January 2012

Nevada State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

431 W Plumb Lane • Reno, NV 89509 • Phone: 775/850-1440 • Fax: 775/850-1444
http://bop.nv.gov

Board Members

Pharmacy Robberies

Given the tragic events earlier this year in New Jersey where a pharmacist was murdered during a pharmacy robbery, the Nevada State Board of Pharmacy wishes to share the following article printed in both the Delaware and New Jersey State Board *Newsletters* dealing with pharmacy robberies.

Robbery is one of the most frightening and dangerous situations any pharmacist could face, making it imperative that pharmacists prepare themselves and their staffs for such an event. Your safety and the safety of your staff, your customers, and your patients must be the overriding objective during any robbery. There is no amount of money or quantity of drugs that are worth the risk of harm; you must avoid any action that might trigger violence. Comply with the robber's demands and let the police handle the rest.

How to React During a Robbery

- Cooperate fully with the robber's demands.
- Do not argue with, insult, or attempt to rehabilitate the robber.
- Do not attempt to thwart the robbery or apprehend the robber yourself.
- Do exactly as you are told by the robber, nothing more, nothing less.
- Remain calm and avoid sudden moves.
- Make a mental note of identifiable features about the robber (size, build, tattoos, gender, race, clothing).

Steps to Follow After the Robbery

- Immediately check with staff and patients to determine if anyone needs medical treatment.
- Lock the doors to prevent reentry.
- Call 911 or trigger your pharmacy alarm if you have one.
- If it is safe, try and see the robber's vehicle/license plate/direction taken.
- Ask witnesses to stay and provide statements to authorities.
- Protect the crime scene.
- Write down all that you have tried to remember.
- Alert company officials and follow company policy.

Hopefully by remaining calm and being observant during the robbery you can increase the likelihood of a safe outcome for yourself and the people around you, and increase the chances of apprehending the robber.

Emergency CII Prescriptions

The Board from time to time gets questions about the statutes and regulations regarding emergency CII prescriptions, and as many of you are aware, the liberal interpretation of the rules has been a focus of the Drug Enforcement Administration recently. See NAC 453.420 for details of Nevada law, which essentially says:

1. In an **emergency** situation, a pharmacist may dispense a CII medication upon receiving an oral authorization from the practitioner.
2. The quantity prescribed and dispensed is **limited to the amount necessary to treat the patient during the emergency situation.**
3. The pharmacist must immediately reduce the oral prescription to writing and write on the face of the prescription "Authorization for Emergency Dispensing."
4. The pharmacist must make a reasonable attempt to determine that the oral authorization came from a registered practitioner if not known to him or her.
5. The practitioner must cause a written prescription for the emergency amount to be delivered to the pharmacy within 72 hours of the oral order (if delivered by mail, the postmark must be within that 72-hour period).
6. The pharmacist must then attach the written prescription to the oral emergency prescription.
7. If the practitioner fails to deliver the written prescription, it must be reported to the Board.

The Questions:

1. **Can a nurse or employee of the practitioner call in the emergency prescription?** No (NRS 453.126).
2. **What constitutes an emergency?** Immediate administration is necessary for the proper treatment of the patient; no alternative treatment is available; and it is not reasonably possible for the practitioner to write the prescription and get it to the pharmacy.
3. **What quantity is allowable?** The amount necessary to cover the emergency situation and **never** more than required to cover 72 hours.
4. **What is the penalty for noncompliance?** Fines up to $10,000 per violation and action against the licenses of the pharmacist, practitioner, and pharmacy.

Welcome Jack Dalton!

The always smiling face of the Board's newest member, Jack Dalton, launched his Board of Pharmacy career in December pursuant to his recent appointment by Governor Brian Sandoval. Jack's long and storied career as a pharmacist began with his graduation from Butler University (the Indiana school that has gained basketball notoriety of late) in 1978. After a 10-year stint with Hook's Drugs in Indiana, Jack began a career with Wal-Mart, where he is currently a district manager in the Las Vegas, NV, area. Board staff looks forward to working with Jack, wishing him

Continued on page 4

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.

Continued from page 1

a gratifying experience in his new role. Jack's appointment came as the result of the retirement of Board of Pharmacy icon Keith Macdonald, who has tirelessly served Nevadans, first as executive secretary, then as a Board member. The Board wishes Keith the best as he enjoys doing laps around his newly built greenhouse on his BMW motorcycle!

Finally, Board staff congratulates Kam Gandhi on his reappointment to the Board. Kam's dedication and experience are indeed an asset to the Board.

Updates on Tetanus, Diphtheria, and Acellular Pertussis Vaccine

By Dan Heller, PharmD

Prevention is the most successful way of curbing epidemic trends with this disease. Recently, the Advisory Committee on Immunization Practices (ACIP) guidelines for tetanus, diphtheria, and acellular pertussis vaccine (Tdap: Adacel®, Boostrix®) has been updated to better reduce the incidence of pertussis.

Pertussis, also known as "whooping cough," is caused by a bacteria known as Bordetella pertussis, and is transmitted by hand to mouth/nose from person to person. Pertussis can cause serious illness in infants, children, and adults and can be life threatening, especially in the infant population. In 2009, nearly 17,000 cases of pertussis were reported in the United States, but many more go undiagnosed and unreported. An epidemic of pertussis has been reported, with a majority of cases occurring in our neighboring state, California. Ten neonatal deaths have been reported due to this disease in the last year in the state of California. As a neighboring state, we need to be aware of these risks, symptoms, treatments, and prevention strategies to impede outbreaks in Nevada.

Pertussis is also known as whooping cough because of the "whooping" sound that is made when gasping for air after a fit of coughing. Pertussis generally presents as rhinorrhea, malaise, nonproductive cough, and low grade fever. Gradually, the cough gets more severe to the "whooping" level and can last for up to 10 weeks or more; sometimes known as the "100-day cough."

Treatment of pertussis is with macrolide antibiotics (ie, azithromycin) or sulfamethoxazole/trimethoprim for those patients with a contraindication to macrolides. However, antibiotics do not have much success if not initiated early in disease progression before the "whooping" phase of the cough occurs. Over-the-counter antitussive products do not have much success on ameliorating cough in the "whooping" stage as well.

It is important to remember the DTaP is the vaccine of choice for infants and children up to ages four to six years old. The capitalized letters indicate higher quantities of diphtheria and pertussis compared to Tdap (upper case and lower case letters may be the cause for wrong dose; please stay vigilant of that concept). Since most immunizing pharmacists vaccinate five-year-olds and up and no immunizing pharmacists standing orders include DTaP, we will restrict its guidelines to Tdap vaccine.

In 2007, the Nevada State Health Division revised the Nevada Administrative Code 392.105 to mandate Tdap vaccinations for those children going into the public school system. All students entering into the 7th grade **must** be vaccinated against Bordella pertussis. The only exception is due to religious beliefs or medical conditions. This intervention has helped to improve adolescent vaccination rates and is in concordance with the ACIP recommendations. 2011 ACIP recommendations for Tdap vaccination follows:

- All children ages seven through 10 years who are not fully vaccinated against pertussis should receive a single dose of Tdap. Those never vaccinated against tetanus, diphtheria, or pertussis, or who have unknown vaccination status should receive a series of three vaccinations. The first of these three doses should be Tdap (fully vaccinated is defined as five doses of DTaP or four doses of DTaP if the 4th dose was administered on or after the child's 4th birthday).
- All adolescents and adults ages 11-64 years who have not received a dose of Tdap or whose vaccination status is unknown should receive a single dose of Tdap as soon as feasible.
- Adults age 65 years and older who have not previously received Tdap, and who have or who anticipate having close contact with a child younger than age 12 months, should receive a single dose of Tdap to reduce the likelihood of transmitting pertussis to an infant. Other adults age 65 years and older who have not previously received Tdap may be given a single dose of Tdap in place of tetanus, diphtheria (Td).
- Tdap can be given regardless of interval since the last Td vaccination was given. The ACIP concluded that while longer intervals between Td and Tdap vaccinations could decrease the occurrence of local reactions, the benefits of protection against pertussis outweigh the potential risk for adverse events.
- Women who intend to become pregnant should be assessed and vaccinated with Tdap at a preconception visit. Tdap is not contraindicated in pregnancy and may be used in certain situations.

Pertussis continues to be poorly controlled despite national immunization programs. For more information on Tdap and pertussis, visit *www.cdc.gov* or *www.immunize.org/acip/*.

The *Nevada State Board of Pharmacy News* is published by the Nevada 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.

Larry Pinson, PharmD - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Larissa Doucette - Communications Manager

NEVADA STATE BOARD OF PHARMACY

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744