

**DEPARTMENT OF HEALTH
BOARD OF PHARMACY
PROFESSIONAL PRACTICE COMMITTEE
MINUTES
MARCH 9, 2007
1:00 P.M.
CONFERENCE CALL 1-888-808-6959
CONFERENCE CODE 5642037**

Committee Members Present:

Albert Garcia, R.Ph, M.H.L., Chair
Bob Parrado, R.Ph., Vice Chair
Eric Alvarez, Pharm.D.
Brigitte Goersch, Consumer Member

Board Members Present:

Ron Salem, Pharm.D.

Board Staff:

Rebecca Poston, R.Ph., Executive Director
Maxine Wenzinger, Administrative Assistant II

Board Counsel:

Debra Loucks, Assistant Attorney General

Department of Health Staff:

John Taylor, Statewide Inspection Program
Manager, Investigative Services Unit
Lynne Quimby-Pennock, J.D., Senior
Attorney
Sara Helen Lowe, Senior Pharmacist,
Investigative Services Unit.

1:00 p.m. Call to Order, Albert Garcia, R.Ph., M.H.L., Chair

TAB 1: Approve Minutes from January 16, 2006, Meeting

MOTION to approve minutes by Alvarez, second by Parrado. Motion carried unanimously.

TAB 2: 64B16-26 – Pharmacist Licensure

1. 64B16-26.1001 Examination and Application Fees

The Committee reviewed the current language in 64B16-26.1001, F.A.C. Ms. Loucks reviewed JAPC letters dated May 11, 2006, April 26, 2006, January 28, 2005, and January 21, 2005, with the committee and recommended the committee adopt the language provided. The Committee had the following recommendations:

~~(4) The non-refundable application fee for a continuing education course approval shall be \$ 50 for each course submitted for approval, payable to the Board.~~

MOTION: by Alvarez, second by Parrado to delete (4) as recommended by Ms. Loucks and forward to full board for ratification. Motion carried unanimously.

2. 64B16-26.1004 Inactive Licensure Election; Renewal; Fees

The Committee reviewed the rule and had the following recommendations:

Line 7-8: \$ 70, a change of status fee of \$ 25 and ~~the current renewal fee set forth in Rule 64B16-26.1003, F.A.C.,~~ or the difference between the inactive status renewal fee and the active

Line 15-17: \$ 25, a change of status fee of \$ 25, and ~~the active consultant pharmacist renewal fee set forth in Rule 64B16-26.1003, F.A.C.~~ the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

MOTION: by Parrado, second by Alvarez to approve the recommendations by Ms. Loucks and forward to full board for ratification. Motion carried unanimously.

TAB 3: 64B16-27 Pharmacy Practice

1. 64B16-27.700 - Office Use Compounding

Ms. Poston advised HB 1553 and SB 2552 were filed to create In-Office Use Compounding. She suggested the committee wait until after legislative session to determine if a rule is needed.

MOTION: by Alvarez, second by Parrado to table and include in legislative bill analysis. Add to next meeting agenda.

TAB 4: 64B16-28 General Requirements- Permits

1. 64B16-28.120 – Storage of Legend Drugs; Prepackaging

The Committee reviewed the proposed language and had the following recommendations for change:

Line 13-14: Insert
Class I Institutional permittees as defined in Section 465.019(2)(a), F.S., and Special ALF Permit 64B16-28.870, F.A.C., shall:

Line 26-29: Delete lines 26-29 and insert:

(4) Medicinal drugs and proprietary preparations as identified above that are stored in treatment areas must be accessible only to licensed staff (pharmacists, nurses, physicians, Advanced Registered Nurse Practitioner's, physician assistants, respiratory and physical therapists, radiology technicians) and pharmacy technicians, etc) in accordance with their license and or practice act.

MOTION by Parrado, second by Alvarez to request Ms. Poston and Mr. Dixon to make suggested changes and forward to full board for ratification. Motion carried unanimously.

2. 64B16-28.141 Requirements for an Automated Pharmacy System in a Community Pharmacy

The Committee reviewed the proposed changes to Rule 64B16-28.141, F.A.C and e-mail correspondence from Reginald Dixon and had the following recommendations:

MOTION by Alvarez, second by Parrado to reconsider this rule at the next meeting. Staff to arrange the appearance of experts in technology and repackaging to answer questions. Mr. Dixon to address Committee concerns.

a. Correspondence from Edwin Bayó

The Committee reviewed the correspondence from Mr. Bayó. No action was taken.

b. Automated Prescription Pick-Up (Wal-Mart presentation)

MOTION by Alvarez, second by Parrado to have Mr. Dixon prepare a notice for rule development. Motion carried unanimously.

3. 64B16-28.450 Centralized Prescription Filling

The Committee reviewed the proposed language provided and had the following recommendations:

Line 3: Delete receiving and insert originating

Line 5-7: Delete: A "receiving pharmacy" is also the pharmacy which will dispense the medication once the prescription has been filled by the supplier pharmacy and then delivered to the receiving pharmacy

Line 8: Delete supplier and insert central fill

Line 9: Insert centralized prescription filling, delivering, and returning for one or more ~~receiving~~ originating pharmacies.

Line 11: Delete and insert
(2) Pharmacies acting as the ~~supplier~~ central fill pharmacy must be authorized to

Line 14: Delete and insert
(3) A community pharmacy which acts as the ~~supplier~~ central fill pharmacy and which

Line 20: Delete and insert
(4) All ~~supplying~~ central fill and ~~receiving~~ originating pharmacies engaged in centralized

Line 23: Delete and insert
(a) Be maintained at the locations of the ~~supplying~~ central fill and ~~receiving~~ originating pharmacies;

Line 26-28: Delete

~~(5) Delivery of medications by the supplying originating or central fill pharmacy shall only be made to the receiving pharmacy for dispensing. Such delivery must be made in a timely manner.~~

Line 29-55: Insert

(5) Delivery of medications. Delivery of medications must be made in a timely manner. The originating and central fill pharmacies shall each be identified on the prescription container.

(a) Delivery by central fill pharmacy to ultimate consumer. A central fill pharmacy may deliver medications for an originating pharmacy to the ultimate consumer or the consumer's agent under the following conditions:

1. The pharmacies are under the same ownership or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with federal and state laws, rules and regulations.
2. The pharmacies shall have a pharmacist available 40 hours a week, either in person or via two-way communication technology, such as a telephone, to provide patient counseling.
3. The pharmacies shall include a toll-free number that allows the patient to reach a pharmacist for the purposes of patient counseling.
4. The pharmacies shall each be identified on the prescription container label. The originating pharmacy shall be identified with pharmacy name and address. The central fill pharmacy may be identified by a code available at the originating pharmacy.
5. The central fill pharmacy shall deliver via carrier to the ultimate consumer or the consumer's agent only those medications which could have been delivered via carrier by the originating pharmacy.
6. The central fill pharmacy shall not deliver to the ultimate consumer or the consumer's agent substances listed as controlled substances under chapter 893, F.S.

(b) The delivery of a filled prescription by a central fill pharmacy to the ultimate consumer or the consumer's agent pursuant to a contract with an originating pharmacy shall not be considered dispensing within the definition set forth in s. 465.003(6), F.S.

Line 56-59: Delete

~~(6) The supplying and receiving pharmacy shall each be identified on the prescription container label. The receiving pharmacy shall be identified with pharmacy name and address. The supplying pharmacy may be identified by a code available at the receiving pharmacy.~~

Line 60-97: Insert

(6) Prescription and labeling requirements for pharmacies participating in central prescription filling, delivering and returning:

(a) Prescriptions may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile. The originating pharmacy transmitting the prescription information must:

1. Write the word "central fill" on the face of the original prescription and record the name, address, and if a controlled substance the DEA registration number of the originating pharmacy from which the prescription has been transmitted and the name of the originating pharmacy's pharmacist transmitting the prescription, and the date of transmittal;
2. Ensure all the information required to be on a prescription pursuant to ss. 456.042 and 893.04, F.S., is transmitted to the central fill pharmacy either on the face of the prescription or in the electronic transmission of information;

3. Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;
4. Maintain the original prescription for a period of two years from the date the prescription was last refilled.
5. Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the originating pharmacy's employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

1. Keep a copy of the prescription if sent via facsimile or an electronic record of all the information transmitted by the originating pharmacy, including the name, address, and DEA registration number if a controlled substance of the originating pharmacy transmitting the prescription;
2. Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;
3. Keep a record of the date the filled prescription was delivered to the originating pharmacy and the method of delivery (private, common or contract carrier).
4. A central fill pharmacy's pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing the date of filling, the originating pharmacy's name and address, a unique identifier such as the central fill pharmacy's DEA registration number indicating the prescription was filled at the central fill pharmacy, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

MOTION: by Parrado, second by Alvarez to approve with suggested changes and forward to full board for ratification. Motion carried unanimously.

4. **64B16-28.501 Institutional Permit - Consultant Pharmacist of Record**

The Committee reviewed the proposed changes to the rule and had the following recommendations:

64B16-28.501 Institutional Permit - Consultant Pharmacist of Record.

Each facility holding a Class I, a Class II, or a Modified Class II Institutional permit shall designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Board office shall be notified in writing within 10 days of any change in the consultant pharmacist of record. The consultant pharmacist of record for a Class I or a Modified Class II, or a Special ALF permit shall conduct Drug Regimen Reviews as required by Federal or State law, inspect the facility and prepare a written report to be filed at the permitted facility at least monthly. In addition, the consultant pharmacist of record must monitor monthly the facility system for providing medication administration records and physician order sheets to ensure that the most current recapitulation of medications is available for the monthly drug regimen review. The consultant pharmacist of record may utilize additional consultant pharmacists to assist in this review and or in the monthly facility inspection.

Ms. Poston reviewed the e-mail comments from Mr. Dixon.

Dr. Salem recommended the board staff invite Frank Mayes, Senior Pharmacist for the Agency of Health Care Administration, to the next meeting.

MOTION by Alvarez, second by Parrado to table until next meeting. Staff will invite Mr. Mayes to the next meeting. Motion carried unanimously.

TAB 5: Correspondence

1. Mylan Pharmaceuticals

Representatives from Mylan requested that the Committee review agenda materials to determine if levothyroxine sodium could be considered for removal from the negative formulary.

MOTION: by Alvarez, second by Parrado to refer to the Negative Drug Formulary Committee for review. Motion carried unanimously.

Chairman Salem will appoint chairperson for the Negative Formulary Committee. Staff will coordinate meeting with the Board of Medicine members.

MOTION: by Parrado, second by Alvarez to adjourn. Motion carried unanimously.

Meeting adjourned at 2:42 p.m.