KENTUCKY BOARD OF PHARMACY
LTC WORKGROUP

125 Holmes Street
Frankfort KY 40601

April 11, 2018
9:00 a.m.

AGENDA

I. Call to Order

II. Minutes – March 21, 2018

III. Discussion Items:

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

IV. Next meeting: April 25, 2018

V. Adjournment

Kentucky Board of Pharmacy

Long-term Care Workgroup

Kentucky Board of Pharmacy

April 11, 2018

MINUTES

Peter P. Cohron, Chair called the meeting to order at 9:03 a.m.

Members present: Ron Poole, Blake Wiseman, Jason Hurt and Scott Anderson. Members absent: Paula York, Paul Daniels, Trent Blacketer and Darren Parks. Staff: Larry Hadley, Amanda Harding, Katie Busroe, Jessica Williams, Cheryl Lalonde and Darla Sayre. Guests: Dudley Ellis, OIG; Tammy Schlensker, PCA Pharmacy; Scott Dilley, Pharmerica; Stephen Lariviere, Pharmerica; JD Majors, student; Leslie Kenney, KSHP and David Gresham.

On motion by Dr. Anderson, seconded by Mr. Poole and passed unanimously, the minutes from the March 21, 2018 were approved. Paula York joined the meeting at 9:17 a.m.

Working from the draft of 201 KAR 2:370 from the March 21, 2018 Board meeting, proposed changes were made to Section 1 Definitions and Section 2 General Requirements. Proposed changes are attached.

The next meeting will be held at the Board office in Frankfort at 9:00 a.m. on April 25, 2018.

On motion by Mr. Poole, seconded by Dr. Anderson and passed unanimously, Dr. Cohron adjourned at 12:45 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.

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

(4) Long Term Care Pharmacy Stock means an Initial dose generated from a new or modified prescription order not to exceed supply until the next pharmacy business day or IV Fluids that are used for replenishment, which contain no additive drugs, or irrigation solutions.

(5) Automated Dispensing System (ADS) 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.

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

(a) Policies and procedures shall be reviewed a minimum of once 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) Labeling and packaging.

(come back)

(3) The services of a pharmacist shall be readily available at all times.

(4) Emergency Drugs.

(a) 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.

(b) Emergency drugs in an EMK shall not exceed six (6) individual doses of thirty (30) different non-controlled substances.

(c) The pharmacist-in-charge may request a waiver from the board to increase the number of non-controlled substances in the EMK based on evidence of use.

(d) EMK shall be assessed for outdated, damaged or adulterated drugs, and stock adequacy by:

1. A pharmacist or any lawful person as stated in 902 KAR 55:070 on a monthly basis for controlled substances.
2. A pharmacist, or a PIC authorized pharmacist intern or certified pharmacy technician on a monthly basis for non-controlled substances.

(e) EMK drugs shall not be stocked in a personal care facility.

(f) EMK drugs shall be supplied in unit dose packaging unless precluded by manufacturer packaging.

(g) An EMK shall be conspicuously labeled.

(h) An EMK drug shall be accessed only upon a lawful prescription order.

(i) A prescription order shall be reviewed by a pharmacist within one pharmacy business day.

(5) 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; or

(c) certified pharmacy technician.

(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.