motion: by Mr. Wright to find that the Respondent was properly served, and the matter was appropriately before the Board as an informal hearing.

Second: by Mr. Philip
Vote: Unanimous

Motion: by Mr. Wright to accept the investigative report into evidence.

Second: by Mr. Philip
Vote: Unanimous

Motion: by Mr. Wright and adopt the findings of fact as set forth in the Administrative Complaint.

Second: by Dr. Ghazvini
Vote: Unanimous

Motion: by Mr. Wright 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. Philip
Vote: Unanimous

The Department presented the following recommendation:

- Revocation
- Fine of \$10,000.00 to be paid within two (2) years of the filing of the Final Order.

After discussion, the following action was taken:

Motion: by Mr. Wright to impose the following penalties.

- Revocation

Second: by Dr. Ghazvini

Vote: Unanimous

The Department withdrew their motion for costs.

iv. Amorntham Intrakamhang, R.P.T., Case No. 2020-35385

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

Mr. Witters presented the case to the Board. The Respondent was charged with the following violation(s): **Count I:** 465.016(1)(e), by violating sections 893.13(6)(a), F.S. (2020) **Count II:** 456.072(1)(m), F.S. (2020) **Count III:** 456.072(1)(c), F.S. (2020) by unlawfully possessing a controlled substance, making deceptive, untrue, or fraudulent representations in or related to the practice of a profession, and being convicted or entering a plea, regardless of adjudication to a crime which relates to the licensee's profession as the Respondent was arrested for theft of alprazolam from his place of employment.

Motion: by Mr. Philip to find that the Respondent was properly served, and the matter was appropriately before the Board as an informal hearing.

Second: by Mr. Meshad

Vote: Unanimous

Motion: by Mr. Philip to accept the investigative report into evidence.

Second: by Mr. Meshad

Vote: Unanimous

Motion: by Mr. Philip and adopt the findings of fact as set forth in the Administrative Complaint.

Second: by Dr. Ghazvini

Vote: Unanimous

Motion: by Mr. Meshad 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. Philip

Vote: Unanimous

The Department presented the following recommendation:

After discussion, the following action was taken:

- Suspension for one (1) year from the filing of the Final Order, and until such time as Respondent appears before the Board and can demonstrate safety to practice to include at a minimum an evaluation by PRN, with the Board retaining jurisdiction to impose a period of probation with duration and terms to be determined by the Board.

Motion: by Mr. Meshad to accept the Department's recommendation.

Second: by Dr. Ghazvini

Vote: Unanimous

Motion: by Mr. Meshad to impose the costs of \$1319.98 payable within of the reinstatement of the license.

Second: by Mr. Philip

Vote: Unanimous

- v. Daniel Glidden, R.Ph., Case No. 2020-23293
(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) by violating chapter 893.13(6)(a) for unlawful possession of a controlled substance and being unfit or incompetent to practice pharmacy by reason of habitual intoxication, medical drug abuse, or physical or mental condition that threatens public safety.

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 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:

After discussion, the following action was taken:

- Revocation

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

Second: by Mr. Meshad

Vote: Unanimous

The Department withdrew their motion for costs.

D. VOLUNTARY RELINQUISHMENT

- i. Drug Store and More, Inc., Case No. 2020-27290
- ii. Drug Store and More, Inc., Case No. 2019-51469
(PCP – Mesaros & Mikhael)

Motion: by Mr. Meshad to accept the voluntary relinquishments for Case No. 2020-27290 and 2019-51469.

Second: by Mr. Wright

Vote: Unanimous

E. FORMAL REQUEST OF PAYMENT EXTENSION

- i. John Barron, R.Ph., Case No., 2019-30770

The Respondent was not present nor represented by Counsel.

The Respondent petitioned the Board for a payment extension to pay the fines and costs as imposed in Case No. 2019-30770.

Motion: by Mr. Wright to approve the payment extension request.

Second: by Dr. Ghazvini

Vote: Unanimous

Motion: by Mr. Wright to extend the payment deadline for one (1) year from the filing of the Final Order.

Second: by Mr. Philip

Vote: Unanimous

F. PETITION FOR REINSTATEMENT

ii. Peter Richard Barski, R.Ph., Case No., 2019-16119

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

The Respondent has petitioned the Board for reinstatement of his license. Mr. Barski's license was placed on suspension on September 21, 2020.

Dr. Jacobs, PRN, was present on behalf of Mr. Barski.

Motion: by Mr. Philip to reinstate Mr. Barski's license

Second: by Dr. Segovia

Vote: Unanimous

G. Prosecution Services Report – Mary A. Wessling

Mr. Witters presented the prosecution services case report to the Board and explained the current caseload is at 196 cases, from 192.

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

Second: by Mr. Philip

Vote: Unanimous

III. RULE DISCUSSION

A. Application Redesign

- i. 64B16-26.1032, F.A.C., Immunization Administration Certification Application and Information
- ii. 64B16-26.203, F.A.C., Pharmacist Licensure by Examination (U.S. Graduates); Application
- iii. 64B16-26.2031, F.A.C., Licensure by Examination (Foreign Graduates); Application
- iv. 64B16-26.204, F.A.C., Pharmacist Licensure by Endorsement; Application

Ms. Sapp provided the Board with a summary of the application revisions.

Mr. Philip suggested to add clarification to the immunization application regarding the signature requirements of the protocol.

Motion: by Mr. Wright to approve the application revisions as amended and open the applicable rules for development.

Second: by Dr. Mesaros

Vote: Unanimous

Motion: by Mr. Wright to find no economic impact, to find that a Statement of Estimated Regulatory Cost was not necessary, and the rule will not need legislative ratification, to find that no part of this rule or a violation of this rule should be designated as a minor violation and to find that this rule shall not include a sunset provision

Second: by Mr. Philip

Vote: Unanimous

IV. REPORTS – Jonathan Hickman, PharmD, Chair

A. Board Chair

i. Board Member Recognition

Dr. Hickman recognized Mr. Montgomery, former Board Member, for his service to the Board during the Rules Committee meeting held on June 9, 2021.

ii. ASHP Virtual Meeting Update, Dorinda Segovia, PharmD, MBA

Dr. Segovia provided an overview of the ASHP meeting she attended.

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

i. 2021 Legislation

Dr. Mesaros provided the legislative summaries during the Rules Committee report to include the proposed rule changes.

ii. Financial Reports

This was provided for informational purposes only.

iii. Staff Recognition

This was provided for informational purposes only.

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

i. Rules Status Report

Mr. Dierlam 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

Committee Chair, Dr. Jeffery Mesaros, provided the Board with an overview of the discussion from the June 9, 2021 Rules Committee meeting.

The Committee voted to amend Rule 64B16-28.108, F.A.C. The proposed language was provided for the Full Board's review.

64B16-28.108 All Permits – Labels and Labeling of Medicinal Drugs.

Each container of medicinal drugs dispensed shall have a label or shall be accompanied by labeling.

(1) Definitions.

(a) "Controlled substance" means any substance named or described in Schedules II-V of Section 893.03, F.S.

(b) "Customized medication package" means a package that:

1. Is prepared by a pharmacist for a specific patient.
2. Is a series of containers.
3. Contains two (2) or more solid oral dosage forms.

(c) "Labeling" means a label or other written, printed, or graphic material upon an agent or product or any of its containers, wrappers, drug carts, or compartments thereof, as well as a medication administration record (MAR) if a medication administration record is an integral part of the unit dose system.

(d) "Radiopharmaceutical" means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any of those drugs intended to be made radioactive. This includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance, but does not include drugs which are carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(e) "Serial number" means a prescription number or other unique number by which a particular prescription or drug package can be identified.

(2) The label affixed to each container dispensed to a patient shall include:

(a) Name and address of the pharmacy.

(b) Date of dispensing.

(c) Serial number.

(d) Name of the patient or, if the patient is an animal, the name of the owner and the species of animal.

(e) Name of the prescriber.

(f) Name of the drug dispensed (except where the prescribing practitioner specifically requests that the name is to be withheld).

(g) Directions for use.

(h) An Expiration Date or Beyond-Use Date: The expiration date must be the date provided by the manufacturer, repackager, or other distributor. The beyond-use date must not exceed the expiration date and it shall not be a date greater than one year from the date the medicinal drug is filled. The board finds that the use of a "discard-after-date" or "do not use after date" to be equivalent of a beyond-use date.

(i) If the medicinal drug is a controlled substance, a warning that it is a crime to transfer the drug to another person.

(3) The label on the immediate container of a repackaged product or a multiple unit prepackaged drug product shall include:

(a) Brand or generic name.

(b) Strength.

(c) Dosage form.

(d) Name of the manufacturer.

(e) Expiration date.

(f) Lot number:

1. Manufacturer's lot number; or

2. Number assigned by the dispenser or repackager which references the manufacturer's lot number.

(4) A medicinal drug dispensed in a unit dose system by a pharmacist shall be accompanied by labeling.

The requirement will be satisfied if, to the extent not included on the label, the unit dose system indicates clearly the name of the resident or patient, the prescription number or other means utilized for readily retrieving the medication order, the directions for use, and the prescriber's name.

(5) A unit dose system shall provide a method for the separation and identification of drugs for the individual resident or patient.

(6) A customized patient medication package may be utilized if:

(a) The consent of the patient or the patient's agent has been secured; and,

(b) The label includes:

1. Name, address and telephone number of the pharmacy.

2. Serial number for the customized medication package and a separate serial number for each medicinal drug dispensed.

3. Date of preparation of the customized patient medication package.

4. Patient's name.

5. Name of each prescriber.

6. Directions for use and any cautionary statements required for each medicinal drug.

7. Storage instructions.

8. Name, strength, quantity and physical description of each drug product.

9. A beyond use date that is not more than 60 days from the date of preparation of the customized patient medication package but shall not be later than any appropriate beyond use date for any medicinal drug included in the customized patient medication package.

(7) Compounded intravenous compounds (this does not include plain IV solutions or floor stock)

The label shall to include:

1. Names of active ingredients

2. Amounts or concentrations of active ingredients

3. BUD and time

4. Storage requirements (if applicable)

5. Identification of responsible compounding personnel

6. Labels for batch-prepared CSPs must also include: • Control or lot number • ~~Appropriate auxiliary labeling (including precautions) • Device-specific instructions (when appropriate)~~

For patient individualized intravenous preparations the label must also include

1. Patient's name

2. The location the medication is to be delivered to

3. Directions for use and applicable accessory and cautionary instructions

Motion: by Mr. Philip to accept the language and ratify the SERC questions completed by the Committee.

Second: by Dr. Hickman

Vote: Unanimous

The Committee voted to amend Rule 64B16-28.830, F.A.C. The proposed language was provided

for the Full Board's review.

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.

Motion: by Mr. Wright to accept the language and ratify the SERC questions completed by the Committee.

Second: by Dr. Segovia

Vote: Unanimous

The Committee voted to amend 64B16-30.001, F.A.C., Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances. The proposed language was provided for the Full Board's review.

<u>28. Failure to comply with the parental consent requirements of s. 1014.06 (Section 456.072(1)(rr), F.S.)</u>	<u>MIN: Reprimand and a fine of \$250; MAX: \$500 fine and one (1) year of probation.</u>	<u>MIN: \$500 fine and one (1) year of probation; MAX: Revocation.</u>	<u>MIN: Reprimand; MAX: Suspension and corrective action plan.</u>	<u>MIN: Suspension and corrective action plan; MAX: Revocation.</u>
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<u>29. Being convicted or found guilty of.</u>	<u>MIN: \$10,000 fine and</u>	<u>:</u>	<u>MIN: \$10,000 fine and</u>	
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entering a plea of guilty or nolo contendere to, regardless of adjudication or committing or attempting, soliciting, or conspiring to commit an act that would constitute a violation of any of the offenses listed in s. 456.074(5) or similar offense in another jurisdiction. (Section 456.072(1)(ss), F.S.)	Revocation MAX: \$10,000 fine and Revocation		Revocation MAX: \$10,000 fine and Revocation	
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The board shall be entitled to deviate from the above-mentioned guidelines upon a showing of aggravating or mitigating circumstances ~~by clear and convincing evidence~~ presented to the board prior to the imposition of a final penalty.

(a) Aggravating circumstances; circumstances which may justify deviating from the above set forth disciplinary guidelines and cause the enhancement of a penalty beyond the maximum level of discipline in the guidelines shall include but not be limited to the following:

1. History of previous violations of the practice act and the rules promulgated thereto.
2. ~~In the case of negligent acts~~, The magnitude and scope of the damage or potential damage inflicted upon the patient or the general public by the licensee's misfeasance.
3. Evidence of violation of professional practice acts in other jurisdictions wherein the licensee has been disciplined by the appropriate regulatory authority.
4. Harm occurred ~~or potential harm~~.

(b) Mitigating circumstances; circumstances which may justify deviating from the above set forth disciplinary guidelines and cause the lessening of a penalty beyond the minimum level of discipline in the guidelines shall include but not be limited to the following:

1. ~~In cases of negligent acts~~, the minor nature of the damage or potential damage to the patient's or the public's health, safety, and welfare resulting from the licensee's misfeasance.
2. Lack of previous disciplinary history in this or any other jurisdiction wherein the licensee practices his profession.
3. Restitution of any monetary damage suffered by the patient.
4. The licensee's professional standing among his peers.
5. Steps already taken by the licensee to insure the non-occurrence of similar violations in the future, including continuing education.
6. The degree of financial hardship incurred by a licensee as a result of the imposition of fines or the suspension of his practice.

(4) All fines imposed by the Board shall be paid within a period of ninety (90) days from the date of the final order entered by the Board. This time limitation may be modified by the Board for good cause shown in order to prevent undue hardship.

Motion: by Dr. Hickman to accept the language and ratify the SERC questions completed by the Committee.

Second: by Mr. Wright

Vote: Unanimous

The Committee voted to amend Rule 64B16-26.1031, F.A.C. The proposed language was provided for the Full Board's review.

64B16-26.1031 Vaccine Certification Program.

(1) All applications for vaccine certification programs shall be made on board approved form DH-MQA 1234, "Board of Pharmacy Immunization Certification Program Provider Application," dated 08/15, which is hereby incorporated by reference. To obtain an application go to <http://www.flrules.org/Gateway/reference.asp?No=Ref-06807>, or contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254 or (850)488-0595, or download the application from the web at <http://www.doh.state.fl.us/mqa/pharmacy> <https://floridaspharmacy.gov>.

(2) The Board shall approve for initial certification of pharmacist and pharmacy intern administration of vaccines, programs of study not less than 20 hours that include coursework covering all of the following:

(a) Mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;

(b) Immunization Schedules;

(c) Immunization screening questions, provision of risk/benefit information, informed consent, recordkeeping, and electronic reporting into the statewide immunization registry;

(d) Vaccine storage and handling;

(e) Bio-Hazardous waste disposal and sterile techniques;

(f) Entering, negotiating and performing pursuant to physician oversight protocols;

(g) Community immunization resources and programs;

(h) Identifying, managing and responding to adverse incidents including but not limited to potential allergic reactions associated with vaccine administration;

(i) Procedures and policies for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS);

(j) Reimbursement procedures and vaccine coverage by federal, state and local governmental jurisdictions and private third party payors;

(k) Administration techniques;

(l) Administration of epinephrine using an autoinjector delivery system;

(m) The immunization and vaccine guidelines in the ~~February 1, 2015~~ February 11, 2021, Adult Immunization Schedule by the United States Centers for Disease Control and Prevention, entitled "Recommended Adult Immunization Schedule – United States – ~~2015~~ 2021," which is hereby incorporated by reference. The Schedule may be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref-06808>, and the Board office at the address in subsection (1);

(n) The immunizations or vaccines recommended by the United States Centers for Disease Control and Prevention for international travel as of ~~July 1, 2015~~ April 30, 2021, which may be found in the CDC Health Information for International Travel (~~2014-2020~~ Edition), which is incorporated herein by reference. The material incorporated is copyrighted material that is available for public inspection and examination, but may not be copied, at the Department of State, Administrative Code and Register Section, Room 701, The Capitol, Tallahassee, Florida 32399-0250, and at the Board office at the address in subsection (1);

(o) State of emergency administration of immunizations or vaccines;

(p) Review of Section 465.189, F.S.; and,

(q) Cardiopulmonary Resuscitation (CPR) training.

Successful completion of the certification program must include a successful demonstration of competency in the administration technique and a cognitive examination.

Motion: by Dr. Hickman to accept the language and ratify the SERC questions completed by the Committee.

Second: by Dr. Segovia

Vote: Unanimous

The Committee voted to repeal Rule 64B16-27.630, F.A.C. The proposed language was provided for the Full Board's review.

~~64B16-27.630 Additional Immunizations or Vaccines Which May Be Administered.~~

~~In addition to the immunizations or vaccines listed in the United States Centers for Disease Control and Prevention Adult Immunization Schedule as of February 1, 2015, the Board hereby authorizes administration of the following additional immunizations or vaccines by persons certified pursuant to Section 465.189, F.S.~~

~~(1) Meningococcal B (MenB).~~

~~(2) Zoster Vaccine Recombinant, Adjuvanted.~~

Motion: by Mr. Philip to accept and the language and ratify the SERC questions completed by the Committee.

Second: by Dr. Ghazvini

Vote: Unanimous

The Committee voted to amend Rule 64B16-26.6021, F.A.C. The proposed language was provided for the Full Board's review.

64B16-26.6021 Institutional Class II and Class III Pharmacy – Emergency Department Dispensing.

(1) Individuals licensed to prescribe medicinal drugs in this state may dispense from the emergency department of a hospital holding a Class II or Class III, Institutional pharmacy permit. Such dispensing must meet the requirements provided in subsection 465.019(4), F.S., and this section.

(2) The following records of prescribing and dispensing must be created by the prescriber/dispenser and maintained by the consultant pharmacist of record within the facility:

(a) Patient name and address.

(b) Drug and strength prescribed/dispensed.

(c) Quantity prescribed/dispensed.

(d) Directions for use.

(e) Prescriber/dispenser.

(f) Prescriber DEA registration, if applicable.

(g) Reason community pharmacy services were not readily accessible.

(3) Labeling of the prescription container must meet the requirements of section 465.0276, F.S.

~~(4) Quantity dispensed must not exceed a 24-hour supply or the minimal dispensable quantity, whichever is greater.~~

Motion: by Mr. Meshad to accept the language and ratify the SERC questions completed by the Committee.

Second: by Mr. Philip

Vote: Unanimous

The Committee voted to amend Rule 64B16-26.1004, F.A.C. he proposed language was provided

for the Full Board's review.

64B16-26.1004 Inactive License Election; Renewal; Fees.

(1) A pharmacist licensee may elect:

(a) At the time of license renewal to place the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of ~~\$245~~ \$200 plus a \$5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of license renewal, if the license is inactive, to continue the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of ~~\$245~~ \$200 plus a \$5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of license renewal to change the inactive status license to active status, provided the licensee meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status, submits the reactivation fee of \$70, and the current active renewal fee set forth in Rule 64B16-26.1001, F.A.C.

(d) At a time other than license renewal to change the inactive status license to active status, provided the licensee meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status and submits the reactivation fee of \$70, a change of status fee of \$25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

(2) A consultant pharmacist licensee may elect:

(a) At the time of license renewal to place the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of \$100 plus a \$5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of license renewal, if the consultant pharmacist license is inactive, to continue the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of \$100 plus a \$5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of license renewal to change the inactive status consultant pharmacist license to active status, provided the consultant pharmacist licensee meets the continuing education requirements of subsection 64B16-26.103(2), F.A.C., for each biennium the license was on inactive status and by submitting a reactivation fee of \$25, and the active consultant pharmacist renewal fee set forth in Rule 64B16-26.1003, F.A.C.

(d) At a time other than license renewal to change the inactive status license to active status, provided the licensee meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status, and submits the reactivation fee of \$25, a change of status fee of \$25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

(3) A nuclear pharmacist licensee may elect:

(a) At the time of license renewal to place the nuclear pharmacist license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of \$100 plus a \$5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of license renewal, if the nuclear pharmacist license is inactive, to continue the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of \$100 plus a \$5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of license renewal to change the inactive status license to active status, provided the nuclear pharmacist meets the continuing education requirements of Rule 64B16-26.304, F.A.C., for each biennium the license was on inactive status, and by submitting a reactivation fee of \$50, and the active nuclear license renewal fee set forth in Rule 64B16-26.1003, F.A.C.

(d) At a time other than license renewal to change the inactive status license to active status, provided the nuclear pharmacist licensee meets the continuing education requirements of Rule 64B16-26.304, F.A.C., for each biennium the license was on inactive status and by submitting a reactivation fee of \$50, a change of

status fee of \$25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

(4) A registered pharmacy technician may elect:

(a) At the time of renewal to place the registered pharmacy technician registration on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of \$50 plus a \$5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of renewal, if the registered pharmacy technician registration is inactive, to continue the registration on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of \$50 plus a \$5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of renewal to change the inactive status registration to active status, provided the registered pharmacy technician meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the registration was on inactive status, and by submitting a reactivation fee of \$50, and the active registration fee set forth in Rule 64B16-26.1003, F.A.C.

(d) At a time other than renewal to change the inactive status registration to active status, provided the registered pharmacy technician meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the registration was on inactive status and by submitting a reactivation fee of \$50, a change of status fee of \$25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

Motion: by Mr. Meshad to accept and the language and ratify the SERC questions completed by the Committee.

Second: by Mr. Meshad

Vote: Unanimous

Dr. Mesaros provided an overview of the White and Brown bagging discussion and requested if the Board has interest in joining an Ad Hoc Committee to submit their interest request to Board Staff.

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

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

As of June 2021 - Non-Sterile Pharmacy inspections currently at 5,222 inspections completed; Sterile Compounding Pharmacy inspections currently at 219 inspections completed.

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

A. Ratification of Issued Licenses/Certificates

- i. Pharmacist (Licensure) – 163
- ii. Pharmacist (Exam Eligibility) – 165
- iii. Pharmacist Interns – 122
- iv. Consultant Pharmacist – 54
- v. Nuclear Pharmacist – 2
- vi. Pharmacy/Facilities – 113
- vii. Registered Pharmacy Technicians – 1,243
- viii. Registered Pharmacy Technician Training Program – 16
- ix. Nonresident Sterile Compound – 4
- x. Approved CE Providers – 2
- xi. Approved CE Courses – 29

Motion: by Dr. Mesaros to accept the ratification lists.
Second: by Dr. Segovia
Vote: Unanimous

B. 2021 Florida Pharmacy Association House of Delegates

The Board voted the below Delegates to attend the Florida Pharmacy Association 131st Annual Meeting and Convention to be held on July 6-10, 2021 in Ponte Vedra Beach, FL.

Delegate: Dr. Segovia
Alternate Delegate: Mr. Wright

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

C. Review and Approval of Meeting Minutes

- i. April 14, 2021 Committee Meeting Minutes
- ii. April 15, 2021 Full Board Meeting Minutes

Motion: by Dr. Mesaros to accept the April 14, 2021 meeting minutes.
Second: by Mr. Meshad
Vote: Unanimous

Motion: by Dr. Mesaros to accept the April 15, 2021 meeting minutes.
Second: by Mr. Meshad
Vote: Unanimous

VII. FOR YOUR INFORMATION

A. Spotlight on ULA

This was provided for information purposes only.

VIII. ADJOURNMENT

There being no further business the meeting adjourned at 12:30 p.m. ET.