68-7-15. Prepackaging or repackaging of oral drugs. All prepackaging or repackaging of oral drugs, whether in a unit-dose container or multiple-dose container, shall meet the requirements of this regulation.

(a) Packaging in advance of immediate need shall be done by a pharmacist or under the pharmacist's direct supervision.

(b) Packaging shall be limited to the drugs dispensed from or supplied by the ~~premises~~ pharmacy or in accordance with a shared services agreement.

(c) All containers used for packaging and the storage conditions shall be maintained according to the manufacturer's recommendations to preserve the stability of the drug. The expiration date shall be the manufacturer's expiration date, the expiration date for the type of packaging material used, or not more than 12 months from the date of packaging, whichever is earlier.

(d) An electronic or a written record shall be established for lot numbers for recall purposes.

(e) If an area apart or separated from the prescription drug area is used for prepackaging or repackaging, the area shall be enclosed and locked when a pharmacist is not in attendance in that area.

(f) In lieu of separately dispensing a drug and an ingestible event marker approved by the food and drug administration to monitor whether a patient is taking the drug as prescribed, any pharmacist may use an ingestible event medication adherence package pursuant to a valid prescription order or after obtaining the consent of the practitioner, caregiver, or patient.

APPROVED
APR 17 2019
DIVISION OF THE BUDGET

APPROVED
APR 18 2019
DEPT. OF ADMINISTRATION

APPROVED
JUL 26 2019
ATTORNEY GENERAL

(g) For purposes of this regulation, "ingestible event medication adherence package" shall mean an ingestible unit-dose package designed to ensure medication adherence that contains drugs from a manufacturer's original container and an ingestible event marker, as defined by 21 C.F.R. 880.6305, ~~in effect on~~ dated April 1, 2016 and hereby adopted by reference.

(h) In addition to meeting the requirements of this regulation, all repackaging of sterile preparations shall meet the requirements of K.A.R. 68-13-4. (Authorized by K.S.A. 65-1630; implementing ~~K.S.A. 2016 Supp. 65-1626, as amended by L. 2017, ch. 34, sec. 1, K.S.A. 2016 Supp. 65-1626a, and~~ K.S.A. 65-1634; effective May 1, 1978; amended Dec. 15, 2017; amended P-_____.)

APPROVED
JUN 25 2019
DIVISION OF THE BUDGET

APPROVED
JUN 27 2019
DEPT. OF ADMINISTRATION

APPROVED
JUL 26 2019
ATTORNEY GENERAL

68-19-1. Minimum program requirements. Each pharmacy's continuous quality improvement program shall meet the following minimum requirements:

(a) Meet at least once each quarter of each calendar year;

(b) have the pharmacy's ~~pharmacist in charge~~ pharmacist-in-charge in attendance at each meeting; and

(c) perform the following during each meeting:

(1) Review all incident reports generated for each reportable event associated with that pharmacy since the last quarterly meeting;

(2) for each incident report reviewed, establish the steps taken or to be taken to prevent a recurrence of the incident; ~~and~~

(3) review each board newsletter published since the last quarterly meeting; and

(4) create a report of the meeting, including at least the following information:

(A) A list of the persons in attendance;

(B) a list of the incident reports and newsletters reviewed; and

(C) a description of the steps taken or to be taken to prevent recurrence of each incident reviewed. (Authorized by and implementing ~~L. 2008, ch. 104, §16~~ K.S.A. 65-1695; effective April 10, 2009; amended P-_____.)

APPROVED
APR 17 2019
DIVISION OF THE BUDGET

APPROVED
APR 18 2019
DEPT. OF ADMINISTRATION

APPROVED
JUL 26 2019
ATTORNEY GENERAL

68-21-6. Reciprocal agreements with other states or government entities to share information. (a) Reciprocal agreements with one or more ~~states in~~ of the following entities within the United States may be entered into by the board to share program ~~information~~ data if the ~~other state's~~ entity's prescription monitoring program is compatible with the program. ~~If the board elects to evaluate the prescription monitoring program of another state, priority shall be given to a state that is contiguous to Kansas.~~:

(1) A state, commonwealth, district, or territory;

(2) a military or veteran health system;

(3) an Indian health system or service; or

(4) a city, county, municipality, or township.

(b) In determining the compatibility of the ~~other state's~~ entity's prescription monitoring program, the following may be considered by the board:

(1) The safeguards for privacy of patient records and the ~~other state's~~ entity's success in protecting patient privacy;

(2) the persons authorized ~~in~~ by the ~~other state~~ entity to view the data collected by the program;

(3) the schedules of controlled substances monitored ~~in~~ by the ~~other state~~ entity;

(4) the data required by the ~~other state~~ entity to be submitted on each prescription; and

(5) the costs and benefits to the board of mutually sharing ~~information~~ data with the ~~other state~~ entity.

(c) ~~Each~~ Any reciprocal agreement ~~shall~~ may be reviewed annually by the board to determine its continued compatibility with the program. (Authorized by K.S.A. ~~2009 Supp.~~ 65-

APPROVED
JUL 09 2019
DIVISION OF THE BUDGET

APPROVED
JUL 11 2019
DEPT. OF ADMINISTRATION

APPROVED
JUL 26 2019
ATTORNEY GENERAL

1692; implementing K.A.S.A. ~~2009 Supp.~~ 65-1685; effective October 15, 2010; amended P-_____

_____.)

APPROVED
APR 0 8 2019
DIVISION OF THE BUDGET

APPROVED
APR 1 1 2019
DEPT. OF ADMINISTRATION

APPROVED
JUL 2 6 2019
ATTORNEY GENERAL