Proposed

State of Kansas
Board of Pharmacy
Notice of Hearing on Proposed Administrative Regulations

A public hearing will be conducted on Thursday, April 21, 2016 at 8:30 a.m. in room 2040 of the University of Kansas School of Pharmacy, 2010 Becker Drive, Lawrence, to review and consider the adoption of proposed permanent regulation K.A.R. 68-7-22 for the administration of the Kansas Pharmacy Practice Act, K.S.A. 65-1625 *et seq*.

This 60-day notice of the public hearing shall constitute a public comment period for submitting written public comments on the proposed regulations.

All interested parties may submit written comments prior to the public hearing as follows: by e-mail at pharmacy.intern@pharmacy.ks.gov or by mail to Alexandra Blasi, Executive Secretary, 800 S.W. Jackson, Suite 1414, Topeka, Kansas 66612-1244. The public shall be given a reasonable opportunity to present their views orally on this regulation during the hearing. In order to give all parties an opportunity to present their views, it may be necessary to request that each participant limit any oral presentation to five minutes. All public comments submitted during this period will be made part of the regulation's written record.

Any individual with a disability may request accommodation in order to participate in the public hearing and may request the regulations and economic impact statements in an accessible format. Requests for accommodation should be made at least ten working days in advance of the hearing to Alexandra Blasi, Executive Secretary, 800 S.W. Jackson, Suite 1414, Topeka, Kansas 66612-1244 or by phone at (785) 296-4056. Handicapped parking is available on the west side of the School of Pharmacy building and throughout the west campus area. Curbs at all entrances are accessible to individuals with disabilities.

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Copies of the proposed regulation and economic impact statement may be accessed at http://www.pharmacy.ks.gov/.

K.A.R. 68-7-22. Collaborative Practice. This regulation provides definitions and standards for collaborative drug therapy management (CDTM) between pharmacists and physicians.

II. Federal Requirements. Though the Board makes every attempt to align Kansas rules and regulations with federal standards and practices, there are no federal requirements implicated by this regulation.

III. Anticipated Economic Impact on the Board. The Board anticipates that any economic impact will be related to general licensing record updates and document processing and storage. The regulation requires pharmacists update the Board with any new or updated collaborative practice agreements within five business days and report the status of any agreement biennially with their license renewal. Costs to the Board might appear in the form of staff time and are negligible in the scheme of current licensing staff functions.

IV. Anticipated Financial Impact Upon Other Governmental Agencies or Units. The Board does not anticipate that this regulation will have any financial impact upon other governmental agencies.

V. Anticipated Financial Impact Upon Small Employers and Private Citizens and Businesses. Pharmacists, physicians, and their respective private businesses engaged in CDTM may experience an economic impact. Additional time to coordinate the agreement as well as the CDTM practice may take additional time or resources, but the amount of any monetary impact is unknown. No other impact on private citizens or businesses is anticipated.

VI. Anticipated Economic Impact Upon Other Entities or Persons. There would be no negative impact on other entities or persons. There would be a positive impact on patient safety and welfare.

VII. Less costly or intrusive Methods that Were Considered, but Rejected, and the Reason for Rejection. The Board is not aware of any less costly or less intrusive methods to achieve the stated purpose and thus none were considered.

Alexandra Blasi
Executive Secretary

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68-7-22. Collaborative practice. (a) Each of the following terms, as used in this regulation, shall have the meaning specified in this subsection:

(1) "Collaborative drug therapy management" and "CDTM" mean a practice of pharmacy in which a pharmacist performs certain pharmaceutical-related patient care functions for a specific patient, and the functions have been delegated to the pharmacist by a physician through a collaborative practice agreement.

(2) "Collaborative practice agreement" and "CPA" mean a signed agreement or protocol voluntarily entered into between one or more pharmacists and one or more physicians that provides for collaborative drug therapy management.

(3) "Pharmacist" means a person licensed, without limitation or restriction, to practice pharmacy in Kansas.

(4) "Physician" means a person who is licensed to practice medicine and surgery in Kansas and who is a signing party to the pharmacist's CPA or update.

(b) Any pharmacist may practice collaborative drug therapy management only pursuant to a collaborative practice agreement or update established and maintained in accordance with this regulation. Although a physician shall remain ultimately responsible for the care of the patient, each pharmacist who engages in CDTM shall be responsible for all aspects of the CDTM performed by the pharmacist.

A pharmacist shall not become a party to a CPA or update that authorizes the pharmacist to engage in any CDTM function that is not appropriate to the training and experience of the pharmacist or physician, or both. A pharmacist shall not provide CDTM to a patient if the pharmacist knows that the patient is not being treated by a physician who has signed the pharmacist's current CPA.

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(c)(1) Each CPA and update shall be dated and signed by each physician and each pharmacist. Each CPA and update shall include the following:

(A) A statement of the general methods, procedures, and decision criteria that the pharmacist is to follow in performing CDTM;

(B) a statement of the procedures that the pharmacist is to follow to document the CDTM decisions made by the pharmacist;

(C) a statement of the procedures that the pharmacist is to follow to communicate to the physician either of the following:

(i) Each change in a patient's condition identified by the pharmacist; or

(ii) each CDTM decision made by the pharmacist;

(D) a statement identifying the situations in which the pharmacist is required to initiate contact with the physician; and

(E) a statement of the procedures to be followed by the pharmacist if an urgent situation involving a patient's health occurs, including identification of an alternative health care provider that the pharmacist should contact if the pharmacist cannot reach a physician.

(2) A CPA shall not authorize a pharmacist to administer influenza vaccine except pursuant to K.S.A. 65-1635a, and amendments thereto.

(d) Each CPA and update shall be reviewed and updated at least every two years. A signing pharmacist shall deliver a digital or paper copy of each CPA and update to the board within five business days after the CPA or update has been signed by all parties.

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(e) Within 48 hours of making any drug or drug therapy change to a patient's treatment, the pharmacist shall initiate contact with a physician, identifying the change.

(f) This regulation shall not be interpreted to impede, restrict, inhibit, or impair either of the following:

(1) Current hospital or medical care facility procedures established by the hospital or medical care facility pharmacy and either the therapeutics committee or the medical staff executive committee; or

(2) the provision of medication therapy management as defined by the centers for medicare and medicaid services under the medicare part D prescription drug benefit.

(g) As part of each pharmacist's application to renew that individual's license, the pharmacist shall advise the board if the pharmacist has entered into a CPA. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2015 Supp. 65-1626a; effective P-_____.)

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KANSAS STATE BOARD OF PHARMACY
ECONOMIC IMPACT STATEMENT

I. Summary of Proposed Regulations, Including Purpose. The Kansas State Board of Pharmacy (Board) is proposing new regulation K.A.R. 68-7-22 for the administration of the Kansas Pharmacy Practice Act, K.S.A. 65-1625 *et seq*.

It is the mission of the Board to ensure that all persons practicing pharmacy are properly licensed and registered, ensure compliance with Kansas statutes regarding proper compounding and dispensing of prescription drugs, maintenance of professional practice standards, and proper manufacture, distribution, and sale of prescription and nonprescription drugs, including controlled substances and poisons. In order to attain these goals, the Board is adding this regulation to comply with professional, healthcare, and safety norms.

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II. Federal Requirements. Though the Board makes every attempt to align Kansas rules and regulations with federal standards and practices, there are no federal requirements implicated by this regulation.

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