Draft Minutes

December 15, 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
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:
Jessica Sapp, Executive Director
Traci Zeh, Program Administrator

BOARD COUNSEL:
David Flynn, Esq.
Senior Assistant Attorney General
Kara Aikens, Assistant Attorney General

COURT REPORTER:
Heather Howard
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
Reginald Howard, 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. Leah Marie Palian, P.S.I., Case No. 2020-36056
(PCP – Weizer & Segovia)

The Respondent was charged with the following violation(s): Section 456.072(1)(z), F.S. by being found unable to practice with reasonable safety and skill.

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

- Appearance
- 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.
- Costs of $2,287.72 to be paid within two (2) years from the reinstatement of the license.

ii. Roland Adamyan, R.Ph., Case No. 2022-04385
(PCP – Montgomery & Meshad)

The Respondent was charged with the following violation(s): Section 456.072(1)(k), F.S., through a violation of Section 465.022(11)(a), by failing to ensure compliance with rule 64B16-28.110, F.A.C., for failure to, as the prescription department manager, ensure CVS pharmacy removed or quarantined one or more expired medications from active stock.

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 $982.33 to be paid within one (1) year of the filing of the Final Order
- Submission of quarterly reports for one (1) year of the filing of the Final Order affirming that all damaged, outdated, expired, deteriorated, misbranded, and adulterated prescription drugs and pharmaceuticals have been removed from active stock.

iii. James Albert Wright, R.Ph., Case No. 2021-24012
(PCP – Weizer & Wright)

The Respondent was charged with the following violation(s): **Count I:** Section 456.072(1)(z), F.S., **Count II:** Section 465.016(1)(d), F.S. by being found unable to practice with reasonable safety and skill.

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

- Appearance
- 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.
- Costs of $12,000.00 to be paid within four (4) years of the reinstatement of the license.

iv. Zhaoqi Zhu, R.Ph., Case No. 2014-13365
(PCP- Fallon & Mesaros)

The Respondent was charged with the following violation(s): **Count I:** Section 456.072(1)(k), F.S., through a violation of Section 465.016(1)(t)(3), F.S., **Count II:** Section 456.072(1)(k), through a violation of Section 465.016(1)(e), F.S., by violating Section 893.04(1)(c)1,5, and 6, F.S. by failing to verify or validate one or more prescriptions and for improperly dispensing controlled substances.

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

- Appearance
- Fine of $1,000.00 to be paid within three (3) years of the filing of the Final Order
- Costs of $5,500.00 to be paid within three (3) years of the filing of the Final Order
- Successful completion of twelve (12) hours of laws and rules to be in addition to their hours required for renewal and to be completed within one (1) year of the filing of the Final Order.
- Probation for two (2) years to include the following terms:
    - Respondent may not be listed as an owner of a pharmacy
    - Respondent may not serve as a PDM for any pharmacy.
    - Respondent may petition the Board after one (1) year to request the probation be lifted.
- Permanent Practice Restriction prohibiting Respondent from owning a pharmacy or serving as PDM for a pharmacy without prior Board approval.

v. Zhaoqi Zhu, R.Ph., Case No. 2020-09204
(PCP – Weizer & Mesaros)

The Respondent was charged with the following violation(s): **Count I:** Section 456.072(1)(k), F.S., through a violation of Section 465.022(11)(a), F.S., **Count II:** Section 456.072(1)(m), F.S., **Count III:** 465.016(1)(e), F.S., through a violation of Section 499.0121(6)(a), F.S. **Count IV:** 456.072(1)(k), F.S., through a violation of Section 465.022(11)(a), F.S., for ceasing operation as the sole owner of ZZ's Pharmacy, which permanently closed. Respondent transferred drugs to Everyday Pharmacy Inc, without properly notifying the Board and failed to maintain records for the transferred drugs. Respondent dispensed one or more prescription drugs to patients at Everyday Pharmacy without maintaining a patient record system.

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

- Appearance
- Fine of $1,000.00 to be paid within three (3) years of the filing of the Final Order
- Costs of $5,500.00 to be paid within three (3) years of the filing of the Final Order
- Successful completion of twelve (12) hours of laws and rules to be in addition to their hours required for renewal and to be completed within one (1) year of the filing of the Final Order.
- Probation for two (2) years to include the following terms:
    - Respondent may not be listed as an owner of a pharmacy
    - Respondent may not serve as a PDM for any pharmacy.
    - Respondent may petition the Board after one (1) year to request the probation be lifted.
- Permanent Practice Restriction prohibiting Respondent from owning a pharmacy or serving as PDM for a pharmacy without prior Board approval.

vi. Animal Health International, Inc., Case No. 2021-39162
(PCP – Mikhael & Mesaros)

The Respondent was charged with the following violation(s): Section 456.072(1)(c), F.S., by being

found guilty of a crime in which related to the practice of pharmacy.

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

- Fine of $3,500.00 to be paid within ninety (90) days of the filing of the Final Order.
- Cost $650.11 of to be paid within ninety (90) days of the filing of the Final Order.

Motion: by Dr. Ghazvini to accept the Settlement Agreements.
Second: by Mr. Philip
Vote: Unanimous

B. DETERMINATION OF WAIVER

i. D One Pharmacy Corp, PH, Case No. 2020-24283
(PCP – Mikhael & Segovia)

The Respondent was not present nor represented by Counsel.

Mr. Howard presented the cases to the Board. The Respondent was charged with the following violation(s): **Count I:** 465.023(1)(c), F.S., by violating 456.072(1)(k), through a violation of Rule 64B16-28.120(1)(a), F.A.C., **Count II:** 465.023(1)(c), F.S. by violating section 456.072(1)(k), F.S., through a violation of Rule 64B16-28.202(5), F.A.C., **Count III:** 65.023(1)(c), F.S., by violating 456.072(1)(k), through a violation of Rule 64B16-28.202(3)(a), F.A.C., for failing to properly store legend drugs and failing to properly transfer prescription files and medicinal drugs when closing a pharmacy.

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, and conclusions of law as set forth in the Administrative Complaint
Second: by Dr. Ghazvini
Vote: Unanimous

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

After discussion, the following action was taken:

- Revocation

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

The Department withdrew their motion for cost.

ii. Laz Pharmacy Corp, PH, Case No. 2022-07481
(PCP – Weizer & Segovia)

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 465.023(1)(c), F.S., through a violation of Rule 64B16-28.202(3), F.A.C., for improperly closing a pharmacy.

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 and to find the conclusions set forth in the Administrative Complaint constitutes a violation of the practice act.
Second: by Ms. Gift
Vote: Unanimous

After discussion, the following action was taken:

- Revocation

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

The Department withdrew their motion for cost.

C. INFORMAL

i. Animal Health International, Inc., Case No. 2021-39162 (PCP – Mikhael & Mesaros)

This case was presented as a Settlement Agreement.

D. VOLUNTARY RELINQUISHMENTS

i. Kevin Charles, P.S.I., Case No. 2022-32631

ii. Mark A. Kaplan, R.Ph., Case No. 2022-33242

iii. Mark A. Kaplan, R.Ph., Case No. 2022-38581

iv. James Schmid, R.Ph., Case No. 2022-26938

Motion: by Dr. Hickman to accept the voluntary relinquishments.
Second: by Dr. Ghazvini
Vote: Unanimous

E. PETITION FOR REINSTATEMENT

i. Christina Lyn Monhollen, R.P.T., Case No. 2021-26536

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

Dr. Michelle Polles was present on behalf of Professional Resources Network (PRN).

On August 25, 2022, case number 2021-09207 came before the Board. A Final Order was filed September 14, 2022, that suspended Ms. Monhollen's license.

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

After discussion, the following action was taken:

Motion: by Dr Ghazvini to approve the removal of the suspension.
Second: by Dr. Mesaros
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 246 cases, from 283.

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

III. APPLICATIONS FOR REVIEW – Patty Ghazvini, PharmD

A. Pharmacists

i. Arie Bolshem

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

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

After further discussion the Board took the following action:

Motion: by Dr. Hickman to approve the application with the following conditions:

- Mr. Bolshem must complete twelve (12) hours of continuing education in laws and rules and pay fines from the previous discipline history within one (1) year of the filing of the Board Order.

Second: by Mr. Wright
Vote: 6/1. Dr. Segovia opposed.

B. Registered Pharmacy Technician

i. David Wright

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.

The application failed to appear at the October 20, 2022, meeting; therefore, was placed on the agenda for final review.

After further discussion the Board took the following action:

Motion: by Mr. Philip to deny the application failure to appear.
Second: by Dr. Mesaros
Vote: Unanimous

ii. Tamika Dixon

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.

The application failed to appear at the October 20, 2022, meeting; therefore, was placed on the agenda for final review.

After further discussion the Board took the following action:

Motion: by Dr Hickman to approve the withdraw of the application.
Second: by Dr. Mesaros
Vote: Unanimous

After further review of Ms. Dixon's criminal history, it was determined that she was not automatically disqualified from licensure due to Section 456.0635, Florida Statutes. The Board continued the discussion of the application.

After additional discussion to the Board to the following action:

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

C. Pharmacy Permits

i. Agropec Trading LLC

The applicant was present and sworn in by the court reporter and represented by Edwin Bayo, Esq.

The applicant submitted an application for a Non-Resident Pharmacy Permit and was required to appear due to their discipline history.

The application failed to appear at the October 20, 2022, meeting; therefore, was placed on the agenda for final review.

After further discussion the Board took the following action:

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

IV. PETITION FOR VARIANCE OR WAIVER

A. DelivRxd LLC d/b/a DeliveRxd Pharmacy #1, 64B16-27.410, F.A.C., Registered Pharmacy Technician to Pharmacist Ratio

The petitioner was present and sworn in by the court reporter and represented by Will Parker.

DelivRxd Pharmacy is a license community pharmacy that provides free same day delivery services within a sixty-mile radius of our location and free next day shipping services to the rest of the State of Florida. They petitioned for a permanent variance of Rule 64B16-27.410, F.A.C., to increase the pharmacy's current registered pharmacy technician ratio of 6:1 to 8:1 to be able to provide a higher level of service to their patients that is sustainable with additional data entry staff.

Motion: by Dr. Mesaros to approve the withdraw of the petition.
Second: by Dr. Ghazvini
Vote: Unanimous

B. Publix Super Markets, Inc., 64B16-27.410, F.A.C., Registered Pharmacy Technician to Pharmacist Ratio

The petitioner was present and sworn in by the court reporter. Laura Churns, Director of Regulations and Compliance addressed the Board.

Publix Super Markets, Inc, was seeking a waiver of rule 64B16-27.410, F.A.C., Registered Pharmacy Technician to Pharmacist Ratio. Per Florida rule, pharmacy technicians are utilized in a pharmacy by a pharmacist at a 6:1 ratio the petitioner requested to utilize professional judgement of the Prescription Department Manager to determine the appropriate ratio for their facility. Publix requested to utilize a pharmacist's ratio they deem appropriate, up to a 12 to 1 ratio in the dispensing are of the pharmacy.

Motion: by Dr. Mesaros to approve the petition for two (2) years.
Second: by Dr. Segovia
Vote: Unanimous

C. Good Samaritan Pharmacy & Health Services, Inc., 64B16-28.1081, F.A.C., Regulation of Daily Operating Hours; Commencement of Operations

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

Good Samaritan Pharmacy is a non-denominational nonprofit organization whose mission is to provide free medication and medical services to uninsured, financially needy members of the community. Due to free-clinic walk-in times, and the clinic providing the medications at time of service, GSPHS does not always have a set operation of service hours. GSPHS requested a waiver of the twenty (20) hours minimum requirement of operating hours outlined in Rule 64B16-28.1081, F.A.C.

Motion: by Dr. Hickman to approve the petition.
Second: by Dr. Mesaros
Vote: Unanimous

D. Ramanarasimha Reddy Gujjula, 64B16-26.2031, F.A.C., Licensure by Examination (Non-U.S. Graduates); Application

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

Pursuant to Rule 64B16-26.2031(2)(b)(1), F.A.C., a foreign pharmacy graduate must demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language (TOEFL), which is demonstrated by the Educational Testing Services, Inc., with a score of at least 550 for the pencil and paper test or 213 for the computer version and by passing the Test of Spoken English (TSE) with a score of 50 on the recalibrated TSE.

As of 2004, Mr. Gujjula passed the TOEFL computer-based exam with a score of 227; however, Mr. Gujjula scored a 45 instead of the required 50 on the TSE test. Mr. Gujjula requested the Board accept his score of 45 on the TSE to comply with Florida's requirements.

Motion: by Dr. Hickman to approve the petition and application.
Second: by Dr Ghazvini
Vote: Unanimous

V. REPORTS – David Wright, BPharm, Chair

A. Board Chair

Mr. Wright addressed the Board and extended his gratitude for his time a Board Chair.

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

i. 2023 Probable Cause Panel Dates

This was provided for informational purposes only.

ii. 2023 Board Meeting Dates and Locations

This was provided for informational purposes only.

iii. Financial Report

This was provided for informational purposes only.

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

i. Rules Status Report

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

At this time, the Board called on Ms. Dixon to review her application.

D. Committee Report

i. Compounding Committee – Dorinda Segovia, PharmD, MBA

Dr. Segovia provided an overview of the Compounding Committee held on December 14, 2022. She advised the Board that the Sterile Compounding Committee will be holding a workshop to review the new USP chapters on February 8, 2023.

ii. Rules Committee – Jeffrey Mesaros, PharmD, JD

Dr. Mesaros provided an overview of the Rules Committee held on December 14, 2022.

a. 64B16-26.2031, F.A.C., Licensure by Examination (Non-U.S. Graduates); Application

b. 64B16-26.600, F.A.C., Tripartite Continuing Education Committee

c. 64B16-27.831, F.A.C., Standards of Practice for the Dispensing of Controlled Electronic Prescribing; Mandatory Continuing Education

64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education.

The Board of Pharmacy recognizes that it is important for the patients of the State of Florida to be able to fill valid prescriptions for controlled substances. In filling these prescriptions, the Board does not expect pharmacists to take any specific action beyond exercising sound professional judgment. Pharmacists should not fear disciplinary action from the Board or other regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice. Every patient's situation is unique and prescriptions for controlled substances shall be reviewed with each patient's unique situation in mind. Pharmacists shall attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.

(1) Definitions: For purposes of this rule the following definitions shall apply:

(a) Valid Prescription. A prescription is valid when it is based on a practitioner-patient relationship and when it has been issued for a legitimate medical purpose.

(b) Invalid Prescription. A prescription is invalid if the pharmacist knows or has reason to know that the prescription was not issued for a legitimate medical purpose.

(c) Validating a Prescription. Validating a prescription means the process implemented by the pharmacist to determine that the prescription was issued for a legitimate medical purpose.

(2) General Standards for Validating a Prescription: Each prescription may require a different validation process and no singular process can fit each situation that may be presented to the pharmacist. There are circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance; however, a concern with the validity of a prescription does not mean the prescription shall not be filled. Rather, when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.

(a) When validating a prescription, neither a person nor a licensee shall interfere with the exercise of the pharmacist's independent professional judgment.

(b) When validating a prescription, the pharmacist shall ensure that all communication with the patient is not overheard by others.

(c) When validating a prescription, if at any time the pharmacist determines that in his or her professional

judgment, concerns with the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.

(3) Minimum Standards Before Refusing to Fill a Prescription.

(a) Before a pharmacist can refuse to fill a prescription based solely upon a concern with the validity of the prescription, the pharmacist shall attempt to resolve those concerns and shall attempt to validate the prescription by performing the following:

1. Initiate communication with the patient or the patient's representative to acquire information relevant to the concern with the validity of the prescription,

2. Initiate communication with the prescriber or the prescriber's agent to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(b) In lieu of either subparagraph 1. or 2., but not both, the pharmacist may elect to access the Prescription Drug Monitoring Program's Database to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(c) In the event that a pharmacist is unable to comply with paragraph (a), due to a refusal to cooperate with the pharmacist, the minimum standards for refusing to fill a prescription shall not be required.

(4) Duty to Report: If a pharmacist has reason to believe that a prescriber is involved in the diversion of controlled substances, the pharmacist shall report such prescriber to the Department of Health.

(5) Electronic Prescriptions: All controlled substances listed in Schedule II through V may be electronically prescribed pursuant to the provisions of section 456.42(2), F.S. ~~(2015)~~, and pursuant to applicable federal law. ~~For more information related to the federal requirements, access http://www.deadiversion.usdoj.gov/ecomm/index.html.~~

(6) Mandatory Continuing Education: All pharmacists shall complete a Board-approved 2-hour continuing education course on the Validation and Counseling of Prescriptions for Controlled Substances and Opioids. The course content shall include the following:

(a) Ensuring access to controlled substances for all patients with a valid prescription;

(b) Use of the Prescription Drug Monitoring Program's Database;

(c) Assessment of prescriptions for appropriate therapeutic value;

(d) Detection of prescriptions not based on a legitimate medical purpose;

(e) The laws and rules related to the prescribing and dispensing of controlled substances.

(f) Proper patient storage and disposal of controlled substances;

(g) Protocols for addressing and resolving problems recognized during the drug utilization review to include but not limited to the following:

1. Drug/drug interactions;

2. Side effects;

3. High dose/low dose guidelines; and

(h) Education on the provision of section 381.887, F.S., Emergency treatment for suspected opioid overdoses and on the State Surgeon General's Statewide Standing Order for Naloxone (eff. May 19, 2017) for as long as the Order is valid and effective.

(i) Pharmacist initiated counseling of patients with opioid prescriptions; and

(j) Available treatment resources for opioid physical dependence, addiction, misuse, or abuse.

(7) All licensed pharmacists shall complete the required ~~course during the biennium ending on September 30, 2019. A~~ 2-hour course ~~shall be taken~~ every biennium ~~thereafter~~. The course shall count towards the mandatory 30 hours of CE required for licensure renewal. All newly licensed pharmacists must complete the required course before the end of their first biennial renewal period. ~~A licensee who completed the mandated Validation of Prescription for Controlled Substances course between October 1, 2017 and July 1, 2018 shall be deemed to have complied with this subsection for the biennium ending on September 30, 2019.~~

(8) Summary Record: Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60

day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of section 893.07(4), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substances being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substances being dispensed to a specific patient.

Motion: by Dr. Mesaros to approve the proposed rule language as amended.
Second: by Mr. Philip
Vote: Unanimous

d. 64B16-28.140, F.A.C., Record Maintenance Systems for All Pharmacy Permits

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, including prescriptions received as provided for in Rule 64B16-28.1003, F.A.C., Transmission of Prescription Orders, shall be reduced to 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 Mr. Philip to approve the proposed rule language
Second: by Dr. Ghazvini
Vote: Unanimous

e. 64B16-31.007, F.A.C., Collaborative Practice Certification; Chronic Health Conditions

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

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

As of December 2022 - Non-Sterile Pharmacy inspections currently at 2,453 inspections completed; Sterile Compounding Pharmacy inspections currently at 266 inspections completed.

Mr. Difiore recognized Mary Crane for her years of service to the Department.

VI. DISCUSSION

A. Accessible Prescription Drug Labels

Camile Tate, 2nd Vice President, National Federation of the Blind of Florida, addressed the Board and requested the Board consider rule making to require accessible prescription labels.

After discussion the Board advised this would be a topic to be discussed at the next Rules Committee meeting.

VII. NEW BUSINESS – David Wright, BPharm, Chair

A. 2023 Election of Officers

Motion: by Mr. Wright to appoint Mr. Philip as the Board Chair.
Seconded: by Dr. Hickman
Vote: Unanimous

Motion: by Dr. Mesaros to appoint Dr. Ghazvini as the Board Vice-Chair.
Seconded: by Mr. Philip
Vote: Unanimous

B. 2023 Delegation

Ms. Sapp provided an overview of the delegation.

C. 2023 Conviction Record Guidelines

Ms. Sapp provided an overview of the conviction record guidelines.

Motion: by Dr. Mesaros to approve the 2023 Delegation and conviction record guidelines.
Seconded: by Dr. Ghazvini
Vote: Unanimous

D. Ratification of Issued Licenses/Certificates

i. Pharmacist (licensure) – 288
ii. Pharmacist (exam eligibility) – 292
iii. Pharmacist Intern – 161
iv. Consultant Pharmacist – 65
v. Nuclear Pharmacist – 4
vi. Pharmacy/Facilities – 88
vii. Registered Pharmacy Technician – 958
viii. Registered Pharmacy Technician Program – 10
ix. Nonresident Sterile Compound – 2
x. Approved CE Courses – 25
xi. Approved CE Providers – 1
xii. Individual Pharmacist Request for Approval of CE – 2

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

Vote: Unanimous

VIII. OLD BUSINESS – David Wright, BPharm, Chair

A. Review and Approval of Meeting Minutes

ii. October 19, 2022 Rules Committee Meeting Minutes
iii. October 20, 2022 General Business Meeting Minutes

Motion: by Dr. Mesaros to accept the October 19, 2022, Rules Committee meeting minutes.
Second: by Ms. Gift
Vote: Unanimous

Motion: by Dr. Mesaros to accept the October 20, 2022, General Business meeting minutes.
Second: by Ms. Gift
Vote: Unanimous

IX. ADJOURNMENT

There being no further business the meeting adjourned at 1:00 p.m. ET.