February 2012

Arkansas State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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New Assistant Director

Brenda McCrady

Pharmacist Brenda McCrady joined the Arkansas State Board of Pharmacy in December 2011 as the Board's assistant director. Brenda is a third generation pharmacist. She completed her pre-pharmacy requirements at the University of Arkansas at Little Rock. Brenda graduated from the University of Arkansas College of Pharmacy in 1986. Brenda has worked as a pharmacist in both retail and hospital settings. She comes to the Board from Sam's Club where she was employed as a pharmacy manager. Prior to her employment with Sam's, Brenda was the director of pharmacy for Harvest Foods. She also spent several years in Jackson, MI, where she was employed as vice president of pharmacy operations for JJSA, Inc. Prior to working in retail, Brenda worked at Arkansas Children's Hospital. Brenda lives in Little Rock, AR, with her son and their two Labradors. She enjoys being outdoors, where she spends most of her recreational time. Brenda is a member of Fellowship Bible Church in Little Rock. Brenda's professional memberships include the Arkansas Pharmacists Association and the American Pharmacists Association.

Medical Board Notification Program

The Arkansas State Medical Board has recently developed a free "online" system to notify individuals when there has been action on a practitioner's license. While the Board of Pharmacy office often gets questions on the status of physician's licensure, physician licensure is handled by the Arkansas State Medical Board. Because pharmacists and pharmacies need to know when a medical practitioner's license has been suspended, revoked, or restricted, the Medical Board has provided this information to pass along to Board of Pharmacy permit holders. If you would like to register for this free service, please visit the Medical Board's home page at *www.armedicalboard.org* and watch for the "Tell Me More" scrolling link in the middle of the page. One of the choices this scrolls over is the User Notification System. The current direct link to that is *https://www.armedicalboard.org/How_To/HowToSignupForNotifications.aspx*. With this system you will need to create an account on their Web site and then sign up for notifications in this system. There are detailed instructions in the user notification system and you can choose to sign up for meeting notifications as well as notifications of disciplinary actions taken by the Medical Board. If you have any questions on this system, please contact the Arkansas State Medical Board through their contact information displayed on their Web site.

Supplying Medications to Correctional Facilities

The Board has received a number of questions recently regarding the processes for supplying medications to correctional facilities such as jails and prisons. While pharmacies licensed with the Arkansas State Board of Pharmacy are permitted to send patient-specific, labeled medications to correctional facilities for inmates, pharmacies are not permitted to sell bulk legend drugs to jails and prisons. This has been a recent point of discussion with several pharmacies that have received requests or orders for cards of "stock medications" from correctional facilities. To be clear on this, the only way to supply any prescription medications to a correctional facility that are not labeled as patient-specific medications is to follow Arkansas State Board of Pharmacy Regulation **04-06-0003 – CLASS #3 INSTITUTIONAL PHARMACEUTICAL SERVICES PERMIT.** This regulation defines the different types of correctional facilities for consideration in this process and also outlines the process by which the facility must have a permit in the name of a consultant pharmacist who is responsible for the supervision of services in the correctional facilities. The biggest point of confusion for this regulation and the supplying of medications to correctional facilities in general is that the pharmacy must submit their policies and procedures to the Board of Pharmacy for review and consideration in order to obtain a permit for the correctional facility. Additionally, the regulations outline the following regarding floor stock or back-up medications:

04-06-0003 – CLASS #3 INSTITUTIONAL PHARMACEUTICAL SERVICES PERMIT – CORRECTIONAL FACILITIES

(e) (1)(C) and (e)(2)(E)

Special floor stock or back up medications to meet the emergency needs of the patients in the correctional facility will be permitted only when specifically outlined in the policies and procedures manual. The policy and procedures manual shall at a minimum include:

i. lists of emergency medications which establish quantity limits for each medication, said list shall be subject to the approval of the Arkansas State Board of Pharmacy;
ii. the method of replacement;
iii. maintenance of records accounting for medications used;
iv. proper preparation and labeling by the pharmacy services provider.

When reviewing these regulations it is important to understand that this is a multistep process that requires not only Board oversight but Board review and approval of the pharmacy's policies and procedures for the supplying and replacement of medications that would be stored in the correctional facility as stock medications for emergency use. If a pharmacy has not completed this process in its entirety then the pharmacy is not able to supply stock medications or bulk legend drugs to a correctional facility.

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.

Preceptor Permits for Supervising Interns

The Board office continues to receive calls daily regarding regulation changes adopted in August 2011 regarding intern supervision. Most of these questions center around the subjects of "Do I need to renew my preceptor permit?" or "Do I need to maintain membership in a professional organization and pay $20 for my preceptor permit to supervise students?" As an additional review on this subject, changes were made in August to amend Regulation 02 in order to simplify the requirements for pharmacist interns to work in pharmacies and also allow consideration of graduation from a nationally accredited college of pharmacy as fully meeting the experiential requirements to apply for pharmacist licensure in Arkansas. These changes greatly reduced the paperwork that pharmacies, pharmacists, and interns are required to file with the Board of Pharmacy to have an intern work in a pharmacy. Instead of needing to file a training plan annually, receive and post a buff card in the pharmacy, and then file an affidavit of experience annually, the intern and pharmacy simply must notify the Board of Pharmacy in writing that the intern will be working in that specific pharmacy. The only exception to these rules is that foreign pharmacy graduates must continue to file these documents when obtaining intern hours toward their eligibility to become a pharmacist in Arkansas. With these changes, pharmacists only need to have a preceptor license with the Board of Pharmacy in order to supervise foreign pharmacy graduates as outlined in the regulations and do not need a preceptor permit to supervise current students from an Accreditation Council for Pharmacy Education (ACPE)-accredited college of pharmacy.

Pharmacist License and Other Permit Renewals

Renewal reminders have been sent out for pharmacists, in-state retail pharmacies, and out-of-state retail pharmacies. This year the Board of Pharmacy sent reminder cards to show once again how to link to its Web site and renew permits. These reminders were sent to the mailing address on record with the Board office. As in years past, part of the renewal process will be for pharmacists to report their continuing education (CE) for the last two years. As a reminder, the CE requirements for the current biennium include a total of 30 hours of CE credit with 12 of the hours being live hours and 12 hours being ACPE accredited. Specific questions regarding CE should be directed to Board staff. Only CE attained during the 2010-2011 biennium will count toward this requirement. Please remember that Board regulations require pharmacists to retain certificates of participation for proof of CE for a period of four years. To renew your pharmacist or pharmacy permit, visit the Board of Pharmacy Web site at *www.arkansas.gov/asbp* and click on the heading CURRENT RENEWAL INFORMATION for full instructions to renew your permit. These permits expired on December 31, 2011.

The Arkansas State Board of Pharmacy allows a renewal grace period on permits until March 31. However, there is a $20 penalty on permit renewals if not renewed by February 1, a $40 penalty if not before March 1, and if a permit is not renewed by April 1, then the license/permit is void. This means that in order to get a pharmacist license reactivated, an individual must apply for reinstatement and undergo a criminal background check, which includes fingerprinting and payment of reinstatement fees. As of January 4, the Board has 609 pharmacists and 48 pharmacies that still have not renewed.

Technician Permit Applications

Pharmacy technician permit applications are available on the Board of Pharmacy Web site in the Forms & Instructions section. The application includes specific instructions on how to fill out the application as well as a description of all other documents that must be included with the application. Since the application is an electronic form, it may be filled out on the computer and printed out in order to send it to the Board office.

Special Notice About the Arkansas State Board of Pharmacy Newsletter

The Arkansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify pharmacists licensed by the Board about information and legal developments. Please read this *Newsletter* and keep it for future reference because this *Newsletter* will be used in hearings as proof of notification of the *Newsletter's* contents. Please contact the Board office (501/682-0190) if you have questions about any of the articles in this *Newsletter.*

Arkansas Pharmacy Support Group Help Line
870/636-0923

The *Arkansas State Board of Pharmacy News* is published by the Arkansas 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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