January 2017

Nevada State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Board Members

Changing Faces

Nevada State Board of Pharmacy staff is delighted to welcome Governor Brian Sandoval's latest appointment to the Board, Robert (Bob) Sullivan, as the public member. Bob replaces Cheryl Blomstrom, who has admirably served the past six years and elected to not reapply for a third term. Cheryl has been an invaluable asset to the Board over her tenure, especially in helping guide the Board through legislative processes. She will be truly missed, and the Board wishes her the best in her retirement.

Bob comes to the Board from the world of education, having retired after more than 30 years of service, 22 of which included serving as a high school administrator. He graduated from the University of Nevada, Reno with a bachelor of science in business administration and then earned a master's degree from the University of San Francisco in educational administration. He has also served on numerous district and state associations as a member as well as in leadership roles.

An accomplished golfer and bona fide sports enthusiast, Bob and his wife, Stephanie, have two children, Erin and Casey.

Bowl of Hygeia Awarded to Adam Porath, PharmD

Congratulations to Adam Porath, PharmD, for being selected by the Nevada Bowl of Hygeia Committee as the 2016 recipient for the state of Nevada. Adam is currently the ambulatory pharmacy manager for Renown Regional Medical Center in Reno, NV. He has been active in virtually every facet of pharmacy from education to politics over the years, including research, and he has also been quite active with the Nevada Society of Health-System Pharmacists. In 2013, Adam was named "Preceptor of the Year" at Idaho State University for his outstanding teaching and leadership for the university with Reno students. Adam is a graduate of Idaho State University (PharmD, 2006) and the University of Nevada, Reno (bachelor of science in biology, 2000). Active in his community as well, Adam is a well-deserving awardee!

No Prescription Needed!

By Yenh Long, PharmD, BCACP, Program Administrator for the Nevada Prescription Monitoring Program

Most of you are well aware by now that the Good Samaritan Drug Overdose Act (Senate Bill 459, 2015) allows a pharmacist to dispense an opioid antagonist (OA) such as naloxone to a person at risk of experiencing an opioid-related drug overdose or to a family member, friend, or other person in a position to assist such a person **without** a prescription!

A pharmacist may dispense an OA **without** a prescription so long as he or she complies with regulations developed by the Board. These regulations were adopted into law and became effective September 9, 2016.[1]

A pharmacist can dispense an OA without a prescription in one of two ways, under a:

1. **Standardized procedure** written and implemented by the pharmacy; **or**
2. **Written protocol** by a physician authorized to prescribe an OA.

The **standardized procedure** must include the following, without limitation:

1. A restriction that the registered pharmacist will not delegate his or her authority to dispense an OA (ie, delegating the task to a pharmacy technician); and
2. Procedures for counseling a recipient of an OA. The counseling must include:
   a. Information relating to the recognition, prevention, and responses to opioid-related drug overdoses;
   b. Methods for the safe administration of an OA;
   c. Potential side effects and adverse events related to the administration of an OA;

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National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at *www.ecfr.gov.*

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at *www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf.* FDA provides more information online at *www.fda.gov/Drugs/DrugSafety/ucm524320.htm.*

Selected Medication Risks to Manage in 2017

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.[1] Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting.[1,2] This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.[1,2]

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.[3,4] Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.[4] Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.[4] Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.[4] Medication rooms should provide illumination at 100 fc.[4] Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy[3] and should be used on mobile medication carts (including those used with bar code medication verification systems)[4] and near ADCs.

References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. www.ismp.org/sc?id=1664.

DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at *www.dea.gov/divisions/hq/2016/hq100416.shtml* and in the final order available at *https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf*.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, "Pharmacists: On the Front Lines," offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at *www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf*.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA's news release indicates the changes are part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm*.

FDA's Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars*.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will "alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse." In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at *www.fda.gov/Drugs/DrugSafety/ucm526206.htm*.

Latest FDA Drug Info Rounds Training Videos Available

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Extortion Scam," pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA's CDER, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

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d. The importance of seeking emergency medical assistance for a person experiencing an opioid-related drug overdose, even after the administration of an OA; and
e. Information regarding the immunity from certain civil or criminal liabilities for those seeking medical assistance for themselves or for another person experiencing an opioid-related overdose (Nevada Revised Statutes (NRS) 453C.150).[2]

The physician **written protocol** must include, without limitation:

1. The name of the physician authorizing the dispensing of the OA by a registered pharmacist;
2. The OA to be furnished;
3. A procedure on the proper steps for furnishing an OA;
4. A procedure for the annual review of the protocol and its operation by the physician and documentation of the review;
5. Specific instructions relating to the age of the patient, if appropriate;
6. A statement that the OA will be dispensed by the pharmacist in accordance with all applicable federal, state, and local laws;
7. The signature of the physician authorizing a registered pharmacist to dispense an OA without a prescription and the time period for which the protocol is effective; and
8. Any other limitations set by the physician.

The physician shall supervise the implementation of the protocol and be readily accessible to the registered pharmacist or the recipient of the OA for consultation, assistance, and direction.

If a pharmacist dispenses an OA under one of the two options above, he or she must complete at least one continuing education unit approved by the Accreditation Council for Pharmacy Education on the use of OA and the counseling of a recipient of an OA.

References

1. LCB File No. R058-16. Adopted Regulation of the State Board of Pharmacy. www.leg.state.nv.us/Register/2016Register/R058-16A.pdf. Accessed November 8, 2016.
2. NRS Chapter 453C. Good Samaritan Drug Overdose Act. https://www.leg.state.nv.us/NRS/NRS-453C.html. Accessed November 8, 2016.

Inspector's Corner

Tip: Do not allow your technician to cover the National Drug Code (NDC) or Universal Product Code of a unit-of-use bottle or package with a label during the filling process. Obviously, doing so disables your ability to scan the bottle for accuracy, which is exactly what happened in a recent case where the wrong strength was dispensed, harming the patient. The scanning process was omitted simply because the NDC was covered.

Ghost Towns and Medicines

The Board office was presented with a copy of a fascinating new book, Volume II of *The Nevada Bottle Book* series by esteemed author Fred N. Holabird, titled *Ghost Towns & Medicines: Drug Store Bottles*. Bernd Schwalbe, a practicing Nevada pharmacist for some 36 years, writes in his forward to the book: "The reader is taken on a journey of medicine in the Old West, specifically as it relates to the field of pharmacy. This task is accomplished by tracing medicinal bottles used in the pharmacies as medicine came to the rough and tough mining towns in Nevada . . . " The dedication, tenacity, travel, and energy that Fred has spent at researching facts for this book is simply amazing. The book is available through Barnes & Noble, Sundance Books and Music in Reno, and state museum bookstores.

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