March 2011

Kansas State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

800 SW Jackson St, Ste 1414 • Topeka, KS 66612 • *www.kansas.gov/pharmacy/*

Drug Disposal

Drug Enforcement Administration (DEA) reports that increasing prevalence of prescription drug abuse, especially among teens, has become an issue of public concern in recent years. The 2009 Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health estimates that greater than seven million Americans currently abuse prescription drugs. Furthermore, the Partnership at Drugfree.org estimates that about 2,500 teens use prescription drugs each day to get high for the first time. Drug disposal programs ("take-back" programs) play an important role in reducing the availability of unused, unwanted, and expired medications, a potential source of abusable drugs.

Pharmacists are uniquely positioned as readily available medication experts, and the public often turns to them for advice on medication disposal. However, there continues to be confusion among Kansas pharmacists who wish to implement take-back programs, especially in regard to two issues: environmentally friendly disposal and disposal of controlled substances.

The Kansas Department of Health and Environment (KDHE) issued guidance relating to the disposal of non-controlled substance pharmaceuticals and the potential for surface and groundwater contamination. KDHE indicates the most desirable disposal method available to pharmacists is reverse distribution (returning medications to manufacturers for credit). Medical or hazardous waste incineration, as well as disposal in a permitted hazardous waste landfill, is also a viable option, though not readily available to most pharmacists. A less desirable method – combination with coffee grounds or kitty litter prior to disposal in the trash – is easier and often preferred by pharmacists. KDHE advises against disposal into sanitary sewer systems ("flushing") due to water contamination concerns, except when specifically indicated by the package insert. Currently, KDHE has defined pharmaceuticals that have been dispensed as hazardous waste. Hazardous waste can only be collected in Kansas at a hazardous waste facility. Further guidance of benefit to pharmacists may be accessed at *www.kdheks.gov/waste*.

The second issue of particular concern to pharmacists is the disposal of controlled substances. The public often asks pharmacies to take back unwanted, unused, and expired controlled substances; however, doing so would violate the Controlled Substances Act (CSA) as it is currently written. DEA registrants (like pharmacies) are only allowed to obtain controlled substances from other registrants. Federal law has not allowed take-back programs to accept controlled substances from non-registrants (like the general public) without special permission from DEA and arrangements for law enforcement officers to receive them directly from the member of the public who wishes to dispose of them.

In an effort to increase disposal of controlled substances, Congress amended the CSA through the Secure and Responsible Drug Disposal Act of 2010. This law allows DEA to develop new regulations regarding the manner in which ultimate users can turn in unwanted pharmaceuticals for disposal. DEA is undergoing the rulemaking process and should publish a Notice of Proposed Rulemaking this year. In the meantime, DEA has scheduled a National Prescription Drug Take-Back Day to be held nationwide on Saturday, April 30, 2011. In order for a pharmacy to participate in the DEA Take-Back Day they must be signed up with DEA and have local law enforcement involved in the process. Details of the program, including local collection sites, will soon be posted at *www.deadiversion.usdoj.gov*.

If a pharmacy wishes to dispose of controlled substances from its own stock, it may transfer them to a DEA-registered reverse distributor. The DEA district office that serves the registrant's area can provide a list of approved reverse distributors. The pharmacy must maintain a record of distribution that includes the drug name, dosage form, strength, quantity, and date transferred. DEA Form 41 provides instructions, and the reverse distributor that destroys the controlled substances is responsible for submitting DEA Form 41 to the special agent in charge at the DEA district office. Form 41 should not be used as the record of transfer of controlled substances between the pharmacy and the reverse distributor. Also, pharmacies should remember to satisfy the requirements of transfer of Schedule II drugs using DEA Form 222.

Kansas, Nebraska, and western Missouri are currently served by DEA's Kansas City District Office, 7600 College Blvd, Ste 100, Overland Park, KS 66210-1853, phone: 913/825-4200, fax: 913/825-4182.

Electronic Prescriptions

The CSA was originally enacted in 1970 at a time when most prescriptions were written on paper. It was subsequently revised and updated to include transmission of controlled substance prescriptions orally and by facsimile. To keep up with today's technology, DEA recently issued an Interim Final Rule to allow for the electronic prescribing, transmission, and processing of controlled substance prescriptions – including Schedule II prescriptions – while maintaining its closed system of controls. DEA's new rules (21 CFR §1311) became effective June 1, 2010. Congress has introduced financial incentives for the implementation of electronic health records, including electronic prescribing.

By definition, an electronic prescription does not take physical form at any point along its transmission from prescriber to pharmacist. If the prescriber creates an electronic prescription, all records of the prescription must be maintained electronically and may not be converted into physical form. Furthermore, intermediaries (ie, SureScripts-RxHub) are not allowed to convert electronic controlled substance prescriptions into facsimiles.

Only pharmacy software that complies with 21 CFR §1311.205 may be used to electronically receive and archive controlled substance prescriptions. A software vendor (termed "pharmacy application provider"

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Obtain Your NABP e-Profile ID Online Now, ID Required for ACPE-Accredited CPE

The new NABP CPE Monitor Program, a collaborative effort between the National Association of Boards of Pharmacy® (NABP®), the Accreditation Council for Pharmacy Education (ACPE), and their providers, will allow pharmacists and technicians to easily track their ACPE-accredited continuing pharmacy education (CPE) credits beginning in fall 2011. In addition, the program will provide a streamlined reporting and compliance verification process for participating state boards of pharmacy. When pharmacists and technicians complete an ACPE-accredited CPE program, their participation data will be sent electronically from the provider to ACPE, then to NABP for recording into the matching NABP e-Profile. Then, if the board of pharmacy participates in CPE Monitor, the pharmacists' or technicians' CPE credits will be automatically transmitted to the board, saving pharmacists and technicians the trouble and expense of documenting and submitting compliance with state-mandated CPE requirements for license renewal. This eliminates paper forms and the overall need to submit paper copies of CPE statements of credit to the board of pharmacy for CPE activities from ACPE-accredited providers.

For convenience, the NABP e-Profile will be available 24/7 for viewing a comprehensive list of the CPE activities completed. Plus, beginning in early April, as an extra benefit, pharmacists and technicians may enter detailed career information relating to education or work history, which may streamline license transfer processing. All information will be maintained in a highly secure environment. NABP does not distribute any personal information for commercial purposes without consent.

To prepare for the new process, pharmacists and technicians are encouraged to obtain their NABP e-Profile identification soon after March 10, 2011 to ensure their e-Profile is properly set up. In fall 2011, the e-Profile ID will be required to receive credit for any accredited CPE activities from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering or when submitting participation data to the provider. Registrants will then be known in the ACPE provider's system by two additional identifiers: their month and day of birth (mmdd) and NABP e-Profile ID. Please note that CPE Monitor does not currently track CPE from non-ACPE accredited providers. This feature will be added in Phase 2 of the CPE Monitor Program, and, until then, pharmacists and technicians will need to submit non-ACPE accredited CPE directly to their board of pharmacy when required to do so.

After March 10, pharmacists can obtain their ID by creating an NABP e-Profile using the portal in the Pharmacists section of the NABP Web site at *www.nabp.net/pharmacists*. Technicians can obtain their ID by creating an NABP e-Profile using the portal in the Technicians section of the NABP Web site at *www.nabp.net/technicians*. Or visit *www.MyCPEmonitor.net* for more information.

DEA Policy Statement on Role of Agents in Communicating CS Prescriptions

Drug Enforcement Administration (DEA) issued a statement of policy that clarifies the proper role of a duly authorized agent of a DEA-registered individual practitioner in communicating controlled substance (CS) prescription information to a pharmacy. The statement, published October 6, 2010, in the *Federal Register,* reminds health care providers that a prescription for a CS medication must be issued by a DEA-registered practitioner acting in the usual course of professional practice. Such a practitioner may authorize an agent to "perform a limited role in communicating such prescriptions to a pharmacy in order to make the prescription process more efficient," and the guidance emphasizes that medical determinations to prescribe CS medications may be made by the practitioner only.

The specific circumstances in which an agent may assist in communicating prescription information to a pharmacy are detailed and include:

- An authorized agent may prepare the prescription, based on the instructions of the prescribing practitioner, for the signature of that DEA-registered practitioner.
- For a Schedule III-V drug, an authorized agent may transmit a practitioner-signed prescription to a pharmacy via facsimile, or may communicate the prescription orally to a pharmacy on behalf of the practitioner.
- An authorized agent may transmit by facsimile a practitioner-signed Schedule II prescription for a patient in a hospice or long-term care facility (LTCF) on behalf of the practitioner.

The guidance also makes clear that generally, Schedule II prescriptions may not be transmitted by facsimile and that hospice and LTCFs are exceptions. Further, Schedule II prescriptions may only be communicated orally by the DEA-registered practitioner and only in emergency situations. DEA stresses that the practitioner should decide who may act as his or her authorized agent and advises that such designation be established in writing. An example written agreement is included in the policy statement, along with additional guidance related to designating an authorized agent. DEA also notes that as electronic prescribing for CS is implemented and its use increases, the role of the agent in communicating CS prescriptions will likely be reduced over time. The DEA policy statement is available on the *Federal Register* Web site.

The ISMP Ambulatory Care Action Agenda: Learn from Others' Mistakes

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes 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. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

No news is **not** good news when it comes to patient safety. Each organization needs to accurately assess how susceptible its systems

are to the errors that have happened in other organizations, and acknowledge that the absence of similar errors is not evidence of safety. Personal experience is a powerful teacher, but the price is too high to learn all we need to know from firsthand experiences. Learning from the mistakes of others is imperative.

A great way to utilize the ISMP Medication Safety Alert!® Community/Ambulatory Care Edition is by using the Ambulatory Care Action Agenda*. Three times a year, selected items are prepared for you and your staff to stimulate discussion and collaborative action to reduce the risk of medication errors previously reported to the ISMP Medication Errors Reporting Program (MERP). The agenda topics appeared in the ISMP Medication Safety Alert! Community/Ambulatory Care Edition during the preceding four months. Each item includes a brief description of the medication safety problem, recommendations to reduce the risk of errors, and the issue number to locate additional information as desired.

The Action Agenda is presented in a format that allows community practice sites to document their medication safety activities, which is important for internal quality improvement efforts but also important for any external accrediting or regulatory organizations. Each pharmacy practice site should convene a staff meeting to discuss each item in the Action Agenda. The staff should ask themselves, "Can this error occur at our site?" If the answer is "yes," the ISMP recommendations for prevention should be reviewed for applicability at that specific site. If the recommendations are germane to the practice site, the columns on the Action Agenda indicating "Organization Assessment" and "Action required/Assignment" should be completed and a reasonable time set for completion. The staff should reconvene in three months time to determine if the proposed recommendation strategies have been implemented, if they are still pertinent, and if other strategies have been offered or considered since the initial meeting.

According to the 2011 *Survey of Pharmacy Law,* published by NABP, at least 19 states regulate, require, or recommend a continuous quality improvement (CQI) program to monitor and prevent quality related events. The purpose of the CQI program is to detect, document, and assess prescription errors in order to determine the cause, develop an appropriate response, and prevent future errors. Utilization of the Action Agenda to review externally reported errors combined with review and analysis of internally reported events constitutes a feasible and effective CQI program.

*The Action Agenda is available at no charge on the ISMP Web site, *www.ismp.org/Tools/communitySafetyProgram.asp.*

FDA and NABP Partner to Help Prevent Acetaminophen Toxicity

In partnership with NABP, and as part of its Safe Use Initiative, Food and Drug Administration (FDA) encourages pharmacies to stop using the abbreviation APAP and to spell out the drug name, acetaminophen, in effort to help patients avoid acetaminophen toxicity. As explained in an FDA drug safety notice, liver injury due to acetaminophen overdose is a serious public health problem, and by spelling out the drug name on prescription labels, pharmacies are enabling patients to know when their medication contains the drug. Patients can then compare their prescription and over-the-counter medications to determine whether both contain acetaminophen and avoid taking two medicines containing the drug. The FDA drug safety notice provides more information and is available at *www.fda.gov/Drugs/DrugSafety/ucm230396.htm.*

In July 2010, NABP recommended that the state boards of pharmacy prohibit the use of the abbreviation APAP on prescription labels, and require that acetaminophen be spelled out. In situations where the board is unable to mandate such a provision, NABP recommended that the boards strongly encourage practitioners to follow this guideline. More information is available on the NABP Web site at *www.nabp.net/news/.*

Stolen Carbatrol, Adderall XR Surfacing in Supply Chain

Shire, along with FDA, alerts pharmacists and distributors that certain lots of Carbatrol® that were stolen on October 17, 2008, have been found in the supply chain as expired returns. The stolen shipment also contained Adderall XR®. The manufacturer warns that more stolen product may still be on the market and that stolen Carbatrol and Adderall XR should not be used or sold because the safety and effectiveness of the product could have been compromised by improper storage and handling or tampering while outside of the legitimate supply chain. The following products and lot numbers are affected:

- Adderall XR 15 mg, Lot No: A38146A, Expiration Date: 02/29/2012
- Carbatrol 200 mg, Lot No: A40918A, Expiration Date: 04/30/2010
- Carbatrol 200 mg, Lot No: A40919A, Expiration Date: 04/30/2010
- Carbatrol 200 mg, Lot No: A41575A, Expiration Date: 05/31/2010

These lots of Carbatrol and Adderall XR were stolen while in transit from Shire's manufacturing facility in North Carolina to Shire Distribution Center in Kentucky. FDA seeks assistance and asks that any information regarding the stolen Carbatrol or Adderall XR, including suspicious or unsolicited offers for these products, be reported by contacting FDA's Office of Criminal Investigations (OCI) at 800/551-3989, or by visiting the OCI Web site at *www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.*

2011 Survey of Pharmacy Law Now Available

Celebrating its 60th edition as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2011 *Survey of Pharmacy Law* is now available.

The *Survey,* produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 18, Drug Control Regulations, asks whether or not states have CS or drugs of concern scheduled differently than the federal Controlled Substances Act.

Updates for the 2011 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of CS in Sections 26 and 27.

The *Survey* can be purchased online for $195 by visiting the Publications section of the NABP Web site at *www.nabp.net/publications.* All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey,* please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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in 21 CFR §1311) must obtain a report every two years certifying that its software application complies with the new DEA requirements. The software vendor must make available a copy of that report to contracting pharmacies, allowing them to verify their compliance.

If a software vendor discovers or is made aware of an issue with its software that makes it noncompliant with 21 CFR §1311.205, the vendor must notify all affected pharmacies within five business days of discovery of the issue. Once notified, pharmacies must cease processing controlled substance prescriptions with the affected software until the issue is resolved and new compliance reports are available to the pharmacies.

DEA estimates that during the transmission of electronic data from the prescriber to the pharmacy, the electronic prescription may pass through three to five intermediaries. DEA is not regulating such transmission; registrants have no control over the string of intermediaries involved in transmission. However, prescribers' and pharmacies' software programs must "digitally sign" the electronic prescription before and after transmission, respectively. DEA understands this will not prevent problems during transmission, but the process will identify transmission problems and prevent registrants from being held responsible for a transmission issue that is not attributable to them.

If a pharmacist does not receive an electronic controlled substance prescription due to a transmission error, the prescriber may print a copy of the prescription. The printed copy must (1) be clearly labeled as a copy, (2) be manually signed by the prescriber, (3) indicate that it was originally transmitted to a specific pharmacy (at a documented date and time), and (4) state that the transmission failed. Before filling the printed prescription, the pharmacist must verify that an electronic prescription was not received and that no controlled substances were filled pursuant to the electronic version. If both an electronic and a printed version were received, the pharmacist must mark one as void.

If, however, the electronic prescription was transmitted to a pharmacy other than the one that received the printed copy, the pharmacist must verify with the identified pharmacy that the electronic prescription was not received and dispensed. If both an electronic and printed copy of the same prescription exists, one must be marked void.

As the CSA mandates, pharmacists are still responsible for ensuring that a practitioner acting in the usual course of professional practice issued the electronic prescription for a legitimate medical purpose. Pharmacists are allowed to make the same lawful changes to the electronic controlled substance prescription that they may make to printed prescriptions. Such changes to an electronic prescription must be annotated electronically, and an internal audit trail must be maintained. Pharmacies that receive unsigned electronic prescriptions must treat them in the same manner as unsigned printed prescriptions for controlled substances.

DEA emphasizes that new regulations governing electronic prescribing of controlled substances are in addition to, and not a replacement of, existing requirements for written and oral controlled substance prescriptions. Prescribers may still write and manually sign prescriptions for Schedule II, Schedule III, Schedule IV, and Schedule V drugs; pharmacists may still dispense medications based on those written prescriptions as they have for years. Furthermore, prescribers may still use an existing computer program that is not compliant with 21 CFR §1311 to generate a printed prescription. Such a paper prescription is subject to existing requirements for written prescriptions and must be manually signed.

The Kansas State Board of Pharmacy is still working on updating legislation and regulations so that a pharmacy may accept electronic prescriptions. Until the Board has made changes to the Kansas law a pharmacy is precluded from accepting electronic prescriptions. Pharmacists are cautioned against using this summary as a complete reference for compliance with new DEA regulations. The regulations may be accessed online at *www.gpo.gov/fdsys/pkg/CFR-2010-title21-vol9/pdf/CFR-2010-title21-vol9-part1311.pdf* . The Board will update pharmacies when they have updated the Kansas laws so that they are reconciled with federal law.

Electronic Logging of Meth Precursors

Recently the state of Kansas passed K.S.A. 65-16,101, *et seq.* This statute requires all pharmacies in the state of Kansas that sell cold and allergy medications containing any discernable amount of ephedrine, pseudoephedrine (PSE), and/or phenylpropanolamine products to participate in a statewide, real-time electronic PSE monitoring program for the purpose of tracking illegal PSE purchases.

In compliance with K.S.A. 65-16,101, *et seq*, the Kansas State Board of Pharmacy joined the National Precursor Log Exchange (NPLEx). As part of the Board's project scheduled to launch in the upcoming weeks, the technology provider, Appriss, will provide a Web-accessed database at **no charge** to pharmacies. Pursuant to the Combat Methamphetamine Epidemic Act (CMEA) of 2005, pharmacies are currently required to capture certain data regarding PSE sales. The NPLEx system enables pharmacies to easily enter the same PSE sales data currently being gathered online rather than recording the information into a manual log or in-store computer system. Data will be stored in a secure, central repository that treats the data collected as if it were Health Insurance Portability and Accountability Act data. Furthermore, the collected data will be viewable by law enforcement, in keeping with CMEA and K.S.A. 65-16,101, *et seq.*

Appriss will provide training sessions for all pharmacies located throughout the state. Members from either the Kansas State Board of Pharmacy or Appriss will be contacting you soon to discuss integration, training, or other related questions. If your pharmacy does not sell over-the-counter PSE products or your pharmacy only administers PSE products by prescription, please notify the Board. Be sure to include your pharmacy contact information and state license number. The Board looks forward to partnering with you on this important effort. Please contact Debra Billingsley of the Kansas State Board of Pharmacy at 785/296-4056 or at debra.billingsley@pharmacy.ks.gov for questions regarding this initiative.

Disciplinary Cases

Jessica J. Duben, Pharmacy Technician Registration #14-008854. Registration revoked on December 2, 2010, based on action from Missouri Board of Pharmacy placing Duben on disqualification list for a period of five years.

Coral Main, Pharmacy Technician Registration #14-02268. Registration revoked for diverting alprazolam, methadone, and oxycodone from her employer.

Gwendolyn Parks, Pharmacy Technician Registration #14-00351. Registration revoked for diverting hydrocodone APAP from her employer and selling to another individual.

Stephanie M. Ketcher, Pharmacy Technician Registration #14-05899. Registration revoked for falsifying prescription for antibiotic for her own use.

Kansas Spine Hospital, Registration #2-09907. Registrant fined $25,000, ordered to provide monthly controlled substance inventory, ordered to provide updated policy and procedures to Board based on insufficient, flawed, or incomplete documentation and record keeping associated with medication management functions.

Quinn Nelson, Pharmacy Technician Registration #14-08397. Registration revoked for diverting sertraline, alprazolam, OxyContin®, and Lortab® from his employer.

Marcus Ortiz, Pharmacy Technician Registration #14-05003. Registration revoked for diverting lorazepam, hydrocodone, alprazolam, cyclobenzaprine, and Viagra® from his employer.

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 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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