AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
RULES COMMITTEE MEETING

October 8, 2013

Wyndham Bay Point Resort
4114 Jan Cooley Drive
Panama City, FL 31408
(850) 236-6000

Committee Members:
Jeffrey J. Mesaros, PharmD, Tampa
Michele Weizer, PharmD, Boca Raton

Board Staff:
Mark Whitten, Executive Director
Tammy Collins, Program Operations Administrator
Jay Cumbie, Regulatory Specialist II

Board Counsel:
David Flynn, Assistant Attorney General
Lynette Norr, Assistant Attorney General

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

Tuesday, October 8, 2013 – 9:00 a.m.

1. 64B16-28.605 Class II Institutional Pharmacies – Automated Distribution and Packaging. Continued Discussion.

2. 64B16-28.810 Special Pharmacy – Limited Community Permit. Proposed Language.

3. For Discussion: Destruction of Controlled Substances.

    a. 64B16-28.301 Destruction of Controlled Substances – Institutional Pharmacies.

    b. 64B16-28.303 Destruction of Controlled Substances – All Permittees (excluding Nursing Homes).

4. 64B16-27.1001(2)(d) Practice of Pharmacy – Professional Responsibility of records and documentation. Discussion.

64B16-28.605 Class II Institutional Pharmacies – Automated Distribution and Packaging.

(1) Definitions.

(a) "Automated medication system" means a robotic, mechanical or computerized device that is not used for medication compounding and is designed to:

1. Distribute medications in a licensed health care facility; or

2. Package medications for final distribution by a pharmacist.

(b) "Centralized automated medication system" means an automated medication system located in a pharmacy department from which medication is distributed or packaged for final distribution by a pharmacist.

(c) "Decentralized automated medication system" means an automated medication system that is located outside of a pharmacy department but within the same institution.

(d) "Distribute" or "Distribution" means the process of providing a drug to an individual authorized to administer medications and licensed as a health care provider in the state of Florida pursuant to an order issued by an authorized prescriber.

(e) "Medication" means a medicinal drug or proprietary preparation.

(f) "Override medication" means a single dose of medication that may be removed from a decentralized automated medication system prior to pharmacist review because a practitioner licensed pursuant to Chapter 458, 459 or 466, F.S., determined that the clinical status of the patient would be significantly compromised by delay.

(g) "Low risk override medication" is a medication determined by a practitioner licensed pursuant to Chapters 458, 459, or 466, F.S., to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, and may be removed from a decentralized automated medication system independent of a pharmacist's review of the medication order or clinical status of the patient.

(h) "Physician controlled medication" is medication distributed in an environment where a practitioner controls the order, preparation and administration of the medication.

(2) General Requirements for the Use of Automated Medication Systems.

(a) The consultant pharmacist of record shall be responsible for:

1. Maintaining a record of each transaction or operation;

2. Controlling access to the system;

3. Maintaining policies and procedures for;

a. Operation of the automated medication system;

b. Training personnel who use the automated medication system;

c. Maintaining patient services whenever the automated medication system is not operating; and

d. Defining a procedure for a pharmacist to grant or deny access to the medication in the system.

4. Security of the system;

5. Assuring that a patient receives the pharmacy services necessary for good pharmaceutical care in a timely manner;

6. Assuring that the system maintains the integrity of the information in the system and protects patient confidentiality;

7. Establishing a comprehensive Quality Assurance program;

8. Establishing a procedure for stocking or restocking the automated medication system; and

9. Ensuring compliance with all requirements for packaging and labeling.

(b) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a medication except an override medication, a low risk override medication or a physician controlled medication.

(c) A pharmacist shall perform retrospective drug use review for an override medication.

(3) Multidisciplinary Committee for Decentralized Automated Medication Systems.

(a) The consultant pharmacist of record shall convene or identify a multidisciplinary committee, which is charged with oversight of the decentralized automated medication system.

(b) The Multidisciplinary Committee shall:

1. Include at least one pharmacist;

2. Establish the criteria and process for determining which medication qualifies as an override medication or a low risk override medication in a decentralized automated medication system;

3. Develop policies and procedures regarding the decentralized automated medication system; and

4. Have its decisions reviewed and approved by the consultant pharmacist of record.

(4) Stocking or Restocking of a Decentralized Automated Medication System.

(a) Medications in a decentralized Automated Medication System shall be stocked or restocked by a pharmacist, registered pharmacy

intern, or by a registered pharmacy technician supervised by a pharmacist.

(b) The stocking or restocking of a decentralized automated medication system shall follow one of the following procedures to assure correct medication selection:

1. A pharmacist shall conduct a daily audit of medications placed or to be placed into an automated medication system that includes random sampling.

2. A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic, or similar verification technology shall require an initial quality assurance validation followed by a monthly quality assurance review by a pharmacist.

(5) Centralized Automated Medication Systems. A pharmacist utilizing a centralized medication system may distribute patient specific medications within the licensed health care facility without checking each individual medication selected or packaged by the system, if:

(a) The initial medication order has been reviewed and approved by a pharmacist; and

(b) The medication is distributed for subsequent administration by a health care professional permitted by Florida law to administer medication; and

(c) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic verification, or similar verification technology shall require an initial quality assurance validation, followed by monthly quality assurance review by a pharmacist.

(6) Quality Assurance Program. The consultant pharmacist of record shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:

(a) Review of override and low risk override medication utilization;

(b) Investigation of a medication error related to the automated medication system;

(c) Review of a discrepancy or transaction reports and identify patterns of inappropriate use or access;

(d) Review of the operation of the system;

(e) Integration of the automated medication system quality assurance program with the overall continuous quality improvement of the pharmacy as defined in Rule 64B16-27.300, F.A.C.; and

(f) Assurance that individuals working with the automated medication system receive appropriate training on the operation of the system and procedures for maintaining pharmacy services when the system is not in operation.

(7) Record Keeping.

(a) The consultant pharmacist of record shall maintain records related to the automated medication system in a readily retrievable manner.

(b) The following records shall be maintained for at least 60 days:

1. Daily audits of stocking or restocking, if applicable;

2. Daily audits for the output of centralized automated medication system, if applicable; and

3. Transaction records for all non-controlled medications or devices distributed by the automated medication system.

(c) The following records shall be maintained for at least two (2) years:

1. Any report or analysis generated as part of the quality assurance program;

2. A report or database related to access to the system or any change in the access to the system or to medication in the system; and

3. Transaction records from the automated medication system for all controlled substances dispensed or distributed.

(8) Compliance. The consultant pharmacist of record shall assure compliance with all requirements of Chapter 465, F.S., and the rules of Chapter 64B16, F.A.C.

(9) Security. A decentralized automated medication system that contains controlled substances shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances, unless otherwise contained in labeled patient-specific form.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.019, 465.022, 465.0235, 465.026 FS. History–New 4-22-07, Amended 1-1-10.

64B16-28.810 Special Pharmacy - Limited Community Permit.

A Special-Limited Community Permit shall be obtained by a Class II Institutional Pharmacy that dispenses medicinal drugs, including controlled substances to:

(1) Employees, medical staff and their dependents for their personal use,

(2) Patients of the hospital who are under a continuation of a course of therapy not to exceed a three (3) day supply,

(3) Patients obtaining medical services in the facility's emergency room and, whenever it is otherwise appropriate, as indicated in the applicant's policy and procedure manual, and~~.~~

(4) Discharged patients of the hospital who are under a continuation of a course of therapy using multi-dose medicinal drugs if the following requirements are met:

(a) The label affixed to a container used in dispensing multi-dose medicinal drugs contains at least the following information:

1. The name of and contact information of the pharmacy;

2. The name of the prescriber;

3. The name of the patient;

4. The date of the original filling and any applicable expiration date;

5. The prescription number or other prescription identification adequate to readily identify the prescription;

6. The directions for use;

7. The name, strength, and size of the medicinal drug dispensed; and

8. The quantity of the drug in the container.

(b) The patient is deemed competent to handle and administer the multi-dose medicinal drug.

(c) A specific order is written by the patient's physician to authorize that the multi-dose medicinal drug is appropriate to dispense upon discharge.

(d) Before the hospital dispenses a multi-dose medicinal drug as specified in paragraph (4) of this section, the hospital shall establish protocols to ensure the following:

1. If the hospital interchanges multi-dose medicinals drugs, the substituted items are only dispensed to the patient upon discharge if they are to be continued upon re-fill;

2. Infection control during transport and handling of multi-dose medicinal drug containers that have been in contact with a patient;

3. Patient or caregiver education on administration of the multi-dose medicinal drug if necessary on an individual basis.

(e) A "multi-dose medicinal drug" as used in this rule means inhalers, ocular products, insulin vials or pens, otic products, bulk antibiotic suspensions, and methylprednisolone dose packets dispened to inpatients, provided in containers that exceed a three (3) day supply, and are intended to be continued by the patient on an outpatient basis. Controlled substances are not considered multi-dose medicinal drugs as defined in this rule.

Rulemaking ~~Specific~~ Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History–New 7-31-91, Formerly 21S-28.810, 61F10-28.810, 59X-28.810, Amended 7-17-05, _____.

64B16-28.301 Destruction of Controlled Substances – Institutional Class I Pharmacies (nursing homes).

(1) Controlled substances that have been dispensed and not used by the patient shall not be returned to the pharmacy and shall be securely stored by the nursing home until destroyed.

(2) A document must be completed showing the name and quantity of the drug, strength and dosage form, patient's name, prescription number and name of the institution. This documentation, at the time of destruction, shall be witnessed and signed by the consultant pharmacist, director of nursing, and the administrator or his/her designee, which may include a licensed physician, ~~pharmacists~~, mid-level practitioner, ~~or~~ nurse, another pharmacist, or a sworn law enforcement officer.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022, 465.019 FS. History–New 4-21-87, Formerly 21S-19.001, Amended 7-31-91, Formerly 21S-28.301, 61F10-28.301, Amended 1-30-96, Formerly 59X-28.301, Amended 7-21-09.

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 41. 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 ~~does not require prior approval from D.E.A., but does~~ requires that a copy of the completed and witnessed D.E.A. Form 41 be mailed to ~~D.E.A. immediately after destruction~~ the D.E.A. office in his/her area immediately after the destruction.

(3) Another method of destruction shall be conducted by at least two persons: ~~who are either a licensed pharmacist, physician or nurse, or a sworn law enforcement officer or any combination thereof, to serve as the witnesses. A copy of the completed D.E.A. Form 41 and a letter providing the proposed date of destruction, the proposed method of destruction and the names and titles of the proposed witnesses must be received by D.E.A. at least two weeks prior to the proposed date of destruction which shall constitute a request for destruction. The drugs may not be destroyed until D.E.A. grants approval of the request for destruction. A copy of the completed and witnessed D.E.A. Form 41 shall be mailed to D.E.A. immediately after destruction.~~ One will be the prescription department manager or the consultant 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 D.E.A Form 41 and the destruction. This method of destruction requires that a copy of the completed and witnessed D.E.A. Form 41 be mailed to the D.E.A.office in the permittee's area immediately after destruction.

(4) In lieu of destruction on the premises as outlined in (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, please refer to the language in 64B16-28.301 (2).

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.

64B16-27.1001 Practice of Pharmacy.

Those functions within the definition of the practice of the profession of pharmacy, as defined by Section 465.003(13), F.S., are specifically reserved to a pharmacist or a duly registered pharmacy intern in this state acting under the direct and immediate personal supervision of a pharmacist. The following subjects come solely within the purview of the pharmacist.

(1) A pharmacist or registered pharmacy intern must:

(a) Supervise and be responsible for the controlled substance inventory.

(b) Receive verbal prescriptions from a practitioner.

(c) Interpret and identify prescription contents.

(d) Engage in consultation with a practitioner regarding interpretation of the prescription and date in patient profile.

(e) Engage in professional communication with practitioners, nurses or other health professionals.

(f) Advise or consult with a patient, both as to the prescription and the patient profile record.

(2) When parenteral and bulk solutions of all sizes are prepared, regardless of the route of administration, the pharmacist must:

(a) Interpret and identify all incoming orders.

(b) Mix all extemporaneous compounding or be physically present and give direction to the registered pharmacy technician for reconstitution, for addition of additives, or for bulk compounding of the parenteral solution.

(c) Physically examine, certify to the accuracy of the final preparation, thereby assuming responsibility for the final preparation.

(d) Systemize all records and documentation of processing in such a manner that professional responsibility can be easily traced to a pharmacist.

(3) Only a pharmacist may make the final check of the completed prescription thereby assuming the complete responsibility for its preparation and accuracy.

(4) The pharmacist, as an integral aspect of dispensing, shall be directly and immediately available to the patient or the patient's agent for consultation and shall not dispense to a third party. No prescription shall be deemed to be properly dispensed unless the pharmacist is personally available.

(5) The pharmacist performing in this state any of the acts defined as "the practice of the profession of pharmacy" in Section 465.003(13), F.S., shall be actively licensed as a pharmacist in this state, regardless of whether the practice occurs in a permitted location (facility) or other location.

(6) The pharmacist may take a meal break, not to exceed 30 minutes in length, during which the pharmacy department of a permittee shall not be considered closed, under the following conditions:

(a) The pharmacist shall be considered present and on duty during any such meal break if a sign has been prominently posted in the pharmacy indicating the specific hours of the day during which meal breaks may be taken by the pharmacist and assuring patients that a pharmacist is available on the premises for consultation upon request during a meal break.

(b) The pharmacist shall be considered directly and immediately available to patients during such meal breaks if patients to whom medications are delivered during meal breaks are verbally informed that they may request that a pharmacist contact them at the pharmacist's earliest convenience after the meal break, and if a pharmacist is available on the premises during the meal break for consultation regarding emergency matters. Only prescriptions with the final certification by the pharmacist may be delivered.

(c) The activities of registered pharmacy technicians during such a meal break shall be considered to be under the direct and immediate personal supervision of a pharmacist if the pharmacist is available on the premises during the meal break to respond to questions by the technicians, and if at the end of the meal break the pharmacist certifies all prescriptions prepared by the registered pharmacy technicians during the meal break.

(7) The delegation of any duties, tasks or functions to registered pharmacy interns and registered pharmacy technicians must be performed subject to a continuing review and ultimate supervision of the pharmacist who instigated the specific task, so that a continuity of supervised activity is present between one pharmacist and one registered pharmacy technician. In every pharmacy, the pharmacist shall retain the professional and personal responsibility for any delegated act performed by registered pharmacy interns and registered pharmacy technicians in the licensee's employ or under the licensee's supervision.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(11)(b), (13), 465.014, 465.026 FS. History–New 11-18-07, Amended 1-1-10.

U.S. Department of Justice · Drug Enforcement Administration

Office of Diversion Control

Information and Legal Resources at your fingertips

Code of Federal Regulations

DISPOSAL OF CONTROLLED SUBSTANCES

Section 1307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant, he/she shall list the controlled substance or substances which he/she desires to dispose of on **DEA Form 41**, and submit three copies of that form to the Special Agent in Charge in his/her area; or

(2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known; and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By destruction in the presence of an agent of the Administration or other authorized person; or

(4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

(c) In the event that a registrant is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the registrant to dispose of such substances, in accordance with paragraph (b) of this section, without prior approval of the Administration in each instance, on the condition that the registrant keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals made by the registrant. In granting such authority, the Special Agent in Charge may place such conditions as he deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail of reports.

(d) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State.

[36 FR 7801, Apr. 24, 1971, as amended at 37 FR 15922, Aug. 5, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 47 FR 41785, Sept. 22, 1982; 62 FR 13967, Mar. 24, 1997]

Here's our authority