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Missouri Board of Pharmacy News

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Mid-Level Practitioner Controlled Substance Guidelines

The Bureau of Narcotics and Dangerous Drugs (BNDD) is now issuing controlled substance registrations to advanced practice registered nurses (APRNs) and physician assistants (mid-level practitioners). As of December 1, 2011, these mid-level practitioners are authorized to prescribe controlled substances, as authorized by Missouri law. To assist in compliance, BNDD has issued the following general guidance:

- Mid-level practitioners must be in a collaborative or supervision agreement with a physician who also has a current BNDD and Drug Enforcement Administration (DEA) registration. Mid-level practitioners may not purchase, stock, dispense, or administer controlled substances independently.
- Mid-level practitioners may prescribe controlled drugs in Schedules III, IV, and V only. There is **no authority** for Schedule II drugs.
- Like other prescribers, mid-level practitioners may not prescribe, administer, or dispense controlled drugs to themselves.
- Mid-level practitioners may not prescribe controlled drugs to family members. "Family" is defined in the state medical board's Rule 20 CSR 2150-5.100(3)(G)(10) as a spouse, parent, grandparent, great-grandparent, child, grandchild, great-grandchild, brother, sister, aunt, uncle, nephew, niece, mother-in-law, father-in-law, brother-in-law, sister-in-law, daughter-in-law, or son-in-law. Adopted and step family members are also included in the definition of "family."
- ***Out-of-State Practitioners:*** Pursuant to Section 195.060.1, RSMo, Missouri pharmacies may in good faith dispense controlled drug prescriptions from out-of-state practitioners, as long as the prescriptions were written in compliance with the laws of the applicable state.

Difference in Schedule III Prescribing Quantities

- ***APRNs:*** When prescribing a Schedule III **opiate/narcotic,** APRNs are limited to a 120-hour (five-day) supply with no refills on the prescription. Section 334.104.2, RSMo, gives APRNs normal prescribing authority for non-opiate/narcotic Schedule III drugs.
- ***Physician Assistants:*** Physician assistants are limited to a 120-hour (five-day) supply for **all** Schedule III drugs, with **no refill.** These practitioners may, however, issue an entirely new prescription after five days that would generate a new prescription and new prescription number. According to BNDD, these would be considered new prescriptions and not refills.

Change in Labeling Requirements

Section 195.100, RSMo, contains amended labeling requirements for controlled drug prescriptions issued by mid-level practitioners. Generally:

- The label on the prescription must document both the names of the prescribing mid-level practitioner and his or her supervising or collaborating physician. If the physician's name is not provided, the pharmacy may call the prescriber and document the name. *Note: This pertains to "prescriptions" and not to internal drug "orders" for inpatients of a licensed hospital.*
- Physician assistants must document both their Missouri BNDD number and DEA number on prescriptions.

The revised statutory requirements can be found in §334.104 (APRNs) and §334.747, RSMo (physician assistants). Additional compliance information can be found on BNDD's Web site at *http://health.mo.gov/safety/bndd/index.php.*

Clarification Regarding Carisoprodol Prescriptions

Effective January 11, 2012, DEA made carisoprodol (Soma®) a Schedule IV drug. As of January 11, 2012, carisoprodol may only be dispensed in accordance with the Controlled Substances Act. DEA has officially issued a guidance statement regarding carisoprodol prescriptions that is now available on its Web site at *www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.*

The Missouri Board of Pharmacy has received multiple inquiries regarding prescriptions for carisoprodol that were written before January 11, 2012, that have valid refills remaining. According to BNDD and the DEA's guidance statement, licensees may continue to dispense these prescriptions if the prescription was written by an authorized DEA registrant with a DEA number and it is within the time frame and refill limit. If the prescriber does not have a DEA number, those prescriptions should be canceled and not dispensed. Licensees are encouraged to review the complete DEA statement to ensure compliance.

Technician Renewals

All pharmacy technician registrations will expire on May 31, 2012. Renewal notices will be mailed shortly. Technician address changes should be submitted to the Board on or before February 10, 2012. Address changes can be submitted online at *https://renew.pr.mo.gov/pharmacists-coa.asp* or faxed to 573/526-3464.

Inspection Tip

Do you know where your records are? Save time and prevent delays during an inspection by knowing where to find pharmacy records. A list of the most commonly requested records can be found on page 2 of the Board's *Inspection Guide.* Develop a contingency plan if you are not present for the inspection so your staff can find records easily. Failure to produce required documents could result in a compliance violation!

FDA Recommends Use of Sterile Needle and Syringe for Administration of Inactivated Influenza Vaccines

Food and Drug Administration (FDA) recommends that health care providers use a sterile needle and syringe to administer inactivated influenza vaccines. The recommendation was released in response to questions regarding the use of jet injector devices to administer inactivated influenza vaccines. FDA advises that "inactivated influenza vaccines that are approved by FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration." Further, FDA clarifies its October 21, 2011 communication "to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector." FDA also notes the following:

- Currently, there is only one vaccine, Measles, Mumps, and Rubella (MMR), that is approved and specifically labeled for administration by jet injector.
- Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by FDA for administration by jet injector.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling, and FDA advises that if a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling. Additional background information is available in the communication posted on the FDA Web site at *www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm276773.htm.*

The Centers for Disease Control and Prevention continues to encourage people to get vaccinated throughout the flu season, which can begin as early as October and last as late as May. For information about the flu vaccine visit *www.cdc.gov/flu.*

'Tell Back' Works Best to Confirm Patient Understanding

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 an 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.*

In the past few years, multiple studies have demonstrated that patients often leave medical encounters with a poor understanding of their health conditions and recommended treatment. One recent study on this subject demonstrates the low level of understanding patients have about follow-up care and medication therapy upon discharge from the emergency department (Engel KG et al. Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Do Not Understand? Ann Emerg Med. Available on the journal Web site).

Given the importance of patient understanding of medical information, there are surprisingly few studies that point out how to approach this task. However, a study published in 2008 offers some insight into what approach to assessing understanding of medical information patients most prefer and perceive to be the most effective (Kemp EC, et al. Patients Prefer the Method of "Tell Back-Collaborative Inquiry" to Assess Understanding of Medical Information. J Am Board Fam Med 2008;21(1):24-30). Researchers tested three types of inquiry about the patient's understanding:

- Yes-No
- Tell Back-Directive
- Tell Back-Collaborative

The Yes-No approach asked closed-ended questions to assess patient understanding. (Example: "I've given you a lot of information. Do you understand?") The Tell Back-Directive method used open-ended questions that were physician-centered and paternalistic in that it was clear authority and control still remained with the physician. (Example: "It's really important that you do this exactly the way I explained. What do you understand?") The Tell Back-Collaborative approach used open-ended questions that were patient centered, making it clear that power and responsibility were shared between the health care provider and patient. (Example: I imagine you are really worried about your blood pressure. I've given you a lot of information. It would be helpful to me to hear your understanding about your clot and its treatment.)

Patients showed a significant preference for the Tell Back-Collaborative inquiry over other tested approaches. Because of the potential for embarrassment if patient misunderstandings are exposed, one might anticipate health care providers' reluctance to put patients "on the spot" with open-ended questions. But a collaborative approach to Tell Back allows the patient to save face for misunderstandings by acknowledging the large amount of information being provided. Patients might also view the request for Tell Back as evidence of the health care provider's care and concern for them personally, or evidence of the provider's attention to detail and competence. So, when counseling patients about their medications, instead of asking "Do you have any questions?" or "Do you understand?" ask them to restate their understanding of the information you provided in their own words within a shame-free, blame-free environment.

DEA Clarifications on Certification Process for Audits of EPCS Software

Drug Enforcement Administration (DEA) emphasizes that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in DEA regulations, including security, and must address "processing integrity" as set forth in the regulations. Further, DEA recommends that where questions or gaps may arise in reviewing a particular applica-

tion, federal guidelines set forth in National Institute of Standards and Technology Special Publication 800 – 53A should be consulted. DEA has also announced the first DEA-approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA's Web site at *www.deadiversion.usdoj.gov/ecomm/e_rx/thirdparty.htm#approved*. Detailed background information is provided in the Federal Register Notice, available for download at *www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf*.

'Script Your Future' Provides Tools and Outreach to Encourage Medication Adherence

United States Surgeon General Regina Benjamin called upon pharmacists, physicians, nurses, and other health care providers to talk with their patients about the importance of taking medications as directed to help prevent serious health complications at the recent launch of the national campaign, "Script Your Future." Benjamin also "encouraged patients with chronic conditions to speak with their health care professionals about their medication" as noted in a press release. A survey released by the National Consumer League, the organization that developed Script Your Future, indicates that "patients who do not always take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of adherence." The Script Your Future campaign is targeting six regional areas with outreach activities and advertising, and more information is available at *www.ScriptYourFuture.org*. The campaign brings together "stakeholders in health care, business, and government to offer practical tools for patients to help them better adhere to their medication, and to help health care professionals better communicate with patients." More information about the campaign is available in a press release at *www.prnewswire.com/news-releases/us-surgeon-general-joins-baltimore-launch-of-the-national-script-your-future-campaign-to-highlight-importance-of-taking-medication-as-directed-133077423.html*.

FDA Releases 'Use Medicines Wisely' Video

FDA Office of Women's Health has released a new public service announcement (PSA) video titled, "Use Medicines Wisely," to help raise awareness about safe medication use. As stated in an FDA news release, "Millions of people benefit from FDA approved medications and are living longer productive lives. However, when medications are used incorrectly, they can cause serious injuries, even death. Many of these injuries can be prevented."

The video shows simple steps women can take to use medications wisely. Viewers are reminded to:

- Make a list of the medications they take
- Keep their medication list with them at all times
- Know the name of each medication, why they are taking it, how much to take, and when to take it
- Talk with their doctor, nurse, or pharmacist to find out how to safely use their medications

In addition to the video, a medications record-keeper, fact sheets, and other safe medication use resources are available on the FDA Web site.

Training Video Provides Tips on Preventing Pharmacy Robbery

Rx Pattern Analysis Tracking Robberies and Other Losses (RxPATROL) has released a training video discussing pharmacy robbery and how to prevent it. The video features a pharmacist and law enforcement liaison as they tour a pharmacy, evaluating security measures and discussing additional steps that can be taken to prevent robbery. RxPATROL is an initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. RxPATROL is designed to gather and disseminate critical information to help protect pharmacists, guard against potential robberies, and assist law enforcement in their efforts to successfully apprehend and prosecute those involved in controlled substance pharmacy crime. The training video can be accessed on the RxPATROL Web site at *http://rxpatrol.org/TrainingVideos.aspx*.

Nearly 20 Products Marketed as Natural Supplements Contain Sibutramine, FDA Warns

FDA has posted public warnings regarding 19 products, frequently marketed as natural supplements, and found to contain sibutramine, a controlled substance that was removed from the US market in October 2010 for safety reasons. These products pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. These products may also interact in life threatening ways with other medications a consumer may be taking. FDA warnings included products marketed as "Slender Slim 11," "Dream Body Slimming Capsule," "Acai Berry Soft Gel ABC," and 16 other product names. The products included in the warnings are being sold on Web sites and in some retail stores. FDA advises consumers not to purchase or use the products listed in the warnings. Consumers who have purchased any of these products should stop use immediately. And if consumers have experienced any negative side effects from using these products, they should consult a health care provider as soon as possible. The complete list of warnings is available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm*.

2012 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2012 *Survey of Pharmacy Law* is now available and can be purchased online for $195 by visiting the NABP Web site at *www.nabp.net/publications*.

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 17, Wholesale Distributor Licensure Requirements, asks which state agency has regulatory authority over medical device distributors. In addition, a newly added question in Section 22, Electronic Transmission of Prescriptions: Computer-to-Computer, asks whether the state allows electronic prescribing of controlled substances.

Updates for the 2012 *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 controlled substances in Sections 26 and 27.

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.

Disciplinary Action

Pharmacists

Jennifer L. Baehr, #2005033291 – Battlefield, MO – December 2, 2011. Suspension for one (1) year followed by probation for five (5) years. While pharmacist-in-charge, misappropriated controlled substances from employer for personal use, impaired pharmacist, and pled guilty to Class C felony. Section 338.055.2(1), (2), (5), (6), (13), (15), and (17), RSMo.

Jodie J. Baker, #1999141844 – Holts Summit, MO – January 19, 2012. Probation for three (3) years. As pharmacist-in-charge, relapsed on alcohol and sought alcohol abuse treatment; and allowed technicians to assist in the practice of pharmacy without proper supervision. Section 338.055.2(5) and (13), RSMo.

Angela A. Campanella, #043404 – Hillsboro, MO – November 11, 2011. Suspension for two (2) years followed by probation for five (5) years. Refused employment-related drug screen, forged a prescription refill for herself and fraudulently documented prescriber authorization, altered controlled substance prescription for herself, removed merchandise from employer without paying, filled prescriptions for herself, and is chemical dependent. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.

James A. Cordes, #028128 – Des Peres, MO – December 2, 2011. Probation for two (2) years. As pharmacist-in-charge, misbranding, compounded prescriptions not logged, prescriptions filled for another pharmacy without a Class J permit, failure to keep complete acquisition/purchase/distribution records, technician allowed to work unsupervised and allowed to dispense prescriptions without a pharmacist on duty, and failed to supervise personnel to ensure compliance with laws/regulations. Section 338.055.2(5), (6), (13), and (15). RSMo.

M. David Kammer, #026334 – Chesterfield, MO – January 19, 2012. Probation for five (5) years. As pharmacist-in-charge, drugs received from non-wholesale, unlicensed drug distributors; failed to complete DEA Schedule II order forms; prescriptions filled for another pharmacy without Class J license; failed to keep complete acquisition, purchase, and distribution records; and Schedule II cabinet not properly locked. Section 338.055.2(5), (6), (10), (13), and (15), RSMo.

Joseph L. Pruett, #041264 – St Louis, MO – December 2, 2011. Probation for three (3) years. Tested positive on employment drug screen without a valid prescription, pharmacy loss of drug for which he tested positive, impaired pharmacist. Section 338.055.2(1), (5), (13), (15), and (17), RSMo.

Shannon T. Welch, #044753 – Camdenton, MO – January 3, 2012. Suspension for six (6) months followed by probation for five (5) years. While pharmacist-in-charge, misappropriated controlled substances from employer for personal use without a prescription, impaired pharmacist. Section 338.055.2(1), (5), (13), (15), and (17), RSMo.

Pharmacies

CVS Pharmacy #8571, #2006015596 – Kansas City, MO – December 6, 2011. Probation for two (2) years. Employee theft of controlled substances, failure to implement security measures to detect and deter theft of controlled substances. Section 338.055.2(6), (13), and (15), RSMo 2000.

Walgreens #05748, #005115 – O'Fallon, MO – December 16, 2011. Probation for two (2) years. Technician misappropriated controlled substances, unable to deter theft of drugs and accurately reflect controlled substances in inventory, and record keeping. Section 338.055.2(5), (6), and (15), RSMo

Walgreens #04972, #006563 – Arnold, MO – December 16, 2011. Probation for two (2) years. Technician theft of controlled substances, failed to timely report technician termination to the Board, failed to maintain adequate security to deter theft of drugs and accurately monitor controlled substances in inventory, failed to provide effective controls and procedures to guard against the theft/diversion of controlled substances, and record keeping. Section 338.055.2(5), (6), and (15), RSMo

Walgreens Pharmacy #05552, #2000172880 – O'Fallon, MO – December 16, 2011. Probation for three (3) years. Technician theft of controlled substances, record keeping, and failed to timely notify BNDD of loss. Section 338.055.2(5), (6), and (15), RSMo.

Walgreens #03017, #005564 – Jefferson City, MO – December 16, 2011. Probation for three (3) years. Theft of controlled substances by technicians, failed to timely report loss to BNDD, unable to maintain adequate security to deter theft of drugs and accurately monitor controlled substances in inventory, and record keeping. Section 338.055.2(5), (6), and (15), RSMo.

Drug Distributors

Community Medical Equipment, #2004013278 – Glasgow, MO – November 11, 2011. Probation for two (2) years. Repeated inspection violations. Section 338.055.2(5), (6), (13), and (15), RSMo.

KV Pharmaceutical Company, #2004027666 – Bridgeton, MO – December 20, 2011. Censure of license. Continued to manufacture and ship into interstate commerce after Food and Drug Administration (FDA) notice was issued; entered into consent decree in federal court. Section 338.055.2(15), RSMo (Supp. 2002).

KV Pharmaceutical Company, #2002018777 – Bridgeton, MO – December 20, 2011. Censure of license. Continued to manufacture and ship into interstate commerce after FDA notice was issued; entered into consent decree in federal court. Section 338.055.2(15), RSMo (Supp. 2002).

KV Pharmaceutical Company, #900757 – St Louis, MO – December 20, 2011. Censure of license. Continued to manufacture and ship into interstate commerce after FDA notice was issued; entered into consent decree in federal court. Section 338.055.2(15), RSMo (Supp. 2002).

Laser Pharmaceuticals, LLC, #2011010765 – Greenville, SC – October 26, 2011. Restricted license issued on probation for four (4) years. Operated with an expired license. Section 338.055.2(6), RSMo.

Teva Animal Health, Inc, #2005040389 – St Joseph, MO – December 6, 2011. Censure of license. Entered consent decree in United States District Court concerning violation of Current Good Manufacturing Practices. Section 338.055.2(15), RSMo.

Teva Animal Health, Inc, #2005040390 – St Joseph, MO – December 6, 2011. Censure of license. Entered Consent Decree in US District Court concerning violation of Current Good Manufacturing Practices. Section 338.055.2(15), RSMo.

Teva Animal Health, Inc, #2005040391 – St Joseph, MO – December 6, 2011. Censure of license. Entered Consent Decree in US District Court concerning violation of Current Good Manufacturing Practices. Section 338.055.2(15), RSMo.

Ther-Rx Corporation, #901520 – Bridgeton, MO – December 27, 2011. Censure of license. Entered into consent decree in federal court. Section 338.055.2(15), RSMo (Supp. 2002).

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