

AGENDA
FLORIDA DEPARTMENT OF HEALTH
BOARD OF PHARMACY
RULES COMMITTEE

October 7, 2014

Embassy Suites South - LBV
4955 Kyngs Heath Road
Kissimmee, FL 34746
(407) 240-1000

Committee Members:

Jeffrey Mesaros, PharmD, Orlando, Chair
Debra Glass, BPharm, Tallahassee
Mark Mikhael, PharmD, Orlando
Jeenu Philip, BPharm, Jacksonville
Michele Weizer, PharmD, Boca Raton

Board Staff:

Patrick Kennedy, Executive Director
Tammy Collins, Program Operations Administrator
Jay Cumbie, Regulatory Specialist II

Board Counsel:

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

Participants in this public meeting should be aware that these proceedings are being recorded.

Tuesday, October 7, 2014 - 9:00a.m.

New Business

1. Rule 64B16-27.410 – Pharmacy Technician Ratios
2. Rule 64B16-28.303 – Destruction of Controlled Substances
3. Rule 64B16-27.104 - Conduct Governing Pharmacists and Pharmacy Permittees

Old Business

1. JAPC Comments on Rule(s) 64B16-27.210, 64B16-27.320, 64B16-27.800, and 64B16-27.851

64B16-27.410 Registered Pharmacy Technician to Pharmacist Ratio

When the pharmacist delegates tasks to a registered pharmacy technician, such delegation must enhance the ability of the pharmacist to practice pharmacy to serve the patient population. A pharmacist shall not supervise greater than one (1) registered pharmacy technician nor shall a pharmacy allow a supervision ratio of greater than one (1) registered pharmacy technician to one (1) pharmacist (1:1), unless specifically authorized to do so pursuant to the provisions of this rule.

(1) General Conditions: Regardless of the technician ratio, every pharmacy, pharmacist, Prescription Department Manager (PDM) or Consultant Pharmacist (CP) that employs or utilizes registered pharmacy technicians must comply with the following conditions:

- a. Establish and maintain a written Policy and Procedural Manual regarding the number of registered pharmacy technician positions and their utilization that includes the specific scope of delegable tasks of the technicians, job descriptions, and task protocols. The Policy and Procedural Manual or Manuals must include policies and the procedures for implementing the policies for each category enumerated below:
 - i. Supervision by a pharmacist;
 - ii. Minimum qualifications of the registered pharmacy technician as established by statute and rule;
 - iii. In-service education or on-going training and demonstration of competency specific to the practice site and job function;
 - iv. General duties and responsibilities of the registered pharmacy technicians;
 - v. All functions related to prescription processing;
 - vi. All functions related to prescription legend drug and controlled substance ordering and inventory control, including procedures for documentation and recordkeeping;
 - vii. All functions related to retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy;
 - viii. All delegable tasks and non-delegable tasks as enumerated in Rule 64B16-27.420;
 - ix. Confidentiality and privacy laws and rules;
 - x. Prescription refill and renewal authorization;
 - xi. Registered pharmacy technician functions related to automated pharmacy systems; and
 - xii. Continuous quality improvement program.

- b. Establish and maintain written documentation that is signed by the registered pharmacy technician acknowledging they have reviewed the Policy and Procedural Manual(s). Each registered pharmacy technician shall have 90 days from the

effective date of this rule,[insert effective date], to comply with this provision and all registered pharmacy technicians hired subsequent to this rules' effective date shall have 90 days from the date of hire.

- c. Establish and maintain written documentation that demonstrates the registered pharmacy technician is knowledgeable in the established job description, delegable tasks, task protocols, and policy and procedures in the specific pharmacy setting where the delegable tasks will be performed.
- (2) Any and all required written documentation and Policy and Procedures Manual(s) required by subsection (1) must be maintained on-site where the pharmacy technician will perform the delegable tasks and must be available during a Department inspection or at the request of the Board of Pharmacy.
 - (3) Three to One (3:1) Ratio: Registered pharmacy technicians assisting with delegable tasks involving sterile compounding shall not exceed a ratio of up to three (3) registered pharmacy technicians to one (1) pharmacist (3:1).
 - (4) Four to One (4:1) Ratio: Any pharmacist or any pharmacy may allow a supervision ratio up to four (4) registered pharmacy technicians to one (1) pharmacist (4:1), as long as the delegable tasks do not involve sterile compounding.
 - (5) Six to One (6:1) Ratio: A pharmacy which does not dispense medicinal drugs, and the pharmacist(s) employed by such pharmacy, may allow a supervision ratio up to six (6) registered pharmacy technicians to one (1) pharmacist (6:1), as long as the delegable tasks do not involve sterile compounding.

Rulemaking Authority 465.005, 465.0125, 465.022 FS. Law Implemented 465.0125, 465.014, 465.022, 893.07(1)(b) FS. History—New 2-14-77, Amended 3-31-81, Formerly 21S-4.02, Amended 8-31-87, Formerly 21S-4.002, Amended 9-9-92, Formerly 21S-27.410, 61F10-27.410, Amended 1-30-96, Formerly 59X-27.410, Amended 2-23-98, 10-15-01, 1-1-10,_____.



September 29, 2014

Patrick Kennedy, Executive Director
Board of Pharmacy
Florida Department of Health
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3258

Dear Mr. Kennedy:

First and foremost, on behalf of the Florida Retail Federation and our members, I appreciate the strides that you all have made in advancing this rule. That being considered, I would like you all to consider including the following guidelines for approving a ratio greater than 4:1 in central fill facilities.

A community pharmacy may apply to the Board for approval of a pharmacy technician to pharmacist supervision ratio greater than 4:1. The application shall provide information on how the pharmacy qualifies for the increased ratio and may include the following to the extent relevant to the applicant's request: the requested ratio, a description of pharmacy operations, anticipated prescription volume, types of medications dispensed, a description of any automation or technology utilized, or any other information relevant to the request. The application shall be considered at a meeting of the Board. The Board shall consider one or more of the following factors in approving an application for a pharmacy technician to pharmacist supervision ratio greater than 4:1:

- 1. Whether the pharmacy is performing remote processing or centralized prescription filling;*
- 2. Whether the pharmacy uses an automated pharmacy system;*
- 3. Whether the pharmacy is closed to the public and does not dispense medications to patients directly on-site;*
- 4. Whether the pharmacy dispenses controlled substances listed in Schedule II;*
- 5. Pharmacist or pharmacy technician training utilized; or*
- 6. Any other factors which the pharmacy can show are relevant to safely utilizing a supervision ratio greater than 4:1.*

Given the advancements in technology and the growth of mail order, call centers and centralized filling facilities, I believe including a means to apply beyond 4:1 is necessary. Thank you for your consideration in this matter and thank you for allowing the members of the Florida Retail Federation to participate in this process.

Respectfully submitted,

Melissa Joiner Ramba
Director of Government Affairs

cc:

David Flynn, Counsel
Geoffrey Becker, Office of the Governor

The attached DEA Form 41 is being submitted for the record of destruction of controlled substances in accordance with The below Florida Administrative Code. James E Martinez, Consultant Pharmacist of Record Ph (813) 245-7500

Thank You

64B16-28.303 Destruction of Controlled Substances All Permittees (Excluding Institutional Class I Nursing Homes).

(1) Controlled substances that cannot be retained as usable shall be securely stored in the pharmacy/prescription department of the permittee pharmacy until destroyed.

(2) Permittees are required to complete a United States Drug Enforcement Administration (D.E.A.) Form DEA-41 "Registrants Inventory of Drugs Surrendered" (effective 8/31/2014), herein incorporated by reference, available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-03998> or http://www.dea diversion.usdoj.gov/21cfr_reports/surrend/. This form, at the time of destruction, shall be witnessed and signed by the prescription department manager or the consultant pharmacist of record and D.E.A. agent, or a Department inspector. This method of destruction requires that a copy of the completed and witnessed Form DEA 41 be mailed to the D.E.A. office in his/her area within one (1) business day after the destruction.

(3) Another method of destruction shall be conducted by at least two persons: One will be the prescription department manager or the consultant pharmacist of record. The other will be one of the following: medical director or his/her physician designee, director of nursing or his/her licensed nurse designee, or a sworn law enforcement officer. These persons shall serve as the witnesses for the Form DEA-41 and the destruction. This method of destruction requires that a copy of the completed and witnessed Form DEA-41 be mailed to the D.E.A. office in the permittee's area within one (1) business day after destruction.

(4) In lieu of destruction on the premises as outlined in subsections (2) and (3) above, controlled substances may also be shipped to reverse distributors for destruction in conformity with federal guidelines.

(5) For patient specific controlled substance prescriptions in a Modified Institutional Class II B pharmacy, the destruction method in subsection 64B16-28.301(2), F.A.C., must be followed.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022, 465.018 FS. History—New 4-21-87, Formerly 21S-19.003, Amended 7-31-91, Formerly 21S-28.303, 61F10-28.303, Amended 1-30-96, Formerly 59X-28.303, Amended 2-5-07, 10-27-09, 2-1-12, 4-20-14.

64B16-27.104 Conduct Governing Pharmacists and Pharmacy Permittees.

(1) A pharmacist or pharmacy shall be permitted to advertise medicinal drugs other than those controlled substances specified in Chapter 893, F.S., and patent and proprietary preparations so long as such advertising is not false, misleading or deceptive.

(2) No pharmacist, employer or employee of a pharmacy shall maintain a location, other than a pharmacy for which a permit has been issued by the Florida Board of Pharmacy, from which to solicit, accept or dispense prescriptions.

(3) No pharmacist or pharmacy, or employee or agent thereof, shall enter into or engage in any agreement or arrangement with any physician or other practitioner or nursing home or extended care facility for the payment or acceptance of compensation in any form or type for the recommending of the professional services of either; or enter into a rebate or percentage rental agreement of any kind, whereby in any way a patient's free choice of a pharmacist or pharmacy is or may be limited.

(4) No pharmacist, employer or employee of a pharmacy may knowingly place in stock of any pharmacy any part of any prescription compounded for, or dispensed to, any customer of any pharmacy and returned by said customer, unless otherwise permitted by Rule 64B16-28.118, F.A.C.

(5) Pursuant to Section 465.018, F.S., a permit for a community pharmacy may not be issued unless a licensed pharmacist is designated as the prescription department manager responsible for maintaining all drug records, providing for the security of the prescription department and following such other rules as relate to the practice of the profession of pharmacy. The Board shall not register a prescription department manager as the manager of more than one pharmacy. The Board shall grant an exception to this requirement upon application by the permittee and the prescription department manager showing circumstances such as proximity of permits and limited pharmacist workload that would allow the manager to carry out all duties and responsibilities required of a prescription department manager.

Specific Authority 465.005, 465.0155, 465.018, 465.022 FS. Law Implemented 465.018, 465.022, 465.024 FS. History—New 10-20-81, Formerly 21S-1.20, 21S-1.020, Amended 7-30-91, Formerly 21S-27.104, 61F10-27.104, 59X-27.104, Amended 11-18-07.

ALAN N. MILLER, M.P.H., R.Ph., C.Ph.
7717 N.W. 79TH STREET
TAMARAC, FLORIDA 33321-2989

July 28, 2014

RECEIVED

Florida Board of Pharmacy
4052 Bald Cypress Way
Bin C-04
Tallahassee, Florida 32399-3258
ATTN: Mr. Patrick Kennedy, M.A.
Executive Director

JUL 30 2014

Florida Board of Pharmacy

Dear Mr. Kennedy:

Listed below is my proposal for a rule dealing with the **PRESCRIPTION DEPARTMENT MANAGER**. This rule is needed to clarify a current omission in the Florida pharmacy rules and regulations. Please submit this proposal to the Board of Pharmacy Rules Committee for their review and consideration, and then for submission to the entire Board to vote on it. As pharmacy practice is now rapidly changing (e.g.: Sterile Compounding Pharmacies, as required by USP Chapter 797, the new third party requirements for the use of Mail Order Pharmacies, etc.), pharmacy rules must also change to keep up with these rapid changes.

All persons designated as a PRESCRIPTION DEPARTMENT MANAGER, as required by Section 465.018, F.S., shall possess an active Florida Pharmacist License, and shall not be under any current pharmacy disciplinary action(s), or be on pharmacy probation or other punitive action. Such a PRESCRIPTION DEPARTMENT MANAGER shall be required to work in a Florida licensed pharmacy department, or on the premises of the pharmacy building, for not less than THIRTY (30) HOURS per week, and take an active role in the operation of the pharmacy. This pharmacist shall be responsible for maintaining all drug records, providing for the security of the prescription department and following such other rules as relate to the practice of the profession of pharmacy.

The only exceptions to the thirty (30) hour rule shall be when the PRESCRIPTION DEPARTMENT MANAGER is absent do to:

- (1) Vacation (the Board of Pharmacy Members shall determine what is a reasonable amount of time to be absent due to vacation, and if this time period is excessive, another Florida licensed pharmacist shall then be designated as the new PRESCRIPTION DEPARTMENT MANAGER of the Florida licensed pharmacy).
- (2) Sickness (which shall require medical proof of such sickness).
- (3) Jury Duty
- (4) Continuing Pharmacy Education (approved by the Florida Board of Pharmacy)
- (5) Other reasons which shall require the unanimous approval of all Board of Pharmacy members present at a general Board of Pharmacy meeting.

A Florida Licensed Pharmacist who is employed by a pharmacy placement agency or other type of temporary employment agency shall not be designated as a PRESCRIPTION DEPARTMENT MANAGER.

The above rule shall apply to all PRESCRIPTION DEPARTMENT MANAGERS of Florida licensed pharmacies located in Florida as well as pharmacies located in any of the other forty-nine (49) states of the United States of America or its territories. This rule shall be added to Section 64B16-27.104 (5), F.A.C., and to Section 64B16-28.100 (2) (a) 2., F.A.C.

Thank you for attention to this matter.

Sincerely,



Alan N. Miller
Former Florida Department of Health Drug Investigator/
Former Florida Board of Pharmacy Inspector (Retired)

cc: Tammy Collins
Program Operations Administrator