Draft Minutes

June 16, 2022
8:30 a.m. ET
Rosen Plaza Hotel
9700 International Drive
Orlando, FL 32819
(407) 996-9700

David Wright, BPharm
Chair

Jeenu Philip, BPharm
Vice-Chair

Jessica Sapp, Executive Director

BOARD OF PHARMACY
GENERAL BUSINESS MEETING
DRAFT MINUTES
June 16, 2022
8:30 a.m. ET
Rosen Plaza Hotel
9700 International Drive
Orlando, FL 32819
(407) 996-9700

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, Mr. Wright, at 8:30 a.m. ET.

Those present during the meeting included the following:

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

STAFF PRESENT:
Traci Zeh, Program Administrator
Genessis Mills, Senior Management Analyst

BOARD COUNSEL:
David Flynn, Esq.
Senior Assistant Attorney General
Christopher Dierlam, Assistant Attorney General

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

PROSECUTION ATTORNEY:
Alejandro Camacho, Assistant General Counsel

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. DISCIPLINARY CASES – David Wright, BPharm, Chair

A. SETTLEMENT AGREEMENTS

i. My Pharmacy of Homestead d/b/a Royal Palm Drug
Case No. 2021-01949 (PCP – Weizer & Meshad)

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

Mr. Camacho presented the cases to the Board. The Respondent was charged with the following

violation(s): **Count I:** Section 465.023(1)(c), F.S. (2020), through Rule 64B16-28.110, F.A.C., **Count II:** Section 465.023(1)(c), F.S., through Rule 64B16-27.100(2), **Count III:** Section 465.023(1)(c), F.S. (2020), through Rule 64B16-28.102(4), F.A.C., by having expired medications among active stock, registered pharmacy technicians and pharmacists not being properly identified, and by having the presence of mold inside the prescription department refrigerator.

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

- Appearance
- Fine of $1,000.00 to be paid within one hundred and eighty (180) days of the filing of the Final Order.
- Costs of $1,690.24 to be paid within one hundred and eighty (180) days of the filing of the Final Order.

After discussion, the following action was taken:

Motion: by Dr. Hickman to accept the Settlement Agreement.
Second: by Mr. Philip
Vote: Unanimous

ii. Bradley Doyt Schaffner, P.S.I., Case No. 2021-17525
(PCP – Mikhael & Gift)

The Respondent was present and sworn in by the court reporter. The Respondent was represented by Luke Lirot, Esq.

Mr. Camacho presented the cases 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 thirty days of entering in a plea of nolo contendere to one count reckless driving.

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

- Appearance
- Fine of $1,000.00 to be paid within one (1) year of the filing of the Final Order.
- Costs of $1,709.83 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 in addition to their hours required for renewal and to be completed within one (1) year of the filing of the Final Order.

After discussion, the following action was taken:

Motion: by Dr. Hickman to reject the Settlement Agreement.
Second: by Dr. Segovia
Vote: Unanimous

Motion: by Dr. Hickman to counteroffer a Settlement Agreement with the following terms:

- Appearance
- Costs of $1,709.83 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 in addition to their hours required for renewal and to be completed within one (1) year of the filing of the Final Order.
- Respondent is required to undergo an evaluation by a PRN approved evaluator and comply with PRN's recommendations.

Second: by Dr. Ghazvini
Vote: Unanimous

The Respondent accepted the counteroffer.

iii. Wayne Lee Wallace, R.Ph., Case No. 2020-03480
(PCP – Weizer & Hickman)

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

The Respondent was charged with the following violation(s): **Count I:** Section 456.072(1)(k), F.S. (2019), through Rule 64B16-27.820(1), F.A.C. **Count II:** Section 456.072(1)(k), through section 465.022(11)(a), F.S. (2019), by Rule 64B16-28.108(2), F.A.C. **Count III:** Section 456.072(1)(k), through section 465.022(11)(a), F.S., (2019), by Rule 64B16-28.110, F.A.C. **Count IV:** Section 456.072(1)(k), through section 465.022(11)(a), F.S., (2019), by Rule 64B16-28.802(1), F.A.C., by failing to perform legal obligations as the prescription department manager of Walfer Corporation d/b/a Medicine Shoppe.

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

- Appearance
- Fine of $1,500.00 to be paid within two (2) years of the filing of the Final Order.
- Costs of $1,391.24 to be paid within two (2) years 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 six (6) months of the filing of the Final Order.
- Practice restriction for two (2) years with the following terms:
    - Respondent may not serve as a PDM at any other pharmacy other than Walfer Corporation d/b/a Medicine Shoppe.

After discussion, the following action was taken:

Motion: by Mr. Philip to accept the Settlement Agreement.
Second: by Dr. Mesaros
Vote: Unanimous

B. DETERMINATION OF WAIVER

i. Ideal Pharmacy Services LLC, Case No. 2021-10568
(PCP – Montgomery & Mesaros)

The Respondent was present and sworn in by the court reporter. The Respondent was represented by Ricky Strong, Esq.

Mr. Camacho presented the cases to the Board. The Respondent was charged with the following violation(s) **Count I:** Section 465.023(1)(c), F.S. (2020), through Rule 64B16-28.108(1), F.A.C., **Count II:** Section 465.023(1)(c), F.S., by violating section 465.022(10), F.S., and/or failing to comply with rule 64B16-27.450(1)(b), F.A.C. by failing to be open for a minimum of twenty hour per week and failing to notify the Board of a prescription department manager change within ten days.

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 of the final investigative file and to adopt as its findings of fact, and conclusions of law as set forth in the Administrative Complaint
Second: by Dr. Ghazvini
Vote: Unanimous

Motion: by Mr. Philip 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 $4,000.00 to be paid within one (1) year of the filing of the Final Order.
- Reprimand

After discussion, the following action was taken:

Motion: by Dr. Segovia to accept the Departments recommendation.
Second: by Dr. Ghazvini
Vote: Motion passes. 4/3 Dr. Hickman, Mr. Philip, and Mr. Meshad opposed.

Motion: by Dr. Hickman to impose the costs of $1,260.00 to be paid within ninety (90) days of the of the filing of the Final Order.
Second: by Dr. Segovia
Vote: Unanimous

ii. Derric Anthony Patmon, P.S.I., Case No. 2020-26814
(PCP – Weizer & Hickman)
(PCP – Montgomery & Mesaros)

The Respondent was not present nor represented by counsel.

Mr. Camacho presented the cases to the Board. The Respondent was charged with the following violation(s) **Count I:** Section 456.072(1)(z), F.S., (2019-2021) **Count II:** Section 456.072(1)(c), F.S. (2020) **Count III:** Section 456.072(1)(x), F.S. (2020) by being unable to practice his profession by reasonable skill and safety, for being convicted of possession of marijuana and paraphernalia in Pasco County and by failing to report the conviction to the Board within 30 days.

Motion: by Mr. Meshad 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 of the final investigative file and to adopt as its findings of fact, conclusions of law as set forth in the Administrative Complaint and to find the conclusions set forth in the Administrative Complaint constitutes a violation of the practice act.
Second: by Mr. Philip
Vote: Unanimous

The Department presented the following recommendation:

- Suspension until Respondent personally appears before the Board and can demonstrate she is safe to practice, to include an evaluation by a PRN approved evaluator. The Board reserves jurisdiction to impose additional terms and conditions upon reinstatement.

After discussion, the following action was taken:

Motion: by Mr. Philip to accept the Departments recommendation.
Second: by Ms. Gift
Vote: Unanimous

Motion: by Mr. Philip to impose the costs of $1,151.78 to be paid within one (1) year of the reinstatement of the license.
Second: by Dr. Ghazvini
Vote: Unanimous

iii. Pharmacy Services of America, Case No. 2021-34882 (PCP – Weizer & Wright)

The Respondent was not present nor represented by counsel.

Mr. Camacho presented the cases to the Board. The Respondent was charged with the following violation(s): Section 456.072(1)(f), F.S. (2019-2021) by having a license revoked, suspended, or otherwise acted on by another jurisdiction.

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, to accept into evidence of the final investigative file and to adopt as its findings of fact, conclusions of law as set forth in the Administrative Complaint and to find the conclusions set forth in the Administrative Complaint 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. Hickman to accept the Departments recommendation.
Second: by Ms. Gift
Vote: Unanimous

The Department withdrew their motion for cost.

iv. Caitlin Jeanne Brady, R.PH., Case No. 2021-19895
(PCP – Weizer & Wright)

The Respondent was not present nor represented by counsel.

Mr. Camacho presented the cases to the Board. The Respondent was charged with the following violation(s) **Count I:** Section 465.016(1)(e), F.S., through a violation of section 893.13(6)(a), **Count II:** Section 465.016(1)(e), F.S., through a violation of section 893.13(7)(a)9, F.S. by unlawfully possessing controlled substances.

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, to accept into evidence of the final investigative file and to adopt as its findings of fact, conclusions of law as set forth in the Administrative Complaint and to find the conclusions set forth in the Administrative Complaint 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 Dr. Hickman
Vote: Unanimous

The Department withdrew their motion for cost.

v. Katharine Violet Brower, R.P.T., Case No. 2021-07729
(PCP – Weizer & Wright)

The Respondent was not present nor represented by counsel.

Mr. Camacho presented the cases to the Board. The Respondent was charged with the following violation(s) **Count I:** Section 465.016(1)(z), F.S., **Count II:** Section 465.016(1)(e), F.S., through a violation of section 893.13(6)(a), F.S. **Count III:** Section 465.072(1)(m), F.S. by being unable to practice pharmacy with reasonable skill and safety and by diverting Tylenol 3 and 4 from her employer.

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, to accept into evidence of the final investigative file and to adopt as its findings of fact, conclusions of law as set forth in the Administrative Complaint and to find the conclusions set forth in the Administrative Complaint constitutes a violation of the practice act.
Second: by Dr. Ghazvini
Vote: Unanimous

The Department presented the following recommendation:

- Suspension until Respondent personally appears before the Board and can demonstrate she is safe to practice, to include an evaluation by a PRN approved evaluator. The Board reserves jurisdiction to impose additional terms and conditions upon reinstatement.

After discussion, the following action was taken:

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

Motion: by Dr. Hickman to impose the costs of $2,555.76 to be paid within one (1) year of the of the reinstatement of the license.
Second: by Dr. Ghazvini
Vote: Unanimous

C. INFORMAL

i. Maikel Moress Bolos, R.Ph., Case No. 2021-19895
(PCP – Mikhael & Philip)

This case was presented as a Voluntary Relinquishment.

Mr. Camacho presented the case to the Board. The Respondent was charged with the following violation(s): Section 456.072(1)(c), F.S. (2020) for entering a plea of guilty to one count conspiracy to commit health care fraud and mail fraud.

Motion: by Dr. Mesaros to accept the voluntary relinquishment.
Second: by Dr. Segovia
Vote: Unanimous

D. VOLUNTARY RELINQUISHMENTS

i. Caridad M. Gonzalez-Limberg, R.Ph., Case No. 2018-15891

This case was tabled to be heard at a future meeting.

ii. Caridad M. Gonzalez-Losada, C.Ph., n/k/a Caridad M. Gonzalez-Limberg, Case No. 2022-09155

This case was tabled to be heard at a future meeting.

E. PETITION FOR REINSTATEMENT

i. Jackie McCall, Jr., R.Ph., Case No. 2015-08919

Mr. McCall was present and sworn in by the court reporter.

On June 8, 2016, case number 2015-08919 came before the Board. A Final Order was filed June 30, 2016, that suspended Ms. McCall's license.

Ms. McCall submitted a petition to the Board for the removal of her suspension.

After discussion, the following action was taken:

Motion: by Dr. Hickman to approve the removal of the suspension.
Second: by Dr. Mesaros
Vote: Unanimous

ii. Delma Deanne Ramsay, R.Ph., Case No. 2021-15092

Ms. Ramsay was present and sworn in by the court reporter.

On April 13, 2022, case number 2021-15092 came before the Board. A Final Order was filed May 6, 2022, that suspended Ms. Ramsey's license.

Ms. Ramsey submitted a petition to the Board for the removal of her suspension.

After discussion, the following action was taken:

Motion: by Dr. Hickman to approve the removal of the suspension.
Second: by Dr. Ghazvini
Vote: Unanimous

F. Prosecution Services Report – Alejandro Camacho

Mr. Camacho presented the prosecution services case report to the Board and explained the current caseload is at 247 cases, from 250.

Motion: by Dr. Hickman to allow prosecution to continue prosecuting cases older than one year.
Second: by Mr. Meshad
Vote: Unanimous

III. APPLICATIONS FOR REVIEW – Patty Ghazvini, PharmD

A. Pharmacists

i. Nicole Ardite

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. Philip
Vote: Unanimous

B. Registered Pharmacy Technician

i. Jasmine Streeter

The applicant was not present nor sworn in by the court reporter.

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

Ms. Streeter failed to appear at the April 2022 board meeting; therefore, her application was placed on the June agenda for review.

After further discussion the Board took the following action:

Motion: by Dr. Ghazvini to deny the application for failure to appear at two consecutive meetings.
Second: by Mr. Philip
Vote: Unanimous

ii. Nicholas Johnson

The applicant was not present nor represented by Counsel.

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

This application will be placed on the August agenda.

iii. Bianca McMillon

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

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

After further discussion the Board took the following action:

Motion: by Mr. Meshad to approve the application.
Second: by Dr. Segovia
Vote: Unanimous

iv. Kelli Grimsley

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

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

After further discussion the Board took the following action:

Ms. Grimsley requested to continue her application.

Motion: by Dr. Hickman to approve the continuance of the application.
Second: by Mr. Meshad
Vote: Unanimous

Motion: by Dr. Hickman to delegate the Chair to review the PRN evaluation.
Second: by Dr. Ghazvini
Vote: Unanimous

v. Manuel Dokur

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

The applicant applied for a registered pharmacy technician license and answered yes to a health history question on his application.

After further discussion the Board took the following action:

Mr. Dokur requested to continue his application.

Motion: by Dr. Hickman to approve the continuance of the application.
Second: by Mr. Philip
Vote: Unanimous

Motion: by Dr. Mesaros to delegate the Chair to review the PRN evaluation.
Second: by Dr. Ghazvini
Vote: Unanimous

vi. Miguel Tulier

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

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

After further discussion the Board took the following action:

Motion: by Dr. Mesaros to approve the application.
Second: by Mr. Philip
Vote: Unanimous

vii. Joseph Garcia

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

The applicant applied for a registered pharmacy technician license and answered yes to a health history question on his application.

After further discussion the Board took the following action:

Motion: by Mr. Wright to approve the application.
Second: by Dr. Segovia
Vote: Unanimous

C. Pharmacy Permits

i. Compound Preferred LLC

The applicant was not present nor represented by Counsel.

The applicant submitted an application for a Non-Resident Sterile Compounding pharmacy permit and was required to appear due to their inspection history.

After further discussion the Board took the following action:

Motion: by Dr. Segovia to deny the application for failure to appear at two consecutive meetings.
Second: by Mr. Wright
Vote: Unanimous

ii. Sofie Co.

The applicant was present and sworn in by the court reporter and represented by Jarrod Brown, Regional Operations Director.

The applicant submitted an application for a Non-Resident pharmacy and a Sterile Compounding pharmacy permit and was required to appear due to their discipline history.

This application will be placed on the August agenda.

IV. PETITION FOR VARIANCE OR WAIVER

A. Guardian Pharmacy

This petition was tabled to be heard at the August meeting.

V. REPORTS – David Wright, BPharm, Chair

A. Board Chair

Dr. Mesaros provided an overview of the National Association of the Boards of Pharmacy (NABP) meeting.

Mr. Wright provided an overview of the NABP meeting and recognized Dr. Mesaros and Mr Philip for their contribution to the NABP.

Reggie Dillard, NABP President, addressed the Board and provided the administrative functions of the association.

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

i. Chair/Vice-Chair Meeting

Ms. Zeh addressed the Board regarding the upcoming Chairs/Vice Chair meeting will be held in Tallahassee on January 6, 2023.

Ms. Zeh also requested the Board provide a delegate to attend the Florida Society of Health-System Pharmacists, Inc. (FSHP) Annual House of Delegates Meeting. After the discussion, it was determined Dr. Hickman would be the delegate to represent the Board.

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

i. Rules Status Report

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

D. Committee Report

i. **Rules Committee – Jeffrey J. Mesaros, PharmD, JD**

a. Rules Committee Update

Dr. Mesaros provided an overview of the rules committee meeting held on June 15, 2022.

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 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 11, 2021, Adult~~ Immunization Schedule by the

United States Centers for Disease Control and Prevention, ~~entitled "Recommended Adult Immunization Schedule – United States – 2021," which is hereby incorporated by reference. The Schedule may be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-13874, 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 April 30, 2021, which may be found in the CDC Health Information for International Travel (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.

(3) The Board shall approve for initial certification of registered pharmacy technician administration of vaccines, programs of study, accredited by the Accreditation Council for Pharmacy Education (ACPE), not less than 6 hours that include coursework covering all of the following:

(a) Technique for preparing and administering immunizations in a safe and effective manner

(b) Administration routes

(c) Recognizing and responding to allergic vaccine reactions and other emergency situations

(d) Needle selection based on vaccines and patient age and size

(e) Documentation procedures

(f) Procedures and requirements for vaccine recalls

(g) A real time competency validation through the observation and return demonstration of a complete successful administration of an intramuscular and subcutaneous injection to a human being which shall include distraction techniques during the administration and universal precautions as they pertain to blood borne pathogens.

Motion: by Mr. Wright to approve the proposed rule language
Second: by Mr. Meshad
Vote: 7/1. Dr. Segovia opposed.

64B16-26.103 Continuing Education Credits; Renewal

(1)Prior to biennal renewal of pharmacist licensure, a licensee shall complete no less than 30 hours of approved courses of continued professional pharmaceutical education within the 24 month period prior to the expiration date of the license. The following conditions shall apply.

(a) Upon a licensee's first renewal of licensure, the licensee must document the completion of one (1) hour of board approved continuing education which includes the topics of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome; the modes of transmission, including transmission from a healthcare worker to a patient and the patient to the healthcare worker; infection control procedures, including universal precautions; epidemiology of the disease; related infections including tuberculosis (TB); clinical management; prevention; and current Florida law on AIDS and its impact on testing, confidentiality of test results, and treatment of patients. In order to meet this requirement, licensees must demonstrate that the course includes information on the State of Florida law on HIV/AIDS and its impact on testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to Sections 381.004 and 384.25, F.S. Any HIV/AIDS continuing education course taken during the second or subsequent renewal of licensure may be applied to satisfy the general continuing education hours requirement.

(b) The initial renewal of a pharmacist license will not require completion of courses of continued professional pharmaceutical education hours if the license was issued less than 12 months prior to the

expiration date of the license. If the initial renewal occurs 12 months or more after the initial licensure, then 15 hours of continued professional pharmaceutical education hours shall be completed prior to the renewal of the license but no earlier than the date of initial licensure.

(c) Prior to renewal a licensee must complete, within the 24 month period prior to the expiration date of the license, a two-hour continuing education course approved in advance by the Board on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. Hours obtained pursuant to this section may be applied by the licensee to the requirements of subsection (1).

(d) Five hours of continuing education in the subject area of risk management may be obtained by attending one full day or eight (8) hours of a board meeting at which disciplinary hearings are conducted by the Board of Pharmacy in compliance with the following:

1. The licensee must sign in with the Executive Director or designee of the Board before the meeting day begins,

2. The licensee must remain in continuous attendance,

3. The licensee cannot receive continuing education credit for attendance at a board meeting if required to appear before the board; and,

4. The maximum continuing education hours allowable per biennium under this paragraph shall be ten (10).

(e) A member of the Board of Pharmacy may obtain five (5) hours of continuing education in the subject area of risk management for attendance at one Board meeting at which disciplinary hearings are conducted. The maximum continuing education hours allowable per biennium under this paragraph shall be ten (10).

(f) Up to five hours per biennium of continuing education credit may be fulfilled by the performance of volunteer services to the indigent as provided in Section 456.013(9), F.S., or to underserved populations, or in areas of critical need within the state where the licensee practices. In order to receive credit, the licensee must make application to and receive approval in advance from the Board. Application shall be made on form DH-MQA 1170 (Rev. 02/09), Individual Request for Continuing Education for Volunteers, which is hereby incorporated by reference. The form can be obtained from the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254. One hour credit shall be given for each two hours volunteered in the 24 months prior to the expiration date of the license. In the application for approval, the licensee shall disclose the type, nature and extent of services to be rendered, the facility where the services will be rendered, the number of patients expected to be serviced, and a statement indicating that the patients to be served are indigent. If the licensee intends to provide services in underserved or critical need areas, the application shall provide a brief explanation as to those facts. A licensee who is completing community service as a condition of discipline imposed by the board cannot use such service to complete continuing education requirements.

(g) Continuing education credit shall be granted for completion of post professional degree programs provided by accredited colleges or schools of pharmacy. Credit shall be awarded at the rate of 5 hours of continuing education credit per semester hour completed within the 24 months prior to the expiration date of the license.

(h) Continuing education may consist of post-graduate studies, institutes, seminars, lectures, conferences, workshops, correspondence courses, or other educational opportunities which advance the practice of the profession of pharmacy if approved by the Board. A course shall be approved prior to completion and will be evaluated by the Tripartite Committee using the standards found in Rule 64B16-26.601, F.A.C. Individuals must submit requests for course approval at least 45 days in advance of the program or course by completing the approved application form DOH/MQA/PH 112, (Rev. 6/12), entitled Individual Requests for Continuing Education Credit, which is incorporated by reference, and which can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-01636, and the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or from the website located at http://www.doh.state.fl.us/mqa/pharmacy. Individuals seeking course approval must attach to the application a detailed program outline, overview or syllabus which describes the educational content, objectives and

faculty qualifications.

(i) Any volunteer expert witness who is providing expert witness opinions for cases being reviewed by the Department of Health pursuant to Chapter 465, F.S., shall receive five (5) hours of credit in the area of risk management for each case reviewed in the 24 months prior to the expiration date of the license, up to a maximum of ten (10) hours per biennium.

(j) The presenter of a live seminar, a live video teleconference or through an interactive computer-based application shall receive 1 credit for each course credit hour presented, however presenter will not receive additional credit for multiple same course presentations.

(k) All programs approved by the ACPE for continuing education for pharmacists are deemed approved by the Board for general continuing education hours for pharmacists. Any course necessary to meet the continuing education requirement for HIV/AIDS, medication errors, or consultant pharmacist license renewal shall be Board approved.

(l) General continuing education earned by a non-resident pharmacist in another state that is not ACPE approved, but is approved by the board of pharmacy in the state of residence can be applied to meet the requirements of license renewal in subsection (1), above.

(m) At least ten (10) of the required 30 hours must be obtained either at a live seminar, a live video teleconference, or through an interactive computer-based application.

(2) Prior to renewal a consultant pharmacist shall complete no less than 24 hours of Board approved continuing education in the course work specified in Rule 64B16-26.302, F.A.C., within the 24 month period prior to the expiration date of the consultant license. The hours earned to satisfy this requirement cannot be used to apply toward the 30 hours required in subsection (1), above. However, if consultant recertification hours are earned and not used to meet the requirements of this paragraph, they may be applied by the licensee to the 30 hours required in subsection (1).

(a) If the initial renewal of a consultant pharmacist license occurs less than 12 months after the initial licensure, then completion of consultant courses of continuing education hours will not be required.

(b) If the initial renewal of a consultant pharmacist license occurs 12 months or more after the initial licensure, then 12 hours of consultant continuing education hours must be completed prior to the renewal date of the license but no earlier than the date of initial licensure.

(3) Prior to renewal a nuclear pharmacist shall complete no less than 24 hours of Board approved continuing education in the course work specified in Rule 64B16-26.304, F.A.C., within the 24 month period prior to the expiration date of the nuclear pharmacist license. The hours earned to satisfy this requirement cannot be used to apply toward the 30 hours required in subsection (1), above. However, if nuclear pharmacist license renewal hours are earned and not used to meet the requirements of this paragraph, they may be applied by the licensee to the 30 hours required in subsection (1).

(a) If the initial renewal of a nuclear pharmacist license occurs less than 12 months after the initial licensure, then completion of courses of nuclear pharmacy continuing education hours will not be required.

(b) If the initial renewal of a nuclear pharmacist license occurs 12 months or more after the initial licensure, then 12 hours of nuclear pharmacy continuing education hours must be completed prior to the renewal date of the license but no earlier than the date of initial licensure.

(c) All programs approved by the ACPE for continuing education for nuclear pharmacists are deemed approved by the Board for general continuing education hours for nuclear pharmacists.

(4) Prior to renewal a registered phamacy technician shall complete no less than twenty (20) hours of Board approved continuing education in the course work specified in Rule 64B16-26.355, F.A.C., within the 24 month period prior to the expiration date of the phamacy technician registration. For a registered pharmacy technician that maintains an immunization certification, an additional two (2) hours of continuing education is required in the area of vaccine administration.

(a) Upon a pharmacy technician's first renewal, registrtant must document the completion of one (1) hour of board approved continuing education which includes the topics of Human Immunodeficiency Virus and

Acquired Immune Deficiency Syndrome; the modes of transmission, including transmission from a healthcare worker to a patient and the patient to the healthcare worker; infection control procedures, including universal precautions; epidemiology of the disease; related infections including tuberculosis (TB); clinical management; prevention; and current Florida law on AIDS and its impact on testing, confidentiality of test results, and treatment of patients. In order to meet this requirement, licensees must demonstrate that the course includes information on the State of Florida law on HIV/AIDS and its impact on testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to Sections 381.004 and 384.25, F.S. Any HIV/AIDS continuing education course taken during the second or subsequent renewal of registration may be applied to satisfy the general continuing education hours requirement.

(b) If the initial renewal of a pharmacy technician registration occurs less than 12 months after the initial licensure, then completion of courses of a pharmacy technician registration education hours will not be required.

(c) If the initial renewal of a pharmacy techician registration occurs 12 months or more after the initial licensure, then 12 hours of registered phamacy technician continuing education hours must be completed prior to the renewal date of the license but no earlier than the date of initial licensure.

(d) All programs approved by the ACPE for continuing education for pharmacy technicians are deemed approved by the Board for general continuing education hours for registered pharmacy technicians. Any course necessary to meet the continuing education requirement for HIV/AIDS license renewal shall be Board approved.

(e) Prior to renewal a licensee must complete, within the 24 month period prior to the expiration date of the license, a two-hour continuing education course approved in advance by the Board on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. Hours obtained pursuant to this section may be applied by the licensee to the requirements of subsection (1).

(f) Five hours of continuing education in the subject area of risk management may be obtained by attending one full day or eight (8) hours of a board meeting at which disciplinary hearings are conducted by the Board of Pharmacy in compliance with the following:

1. The registratrant must sign in with the Executive Director or designee of the Board before the meeting day begins,

2. The registrant must remain in continuous attendance,

3. The registrant cannot receive continuing education credit for attendance at a board meeting if required to appear before the board; and,

4. The maximum continuing education hours allowable per biennium under this paragraph shall be ten (10).

(g) At least four (4) of the required 20 hours must be obtained either at a live seminar, a live video teleconference, or through an interactive computer-based application.

Motion: by Dr. Hickman to approve the proposed rule language
Second: by Mr. Wright
Vote: Unanimous

64B16-28.140 Record Maintenance Systems for All Pharmacy Permits.

(1) Requirements for records maintained in a data processing system.

(a) The pharmacy must comply with the provisions of 21 C.F.R. Section 1304.04 (a regulation of the Federal Drug Enforcement Administration), which is hereby incorporated by reference as of March 1, 1998, when such is applicable to operate such a data processing system if any controlled substances (as that term is used in Chapter 893, F.S.) are dispensed from the pharmacy.

(b) Any pharmacy using a data processing system must meet the requirements of 21 C.F.R. Section 1306.22, which is hereby incorporated by reference as of March 1, 1998.

(c) If a pharmacy's data processing system is not in compliance with this subsection, the pharmacy must maintain a manual recordkeeping system as specified in Rule 64B16-27.800, F.A.C., and Section 893.07, F.S.

(d) Original prescriptions, not received in written form including prescriptions received as provided for in ~~Rule 64B16-28.1003, F.A.C., Transmission of Prescription Orders~~, shall be reduced to writing or recorded electronically if permitted by federal law ~~a hard copy if not received in written form~~. All original prescriptions shall be retained for a period of not less than four (4) years from date of last filling. To the extent authorized by 21 C.F.R. §1304.04, a pharmacy may, in lieu of retaining the actual original prescriptions, use an electronic imaging recordkeeping system, provided such system is capable of capturing, storing, and reproducing the exact image of the prescription, including the reverse side of the prescription if necessary, and that such image be retained for a period of no less than four (4) years from the date of last filling.

(e) Original prescriptions shall be maintained in a two or three file system as specified in 21 C.F.R. §1304.04(h).

(f) Requirements for back-up systems.

1. The pharmacy shall maintain a back-up copy of information stored in the data processing system using disk, tape or other electronic back-up system and update this back-up copy on a regular basis, at least weekly, to assure that data is not lost due to system failure.

2. Data processing systems shall have a workable (electronic) data retention system which can produce an audit trail of drug usage for the preceding four (4) years as specified in Rule 64B16-27.800, F.A.C.

(g) Change or discontinuance of a data processing system.

1. Records of dispensing. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records of dispensing to the new data processing system, or

b. Purge the records of dispensing to a printout which contains the same information required on the daily printout as specified in paragraph (3)(b), of this section. The information on this hard-copy printout shall be sorted and printed by prescription number and list each dispensing for this prescription chronologically.

2. Other records. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records to the new data processing system, or

b. Purge the records to a printout which contains all of the information required on the original document.

3. Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for four (4) years from the date of initial entry into the data processing system.

(h) Loss of Data. The prescription department manager shall report to the Board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(2) All transfers of prescriptions must be strictly in accordance with the provisions of Section 465.026, F.S., and Rule 64B16-27.105, F.A.C.

(3) Records of dispensing.

(a) Each time a prescription drug order is filled or refilled, a record of such dispensing shall be entered into the data processing system.

(b) The data processing system shall have the capacity to produce a daily hard-copy printout of all original prescriptions dispensed and refilled. This hard copy printout shall contain the following information:

1. Unique identification number of the prescription,

2. Date of dispensing,

3. Patient name,

4. Prescribing practitioner's name,

5. Name and strength of the drug product actually dispensed, if generic name, the brand name or manufacturer of drug dispensed,

6. Quantity dispensed,

7. Initials or an identification code of the dispensing pharmacist; and,

8. If not immediately retrievable via CRT display, the following shall also be included on the hard-copy printout:

a. Patient's address,

b. Prescribing practitioner's address,

c. Practitioner's DEA registration number, if the prescription drug order is for a controlled substance,

d. Quantity prescribed, if different from the quantity dispensed,

e. Date of issuance of the prescription drug order, if different from the date of dispensing; and,

f. Total number of refills dispensed to date for that prescription drug order.

(c) The daily hard-copy printout shall be produced within 72 hours of the date on which the prescription drug orders were dispensed and shall be maintained in a separate file at the pharmacy. Records of controlled substances shall be readily retrievable from records of non-controlled substances.

(d) Each individual pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard-copy printout is correct, by dating and signing such document in the same manner as signing a check or legal document (e.g., J.H. Smith, or John H. Smith) within seven days from the date of dispensing.

(e) In lieu of producing the printout described in paragraphs (b) and (c), of this section, the pharmacy shall maintain a log book in which each individual pharmacist using the data processing system shall sign a statement each day, attesting to the fact that the information entered into the data processing system that day has been reviewed by him or her and is correct as entered. Such log book shall be maintained at the pharmacy employing such a system for a period of four (4) years after the date of dispensing provided, however, that the data processing system can produce the hard-copy printout on demand by an authorized agent of the Department of Health. If no printer is available on site, the hard-copy printout shall be available within 48 hours with a certification by the individual providing the printout, which states that the printout is true and correct as of the date of entry and such information has not been altered, amended or modified.

(f) The prescription department manager and the permit holder are responsible for the proper maintenance of such records and responsible that such data processing system can produce the records outlined in this section and that such system is in compliance with this subsection.

(g) Failure to provide the records set out in this section, either on site or within 48 hours for whatever reason, constitutes failure to keep and maintain records.

(h) In the event that a pharmacy which uses a data processing system experiences system downtime, the following is applicable;

1. An auxiliary procedure shall ensure that refills are authorized by the original prescription drug order and that the maximum number of refills has not been exceeded or that authorization from the prescribing practitioner has been obtained prior to dispensing a refill; and,

2. All of the appropriate data shall be retained for online data entry as soon as the system is available for use again.

(4) Compounding records. A written record shall be maintained for each batch/sub-batch of a compounded product under the provisions of Rule 64B16-27.700, F.A.C. This record shall include:

(a) Date of compounding.

(b) Control number for each batch/sub-batch of a compounded product. This may be the manufacture's lot number or new numbers assigned by the pharmacist. If the number is assigned by the pharmacist, the pharmacist shall also record the original manufacture's lot number and expiration dates. If the original numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the component.

(c) A complete formula for the compounded product maintained in a readily retrievable form including methodology and necessary equipment.

(d) A signature or initials of the pharmacist or pharmacy technician performing the compounding.

(e) A signature or initials of the pharmacist responsible for supervising pharmacy technicians involved in

the compounding process.

(f) The name(s) of the manufacturer(s) of the raw materials used.

(g) The quantity in units of finished products or grams of raw materials.

(h) The package size and number of units prepared.

(i) The name of the patient who received the particular compounded product.

(5) Authorization of additional refills. Practitioner authorization for additional refills of a prescription drug order shall be noted as follows:

(a) On the daily hard-copy printout, or

(b) Via the CRT display.

(6) Any other records, policy and procedure manuals, or reference materials which are not specifically required by statute or rule to be kept in a hard copy may be kept in a readily retrievable data processing system which complies with the provisions of subparagraph (1)(f)1.

Motion: by Dr. Hickman to approve the proposed rule language
Second: by Mr Wright
Vote: Unanimous

64B16-28.1191 Unclaimed Prescriptions.

Prescriptions that are unclaimed may be retained by a pharmacy and reused for a period up to one year from the date of filling; however, any product reaching the product's expiration date prior to one year or any product subject to a recall shall not be reused. If the unclaimed product is in its original manufacturer's packing, then the expiration date shall revert back to the date as listed on the original manufacturer's packaging.

Motion: by Mr. Meshad to approve the proposed rule language
Second: by Dr. Segovia
Vote: Unanimous

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

Robert Difiore provided a brief update on the inspection results as of June 2022.

As of June 2022 - Non-Sterile Pharmacy inspections currently at 6,018 inspections completed; Sterile Compounding Pharmacy inspections currently at 522 inspections completed.

VI. NEW BUSINESS – David Wright, BPharm, Chair

A. Ratification of Issued Licenses/Certificates

i. Pharmacist (licensure) – 170
ii. Pharmacist (exam eligibility) – 170
iii. Pharmacist Intern – 112
iv. Consultant Pharmacist – 59
v. Pharmacy/Facilities – 107
vi. Registered Pharmacy Technician – 1,857
vii. Registered Pharmacy Technician Training Program – 26
viii. Nonresident Sterile Compound – 8
ix. Approved CE Courses – 34
x. Approved CE Providers - 2

Motion: by Dr. Hickman to accept the ratification lists.
Second: by Dr. Ghazvini
Vote: Unanimous

B. 2022 Florida Pharmacy Association House of Delegates

The Florida Pharmacy Association's Annual Meeting will be held July 6 – July 10, 2022. The Board selected the Delegates to attend.

Delegate - Dr. Segovia

Alternate Delegate - Dr. Ghazvini

VII. OLD BUSINESS – David Wright, BPharm, Chair

A. Review and Approval of Meeting Minutes

i. April 12, 2022 Rules Committee Meeting Minutes
ii. April 13, 2022 General Business Meeting Minutes

Motion: by Dr. Hickman to accept the meeting minutes.
Second: by Dr. Ghazvini
Vote: Unanimous

VIII. ADJOURNMENT

There being no further business the meeting adjourned at 1:30 p.m. ET.