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Kansas State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Board Meeting Dates

The next Kansas State Board of Pharmacy meeting has been scheduled for September 21-22, 2004, at Kansas University School of Pharmacy, Malott Hall, Lawrence, KS. A meeting will be held on November 30 and December 1, 2004, at the Clubhouse Inn & Suites, 924 SW Henderson, Topeka, KS. We encourage you to join us. The public is welcome and pharmacists can get continuing education credit for attending.

State Pharmacy Board Orders/ Disciplinary Matters

Jeffrey E. Hodgson, RPh; Lawrence – was disciplined by the Board for misappropriating controlled substances from his employer for personal use in violation of K.S.A. 65-1627 (a)(4). He was also cited for failure to fill a prescription in strict conformity by dispensing the incorrect drug. This was a violation of K.S.A. 65-1637(a). Mr Hodgson was placed on a 60-day suspension and placed on a five-year probationary period requiring compliance with the impaired provider program.

Ronald A. Terry, DPh; Ponca City, Oklahoma – was disciplined by the Board for having his license restricted in the state of Oklahoma for billing irregularities in violation of K.S.A. 65-1627(a)(12). Mr Terry was placed on probation until 2008 and was ordered to attend a one-day law seminar.

Electronic Prescriptions Using an 'E-Signature'

The Board reviewed the use of electronic prescriptions using an "e-signature" at the June Board meeting. "E-signatures" are permitted if the computer system has security features built in that assure that the electronic signature belongs to the appropriate physician. The prescription should be transmitted directly from the computer to the facsimile machine of the receiving pharmacy for use in prescription Schedules III through V and for non-controlled medications. It cannot be used for a Schedule II prescription. All other requirements of K.A.R. 68-2-22 shall be met. If the prescription is sent via facsimile to a receiving fax machine the transaction is treated as a phone-in prescription; therefore, no signature is required for a faxed document. This is because there are safety measures in place that identify the time, date, and location of the sending facsimile. If a Schedule II is faxed to a retail setting it must be followed up with a signed hard copy before the drug is dispensed. (Exceptions: orders for compounded parenteral used for direct administration, long-term nursing care patients, or home hospice patients.) A prescription that is handed to the patient shall always be countersigned. This applies to all types of prescriptions whether controlled or not. There are no assurances in place that a prescription is legitimate if an unsigned or printed copy is in the hands of the patient.

Prescription Drug Monitoring Program

The United States Department of Justice recently approved funding to the Board of Pharmacy in the amount of $50,000 for the purpose of creating a Prescription Drug Monitoring Program.

Prescription drug monitoring programs are systems in which prescription data for controlled substances are submitted to a central database administered by an authorized state agency. These programs help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level where no other automated information collection system exists.

States with prescription drug monitoring programs have the ability to collect and analyze prescription data much more efficiently than states without such programs, where the collection of prescription information requires the manual review of pharmacy files – a time-consuming and invasive process. The increased efficiency of prescription drug monitoring programs allows for early detection of trends in abuse and possible sources of diversion. Analyzing the data collected also allows for the identification of outmoded prescribing practices, which may result in the development of new educational programs for medical professionals.

The purpose of the Prescription Drug Monitoring Program is to enhance the capacity of regulatory and law enforcement agencies to collect and analyze controlled prescription data. This

Continued on page 4

FDA Issues Final Rule Prohibiting the Sale of Ephedra Supplements

On February 6, 2004, Food and Drug Administration (FDA) announced the issuance of a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra).

At the end of last year, FDA issued letters to manufacturers who market ephedra-containing supplements, informing them of the upcoming rule. FDA also urged consumers to stop using ephedra-containing dietary supplements immediately. Studies show that ephedra-containing dietary supplement have adverse effects on the cardiovascular and central nervous systems including high blood pressure, heart palpitations, tachycardia, stroke, and seizures. FDA has linked at least 155 deaths with the use of dietary supplements containing ephedra.

For more information, including a Web link to the final rule, visit the following Web site: www.fda.gov/bbs/topics/NEWS/2004/NEW01021.html.

The final rule became enforceable on April 12, 2004. California, Illinois, and New York were the first states to ban the sale of ephedra.

DEA Issues Clarification of the Exemption of Sales of Pseudoephedrine and Phenylpropanolamine

In attempts to clarify existing laws and regulations regarding the over-the-counter (OTC) sale of pseudoephedrine and phenylpropanolamine, Drug Enforcement Administration (DEA) issued an interpretive rule this past January. This interpretive rule does not change any of DEA's regulations, nor will it have an impact on individual retail customers of such products who have been purchasing them from retailers that have been properly following DEA's regulations.

Specifically, the interpretive rule emphasizes that sales transactions of ordinary OTC pseudoephedrine and phenylpropanolamine products ("safe harbor" products) are exempt from being regulated transactions as long as each transaction is below the 9-gram threshold to an individual for legitimate medical use. Apparently, some retail distributors have misinterpreted current DEA regulations and believe that they may sell as much "safe harbor" pseudoephedrine and phenylpropanolamine to any person for any purpose as often as that person wishes to make a purchase. The DEA interpretative rule clearly dispels that belief.

Currently, retail distributors of ordinary OTC pseudoephedrine and phenylpropanolamine products are exempt from registering with DEA as a distributor of List I chemicals and complying with the record keeping and other regulatory requirements as long as individual transactions for legitimate personal medical use remain below the 9-gram threshold (in packages of not more than 3 grams).

To obtain more information, please visit DEA's Diversion Control Program Web site, www.DEAdiversion.usdoj.gov.

Note: Although most products containing phenylpropanolamine were discontinued pursuant to the action of FDA in November 2000, there remains some legitimate veterinary uses for phenylpropanolamine that will ensure some level of its continued production and availability. Therefore, these products are subject to the existing DEA regulations and this interpretive rule.

DEA Introduces Pharmacy Theft Prevention Program

In response to increasing theft and armed robberies against pharmacies, DEA's Office of Diversion Control has introduced the Pharmacy Theft Prevention Program. The program is based on a previous initiative that was developed during the late 1970s and early 1980s when there was a similar unprecedented spike in the occurrence of thefts and robberies against pharmacies.

The intent of the program is to provide education and increased communication to pharmacists and pharmacy staff to prevent pharmacy theft. The program includes collaboration with and participation from law enforcement, regulators including state pharmacy boards, state and federal prosecutors, the media, and the public along with the pharmacy community. The Pharmacy Theft Prevention Program will also provide a means to maximize the use of limited resources available to law enforcement to address, minimize, and eliminate pharmacy thefts in areas that experience such problems.

Staff members of the DEA's Office of Diversion Control have begun a series of regional meetings to promote the program to DEA Diversion field elements, state pharmacy boards, and local pharmacy associations. To implement the program in your community, or to obtain more information regarding the program and its operation, call DEA Headquarters, Office of Diversion Control, Liaison and Policy Section, at 202/307-7297.

Concentrated Morphine Solutions and Serious Medication Errors

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

According to a recent newspaper report, a 91-year-old man being treated for a mild heart attack was mistakenly given a 100-mg dose of ROXANOL™ (concentrated morphine solution) instead of 5 mg as prescribed. The error may have contributed to the patient's death the following day. Last fall, Elan Pharmaceuticals (the manufacturer of Roxanol at the time; aaiPharma recently acquired the product from Elan) issued a safety alert warning about deaths from accidental overdoses (www.fda.gov/medwatch/SAFETY/2003/roxanol.htm). Most overdoses involved morphine solutions that were mistakenly ordered, dispensed, and labeled by volume (mL), not milligrams. For example, in some cases, patients received 5 mL of

Roxanol 20 mg/mL (100 mg) instead of the prescribed 5 mg. The newspaper report did not describe how this most recent error happened; however, it mentioned that Roxanol 100 mg had been given instead of 5 mg, pointing once again to the scenario described in the recent safety alert from Elan.

Several manufacturers distribute morphine solution in different formulations, primarily labeled (and listed in drug references) in mg/mL (eg, 20 mg/mL) or mg/5 mL (eg, 100 mg/5 mL, 20 mg/5 mL). When concentrated morphine is stored in pharmacies or in patient care areas in hospitals or long-term care facilities, it is often kept next to conventional concentrations. Thus, it is easy to confuse these products and dosage strengths. Also, some physicians have prescribed the medication in terms of mL instead of mg, which has led to errors because multiple concentrations exist. Because we continue to hear about these tragic overdoses, we make these recommendations to reduce the risk of errors with concentrated morphine products:

- If you consult with nursing homes or hospitals, avoid stocking concentrated morphine solutions in patient units when possible, including the emergency department. Keep in mind that the drug is used primarily to treat chronic pain.
- Dispense concentrated solutions only when ordered for specific patients who require higher-than-usual doses due to severe chronic pain.
- Affix an auxiliary label to the morphine concentrate bottle to warn about its high concentration and segregate the solution from the other concentrations.
- Working with local physicians, purchase and dispense concentrated solutions in dropper bottles (available from at least two manufacturers) to help prevent dose measurement errors and differentiate the concentrated product from the conventional products. For patients in hospitals or long-term care, dispense concentrated solutions in unit doses whenever possible.
- Educate others to never prescribe or dispense liquid medications without the dose specified in milligrams.
- Educate staff about the risk of morphine errors and develop guidelines to promote its safe use.
- Manufacturers should standardize the way strength is expressed on labels, preferably in terms of mg/mL for all forms. This would improve clarity when comparing product labels (eg, it is easier to differentiate 4 mg/mL and 20 mg/mL; harder to differentiate 20 mg/mL and 20 mg/5 mL).

Finally, we disagree with Elan's suggestion in its recent safety alert for prescribers to include the desired concentration of morphine along with the patient's dose in milligrams and the corresponding volume (eg, Roxanol 10 mg/5 mL, give 10 mg [5 mL] prn pain). Listing the desired concentration could actually lead to confusion and errors. If the prescribed concentration is not available and a different concentration is substituted, the prescriber's directions regarding the volume to administer would no longer apply. Yet, if these directions remain on a medication administration record, or a prescription bottle, the wrong dose could be administered.

NABP Releases Updated Model Rules for the Licensure of Wholesale Distributors

On February 20, 2004, the National Association of Boards of Pharmacy® (NABP®) released the updated Model Rules for the Licensure of Wholesale Distributors. The updated Model Rules, part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, were provided to assist state boards of pharmacy in maintaining the integrity of the US medication distribution system through the regulation of wholesale distributors. The updated Model Rules are the result of a concerted effort between NABP and other representatives from pharmacy, government, and the wholesale distributor industry to protect the public from the ill effects of counterfeit drugs and devices.

In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific drug pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products." Also, the updated Model Rules introduce the position of "Designated Representative." The "Designated Representative" of a wholesale distributor is the person who is actively involved in and aware of the actual daily operation of the Wholesale Distributor.

The Model Rules for the Licensure of Wholesale Distributors along with the National Specified List of Susceptible Products can be downloaded from NABP's Web site, www.nabp.net.

New Bar Code Requirements Aim to Reduce Risk of Medication Errors

In late February, FDA issued the final rule Bar Code Label Requirements for Human Drug Products and Biological Products. This final rule requires the inclusion of linear bar codes on most prescription drugs and certain OTC drugs. Each bar code must, at minimum, contain the drug's National Drug Code number, but companies are encouraged to include additional information such as the product's lot number and expiration date. For blood and blood products used in a transfusion, the final rule also requires the use of machine-readable information in a format approved for use by FDA. The machine-readable information must include, at a minimum, the facility identifier, the lot number relating to the donor, the product code, and information on the donor blood type.

FDA is hoping that the bar code rule will encourage the widespread adoption of advanced information systems that, in some institutions, have reduced medication errors by 85%.

FDA expects that, with full implementation, the linear bar codes will result in more than 500,000 fewer adverse events over the next 20 years and a 50% reduction in medication errors that would otherwise have occurred upon dispensing or administration. New medications covered by the rule must comply within 60 days of their approval and previously approved medications and blood/blood products must comply within two years.

More information including a link to the final rule is available on FDA's Web site at www.fda.gov/oc/initiatives/barcode-sadr.

Continued from page 1

program focuses on providing help for states that want to either establish a prescription drug monitoring program or enhance an existing program.

There are approximately 18 states that currently have prescription drug monitoring programs. Prescription drug abuse is emerging as one of the most serious prevention issues in the country today. No longer just the "silent" misuse of medications by women, people with chronic pain, and the elderly, prescription drug abuse is fast becoming a trend among young people, cutting across economic and cultural boundaries and affecting metropolitan and rural areas.

The National Institute on Drug Abuse reports that prescription drug abuse accounts for about one third of all drug abuse in the US. Clearly, this is an issue we can no longer ignore.

The approach must address the concerns of people who have a legitimate need for prescription medications and patients whose lives have been made more livable because of prescription drugs. Most people who are prescribed prescription drugs by a doctor do not abuse them. Effective pain control, in particular, is clearly a vital aspect of modern medical care that needs to be preserved and maintained, not diminished. A distinction needs to be drawn between physical dependence on a drug and addiction. Much can be done to prevent and reduce the often devastating effects of prescription drug abuse, but without the involvement of committed groups at the local community level this program cannot be effective.

The Board would like to assemble and conduct a multidisciplinary statewide coalition to develop a voluntary pilot program. The grant would be used to plan, establish, or build a data collection and analysis system; develop an infrastructure to support programmatic activities; facilitate the exchange of information and collected prescription data among states; and to assess the efficiency and effectiveness of a program. The coalition should include pharmacists, physicians, licensing board officials, public health officials, law enforcement, legislators, addiction treatment professionals, and community members. If anyone is interested in participating in this task force, please contact the Board office by calling 785/296-4056 or via e-mail at pharmacy@pharmacy.state.ks.us.

Frequently Asked Questions of DEA and Board-Agreed-Upon Responses

Question: Can an individual return his or her controlled substance prescription medication to a pharmacy?

Answer: No. An individual patient may not return his or her unused, controlled substance prescription medication to the pharmacy. Federal laws and regulations make no provisions for an individual to return his or her controlled substance prescription medication to a pharmacy for further dispensing or for disposal. There are no provisions in the Controlled Substances Act or Code of Federal Regulations (CFR) for a Drug Enforcement Administration (DEA) registrant (ie, retail pharmacy) to acquire controlled substances from a nonregistrant (ie, individual patient).

The CFR does have a provision for an individual to return his or her unused controlled substance medication to the pharmacy in the event of the controlled substance being recalled or if a dispensing error has occurred.

An individual may dispose of his or her own controlled substance medication without approval from DEA. Medications should be disposed of in such a manner that does not allow for the controlled substance to be easily retrieved. In situations where an individual has passed away, a caregiver or hospice staff member may assist the family with the proper disposal of any unused controlled substance medications.

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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