KENTUCKY BOARD OF PHARMACY
LTC WORKGROUP

Kentucky Board of Medical Licensure
310 Whittington Parkway, Ste 1B
Louisville KY 40222

March 21, 2018
9:00 a.m.

AGENDA

I. Call to Order

II. Selection of Members

III. Selection of Chair

IV. Discussion Items:

   a. 201 KAR 2:074 Pharmacy Services in Hospitals

   b. 201 KAR 2:370 Pharmacy Services in Long-term Care Facility [LTCF]

V. Next meeting: April 11, 2018

VI. Adjournment

Kentucky Board of Pharmacy

Long-term Care Workgroup

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MINUTES

President Cathy Hanna called the meeting to order at 9:11 a.m. President Hanna thanked everyone for their attendance and willingness to serve. Under direction of the Board, President Hanna named the following as members of the task force: Peter Cohron, Board Member; Ron Poole, Board Member; Paul Daniels, Pharmacy and Drug Inspector; Trent Blacketer, PCA; Paula York, DEPP; Jason Hurt, Bluegrass Drugstore; Scott Anderson, Pharmerica; Blake Wiseman, J & R Pharmacy and Darren Parks, Omnicare. President Hanna named Peter Cohron as chair and Ron Poole as co-chair.

Members present: Ron Poole, Paul Daniels, Trent Blacketer, Paula York and Scott Anderson. Members absent: Peter Cohron, Jason Hurt, Blake Wiseman and Darren Parks. Staff: Larry Hadley, Amanda Harding and Darla Sayre. Guests: Stephen Lariviere, Pharmerica.

Mr. Poole stated the main purpose of the task force was to propose changes to 201 KAR 2:370, Pharmacy Services in Long-term Care Facility [LTCF] with a focus on emergency drug kits and initial dose automation. Peter Cohron joined the meeting at 10:27 a.m.

Working from the draft of 201 KAR 2:370 from the March 14, 2018 Board meeting, proposed changes were made to Section 1 Definitions and Section 2 General Requirements. Proposed changes are attached. Mr. Daniels suggested inviting Dudley Ellis or Jackie Akin to the next meeting for further input.

The next meeting will be held at the Board office in Frankfort at 9:00 a.m. on April 11, 2018.

On motion by Mr. Daniels, seconded by Dr. Blacketer and passed unanimously, Dr. Cohron adjourned at 12:06 p.m.

201 KAR 2:370. Pharmacy services in long-term care facility (LTCF).

RELATES TO: KRS 315.010, 315.020, 315.030, 315.121

STATUTORY AUTHORITY: KRS 315.002, 315.005, 315.191

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the Kentucky Board of Pharmacy to establish requirements to regulate and control pharmacies. KRS 315.002 and 315.005 require standards of practice in all settings where drugs are handled and requires the board to ensure safety of all drug products provided to the citizens of Kentucky. This administrative regulation establishes requirements for pharmacy services in long-term care facilities.

Section 1. Definitions. (1) "Long-term care facility" or "LTCF" means:

(a) An intermediate care facility;

(b) A skilled nursing facility;

(c) An intermediate care facility for intellectually and developmentally disabled; or

(d) A personal care facility.

(e)A nursing home.

(2) “Emergency Drug”: are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients or residents because of delay resulting from obtaining such medications from such other source. (Louisiana Title 46 Part LIII 1709)

(3) ”Emergency Medication Kit” (EMK) means an onsite manual or automated mechanism for delivering emergency medications.

(4) "Immediate Supervision" is defined by KRS 315.010(12)

(5) "Supervision" is defined by KRS 315.010(27)

(6) "Pharmacist-in-charge" means a pharmacist mandated as in charge under KRS 315.020 and who meets the requirements of 201 KAR 2:205.

(7) Long Term Care Pharmacy Stock means:

(a) An Initial dose generated from a new or modified prescription order not to exceed supply until the next pharmacy business day.

(b) IV Fluids that are used for replenishment which contain no additive drugs or irrigation solutions,

(8) Automated Pharmacy System means: a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information.

(a) The EMK may be a separate mechanism or consist of a section of a larger automated mechanism used for purposes other than delivering emergency medications or initial dose therapy.

(b) If part of a larger automated mechanism, the section of the automated mechanism dedicated as an EMK shall be conspicuously labeled.

(c) If part of a larger automated mechanism, the section of the automated mechanism dedicated as an EMK shall be supplied and have access in the same manner as a separate mechanism as defined below under Section 2, (3) Emergency Drugs.

(3)[~~(11)~~].

(4)

(5) (7) [~~(25)~~].

Section 2. General Requirements. (1) The pharmacist-in-charge of the dispensing pharmacy shall be responsible for policy and procedures governing the procurement, distribution, transportation and control of all drugs that are provided to a long-term care facility.

(a) Policies and procedures shall be reviewed at least every 12 months.

(2) Dispensing.

(a) Medications shall be dispensed only on the medical order (for a non-controlled substance) or a prescription drug order of a licensed practitioner.

(b) A medical order (for a non-controlled substance) shall be considered a prescription drug order if it is entered on the medical record of a patient at an LTCF and if the medical order contains the:

1. Name of patient;

2. Date of issuance;

3. Name, strength, and dosage form of drug prescribed;

4. Directions for use;

5. Quantity of length of therapy as defined in policy and procedures or as defined by medical order; and

6. Practitioner's name.

(c) The pharmacist may dispense medications by the unit dose or multi-dose distribution system if feasible. If the unit dose distribution system is not utilized, adequate safeguards shall be in place to protect patients.

3. Pharmacy Services.

(a) The dispensing pharmacy and personnel shall be licensed and/or registered as required by law.

(b) The dispensing pharmacy shall carry an inventory appropriate and consistent with the usual and customary inventory for the LTCF population, making such additions as needed to fill prescription orders.

(c) The services of a pharmacist shall be available to the LTCF 24 hours a day. (d)

(e) The dispensing pharmacy and LTCF shall devise appropriate means and devices for the proper, safe and secure storage of patient medications.

(f)

(g)

(i)) Labeling and packaging.

(a) Each licensee shall comply with U.S.P. Standards established pursuant to federal law and all state and federal laws and regulations regarding labeling and packaging.

(b) Labeling and packaging of medications used for outpatients shall meet the requirements of state and federal law.

(j)) Stop orders. There shall be established written stop order policies or other methods of assuring that drug orders are not continued inappropriately in accordance with the status of the patient.

3) Emergency Drugs.

(a) The pharmacist-in-charge of the dispensing pharmacy shall establish policy and procedures for supplying emergency drugs through the use of Emergency Medication Kits (EMK).

(b) For expediency and efficiency, emergency drugs in an EMK shall be limited in number to include controlled substances stocked pursuant to 902 KAR 55:070 that shall not exceed six (6) individual doses of six (6) different controlled substances and shall not exceed six (6) individual doses of thirty (30) different non-controlled substances, and whose prompt use and immediate availability are generally regarded as essential in the proper treatment of sudden and unforeseen patient emergencies.

(c) The pharmacist-in-charge may request from the board a waiver to increase the number of non-controlled substance items to be included in the emergency kit based upon evidence of use.

(d) Emergency drug stock shall be inspected by pharmacy personnel on at least a monthly basis and documentation maintained to determine if contents have become outdated and if the stocks are being maintained at adequate levels.

(e) Emergency drug stock shall not be stocked in a personal care facility.

(f) Emergency drugs shall be supplied in unit dose packaging when feasible.

(4) Long Term Care Facility Pharmacy Stock. (LTCF Pharmacy Stock)

Initial Dose:

(a) LTCF Pharmacy stock of drugs in an LTCF shall not exceed fifteen (15) individual doses each of 150 non-controlled substances.

(b) LTCF Pharmacy stock of drugs in a personal care facility shall not exceed five (5) individual doses each of thirty (30) non-controlled substances.

(c) The pharmacist-in-charge may request from the board a waiver to increase the number of non-controlled substance items to be placed in LTCF pharmacy stock based upon evidence of use.

(d) The pharmacist-in-charge shall be responsible for authenticating the need for LTCF pharmacy stock.

(e) A pharmacist shall review the prescription drug or medical order before the release of medication.

(f) LTCF Pharmacy stock shall be inspected by pharmacy personnel on at least a monthly basis and documentation maintained to determine if contents have become outdated and if stocks are being maintained at adequate levels.

(g) LTCF Pharmacy stock shall be used for a patient's initial dose, for no more than the next business day.

(h) Except for LTCF pharmacy stock of intravenous fluids with no additive drugs or irrigation solutions, the LTCF pharmacy stock shall be replenished by:

1. A tamper-resistant secure container delivered for the pharmacy or

2. A tamper-resistant secure container for the stocking of an automated pharmacy system; or

3. A pharmacist or a pharmacist intern, or a certified pharmacy technician, who shall be under the immediate supervision of a pharmacist on-site, unless there is a pharmacy on-site, then the LTCF pharmacy stock shall be replenished by a pharmacist or a pharmacist intern or a certified pharmacy technician under the supervision of a pharmacist on-site.

Section 3. Automated Pharmacy System in a LTCF. (1) The pharmacist-in-charge of a pharmacy utilizing an automated pharmacy system in a LTCF shall be responsible for the following:

(a) An initial validation of the automated pharmacy system accuracy prior to use for distribution to patients assuring that the automated pharmacy system:

1. Is in good order and accurately dispenses the correct strength, dosage form, and quantity of drug prescribed; and

2. Complies with the recordkeeping and security safeguards pursuant to Section 4 of this administrative regulation.

(b) Assuring that non-controlled substance prescription drug orders and medical orders are reviewed and approved by a pharmacist prior to access, except those emergency stocked drugs; and

(c) Assuring that controlled substance prescription drug orders are reviewed and approved by a pharmacist prior to accessing the controlled substance emergency stock.

(d) Implementing an ongoing quality assurance program that monitors performance of the automated system, which is evidenced by written policies and procedures.

(e) Assigning, discontinuing or changing personnel access to the system.

(f) Assuring that access to medications complies with state and federal laws.

(g) Assuring that the automated pharmacy system is stocked accurately and is checked monthly by a pharmacist in accordance with established written policies and procedures, including the following:

1. Accuracy;

2. Integrity; and

3. Expiration date.

Section 4. Standards. (1) A permit holder shall utilize an automated pharmacy system shall complies with the following provisions:

(a) A pharmacy shall maintain on-site the following documentation related to an automated pharmacy system:

1. Name and address of the pharmacy or long term care facility where the system is being used;

2. The automated pharmacy system manufacturer’s name, model, and serial number;

3. An operations manual;

4. Description of how the system is used;

5. Written quality assurance procedures to determine continued appropriate use of the system; and

6. Written policies and procedures for system operation, safety, security, accuracy, access and malfunction.

(2) All written policies and procedures shall be maintained in the pharmacy responsible for the automated pharmacy system.

(3) An automated pharmacy system shall maintain adequate security systems and procedures, evidenced by written policies and procedures, that prevent unauthorized access to patient records and maintain patient confidentiality.

(4) Records and data kept by the automated pharmacy system shall meet the following requirements:

(a) All events involving the contents of the automated pharmacy system shall be recorded electronically; and

(b) Records shall be maintained by the pharmacy, be available to the Board, and shall include the following:

1. The time and location of the system accessed;

2. Identification of the individual accessing the system;

3. Name of the patient for whom the drug was ordered;

4. Name, strength, dosage form and quantity of drug accessed;

5. Type of transaction;

6. The prescription number; and

7. The name of the prescriber.

(c) All events involving user database modifications shall be recorded electronically and maintained.

(d) A 24-hour emergency call center shall be available for any automated pharmacy system malfunction.

(5) The stocking of all medications in an automated pharmacy system shall be performed by a:

(a) pharmacist;

(b) pharmacist intern; or

(c) certified pharmacy technician who shall be under the general supervision of a pharmacist on-site.

(6) If an automated pharmacy system utilizes tamper resistant barcoding technology, microchip, or other equivalent tamper-resistant technologies, the stocking of an automated pharmacy system, after training by the pharmacist-in-charge, may be performed by a:

(a) pharmacist;

(b) pharmacist intern;

(c) certified pharmacy technician; or

(7) A record of medications stocked into an automated pharmacy system shall be maintained for five (5) years and shall include identification of the person stocking and pharmacist checking for accuracy.

(8) All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws.

(9) The pharmacy shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to a quarantined area, including wasted medications, in accordance with federal and state laws.

(10) The pharmacy shall provide a mechanism for securing and accounting for medications returned to the system, in accordance with federal and state laws.