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Kansas State Board of Pharmacy

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Investigations by the State Board of Healing Arts: Access to Pharmacy Records

By Mark W. Stafford, BHA General Counsel

Questions abound regarding the professional duty to disclose patient records in light of the rules adopted under the Health Insurance Portability and Accountability Act (HIPAA), which protects patient privacy. In many situations the patient must give consent or authorization, or the patient must have an opportunity to agree or object to disclosure. But the HIPAA rule allows protected health information to be disclosed to a health oversight agency without a patient's knowledge or approval, at least if the oversight agency is acting within its authority in seeking the information.

The Board of Healing Arts is a health oversight agency within the meaning of the federal rule, and, thus, HIPAA does not interfere with the Board's authority to obtain patient information in the course of an investigation. The practitioner is only obligated to verify that the request for information or records is indeed authentic.

The statutory authority for investigations by the Board of Healing Arts appears at K.S.A. 65-2839a. That section states in relevant part:

> In connection with any investigation by the board, the board or its duly authorized agents or employees shall at all reasonable times have access to, for the purpose of examination, and the right to copy any document, report, record or other evidence . . . maintained by and in possession of any clinic, office of a practitioner of the healing arts, laboratory, pharmacy, medical care facility or other public or private agency if such document, report, record or evidence relates to medical competence, unprofessional conduct or the mental or physical ability of a licensee safely to practice the healing arts.

A board investigator might contact the pharmacist in person, by telephone, or with a letter or subpoena. An investigator's authority may be verified by presentation of a badge or identification card. Staff at the Board office can verify the investigator's employment but will not confirm the existence or details of any investigation. Official correspondence from the Board is prepared on letterhead. Subpoenas bear the signature of the Board's executive director or his designee.

Next Board of Pharmacy Meeting

The next Kansas State Board of Pharmacy meeting is scheduled for January 8 and 9, 2002. Location to be announced. Pharmacists who wish to discuss any issues are encouraged to notify Susan Linn so these issues can be put on the agenda. All meetings are open to the public. Pharmacists may receive continuing education credit for attending Board meetings.

Controlled Substance Destruction at Long-term Care Facilities

Inspectors continue to find controlled substances that are returned to community retail pharmacies that were previously dispensed to patients residing in long-term care facilities. Once a controlled substance is dispensed to any patient, it may **not** be returned to the dispensing pharmacy. Long-term care facilities, including patients residing there, are not Drug Enforcement Administration (DEA)-registered distributors. Therefore, after discontinuation, controlled substances must be destroyed by the consultant pharmacist at the long-term care facility. This is pursuant to KAR 68-20-10(A), which states: "Every person who . . . distributes . . . any controlled substances, within this state, or proposes to engage in the . . . distribution . . . of any controlled substance in this state shall obtain annually a registration . . . " and 21 CFR 1301.11(a), which states: "Every person who…distributes . . . or proposes to engage in the . . . distribution . . . of any controlled substance shall obtain a registration. . . ."

Repackaging Medications Originally Repackaged at Another Pharmacy

Inspectors are also finding medications repackaged in pharmacies that were previously repackaged for a patient at another pharmacy. This usually occurs when a patient, before admission into a long-term care facility, receives medication repackaged into a multi-dose container from a pharmacy that offers no other repackaging system. Once a patient is admitted into a long-term care facility, requests are sometimes made to have this medication repackaged into the unit dose system (ie, bubble package) by another pharmacy that offers such a repackaging system. Medications can only be repackaged and labeled by the pharmacy that originally repackaged the medication for that patient.

This is pursuant to KAR 68-7-15(b), which states: "This packaging shall be limited to drugs to be dispensed from the premises" and KAR 68-7-14(b), which states: "A pharmacy shall be permitted to label or relabel only those drugs . . . originally dispensed from the providing pharmacy."

Committee on Impaired Pharmacy Practice

The Committee on Impaired Pharmacy Practice (CIPP) is a voluntary program established by the Kansas Pharmacists Association (KPhA) for the purpose of assisting any pharmacist or pharmacy intern whose health and/or professional effectiveness has been or is likely to be impaired by the disease of chemical dependency and/or other physical or mental disabilities. Services provided by CIPP are intended to be in the best interest of the pharmacist/intern and the public. Through CIPP, troubled/impaired pharmacists and pharmacy interns are encour-

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aged to seek treatment and rehabilitation.

Under Kansas law, anyone with knowledge of a practice that is or could be below the standard of care must immediately notify the appropriate authorities. Since CIPP acts as an agent of the Board of Pharmacy, these reports or self-referrals can be made directly to CIPP.

CIPP assures all participants in its program the utmost confidentiality. No one outside of CIPP, not even the Board of Pharmacy, will be notified of the referred pharmacist's condition unless he or she fails to cooperate with the CIPP program.

If you have a problem, or you are concerned about someone who does, remember **you are not alone. CIPP can help**. Do not wait until a problem threatens someone's career and pharmacy license. Call and see if CIPP can help. For more information on the services available through CIPP, call 785/228-2327 and ask to speak with the CIPP representative. **All calls to CIPP are completely confidential**.

Pharmacy Inspectors

Applications are being accepted for an inspector opening in western Kansas. If you are interested in the position, please send your resume to Susan Linn at the Topeka office. Job description and salary can be found at www.da.state.ks.us/ps/aaa/recruitment. Jim Kinderknecht is the inspector in Topeka, Lawrence, and northeast Kansas. Chris Gassen now covers Wichita and southeast Kansas. Questions concerning western Kansas should be directed to the Board office.

Changes to Schedule II Prescriptions

The Drug Enforcement Administration (DEA) allows for certain changes to Schedule II prescriptions. The majority of changes can be made only after the pharmacist contacts the prescribing practitioner. After consulting with the prescriber, the pharmacist is permitted to change the **patient's address, drug strength, drug quantity, and directions for use**. The pharmacist may also add the dosage form to the prescription order after verification with the prescriber. **The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution as permitted by Kansas law), or the prescriber's signature. These types of changes challenge the necessity of the original prescription and would require a new prescription from the prescriber**. This allows for corrections to be handled by a phone call; however, the pharmacist should always document the time and date that the prescriber was contacted and ask the prescriber to document the change in the patient's chart. Please contact your inspector or the office if you have further questions regarding this policy.

FDA Issues Warning Against Web Sites Selling Unapproved Foreign Ciprofloxacin

The Food and Drug Administration (FDA) issued warnings to 11 Internet vendors abroad who are offering ciprofloxacin, the generic name for Cipro®, to American consumers. The FDA is unable to determine whether these products were made in accordance with US specifications and, therefore, their sale and distribution in the US may be illegal. The FDA is warning US citizens that foreign drugs promoted on the Internet may not be approved for marketing in this country and may not be legally imported. The agency is advising the US Customs Service that shipments from these vendors may be detained and refused entry.

Physicians Writing Prescriptions for Themselves and Family Members

In Kansas, there is no prohibition against physicians writing prescriptions for themselves or family members. Both for controlled and noncontrolled drugs, as long as the physician has an "Active" or "Exempt" license. They should, however, keep an adequate record (K.A.R. 100-24-1). Those with an "Inactive" license cannot engage in any practice, including writing prescriptions for themselves or family members.

Disciplinary Actions

Although every effort is made to ensure that the disciplinary action information is correct, you should check with the Board of Pharmacy (785/296-4056) to verify the accuracy of the listing before making any decision based on this information. These disciplinary actions become a permanent part of a pharmacist's file.

John Wagonner, Bonner Springs, Kan, was disciplined by the Board entering an order suspending his license, but provided the suspension would not be effective if no further violations of the Kansas pharmacy laws occurred during a 12-month probation period, and assessing an administrative fee of $5,000.

Joan Wagonner, Bonner Springs, Kan, was disciplined by the Board entering an order assessing an administration fee of $1,000.

The *Kansas State Board of Pharmacy News* is published by the Kansas State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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