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Nevada State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Attention Managing Pharmacists

Housekeeping

NAC 639.469, Standards for Premises, Section 2, states, "The pharmacy must be kept clean and arranged in an orderly manner. All required equipment must be clean and in good operating condition." Board inspectors have recently wondered if any pharmacy in the state even owns a vacuum cleaner! They are reporting dirty, dusty shelves; filthy un-vacuumed carpets; tablets and capsules on the floors; many outdated products; and simply unacceptably messy conditions in an environment that is providing health care to our citizens. Be forewarned, managing pharmacists! Board inspectors will be enforcing the above-referenced regulation. Your working environment should be one that you can be proud of; your patients deserve it and your staff deserves it.

Licensing Issues

Board staff is forever amazed that a managing pharmacist would ever allow an unlicensed pharmacist, intern, or technician to work in his or her pharmacy, yet meeting after meeting, the Nevada State Board of Pharmacy is prosecuting both pharmacy managers and their unlicensed personnel for simply that. **You must check and verify!** This is part of your job. The Board recently found an intern pharmacist who had worked for over a year at four different pharmacies totally unlicensed (none of the pharmacies bothered to check, much less hang a copy of her registration on the wall, as required by law). Similarly, the Board discovered a pharmacy technician who had moved to Nevada from Florida and just began working as a technician in a pharmacy, never even being licensed in Nevada, and in fact, just never asked about licensure. Again, no one bothered to check and again, there was no certificate hung on the wall. The managing pharmacist is responsible for this obvious diligence and will be disciplined along with the culprit. So, possibly while your pharmacy is being vacuumed, you might glance at the wall and verify that all of your staff members are properly licensed!

Continuing Education Audit for Pharmacists

Board staff has completed the biannual audit of compliance with continuing education (CE) regulations through a random selection process, and is once again aghast at the findings. The CE requirements are straightforward and simple:

- 30 hours every two years
- CE must be Accreditation Council for Pharmacy Education (ACPE)-accredited
- The 30 hours must include one hour of law provided by the Board

Yet the Board has a stack of paperwork representing pharmacists who just did not comply, and the consequences are not pretty. The Board takes CE seriously, as does the Nevada Legislature, and the Board reminds you that when you renew online, you are checking a box **attesting under the penalty of perjury** that you have **completed** your CE per the regulations. When the Board discovers that you have not, you have committed perjury. A few fundamental points to remember:

- The Board accepts as accredited CE only **ACPE-accredited courses.**
- The law CE is only acceptable if the course is given by Board staff; a Board staff presentation is obtained through "Pharmacist's Letter" (the link is on the Board website's CE page); or by attending a **full day** of a Board meeting.
- When audited, a pharmacist is required to provide **copies** of CE certificates to Board staff. Pharmacists may print statements of continuing pharmacy education from CPE Monitor®.
- Advanced Cardiac Life Support CE credit can only be claimed one time and for a **maximum of six hours** only.

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New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled "Red Flags," encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described "red flags" as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARERX.ORG/pharmacists*.

Root Causes: A Roadmap to Action

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 Error Reporting Program Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for car**bam**azepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of car**bam**azepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient's medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child's car**bam**azepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.[i]

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy.* The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event.**

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event.** For more information and to access the **free** workbook, visit *www.ismp.org/tools/rca/.*

[i] *http://pediatrics.aappublications.org/content/113/2/406.abstract*

FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety*.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- The millimeter (mL) should be used as a standard unit of measurement.
- Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.
- Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* is available for download from the NCPDP website at *http://ncpdp.org/Education/Whitepaper*.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum,* and may currently be viewed on the USP website at *www.usp.org/usp-nf*. Comments will be accepted until July 31, 2014.

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

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Basic CPR courses can be claimed for a maximum of two hours.

Bottom line: Do your CE and keep good records so that you can prove it. It is common sense and is required by law.

FDA Link Now on Website

Board staff is happy to report that the Board now has a link on its website to Food and Drug Administration (FDA) to sign up for FDA e-mail alerts for quick access to drug-related issues: *https://public.govdelivery.com/accounts/USFDA/subscriber/new?topic_id=USFDA_19*.

Federal Drug Quality and Security Act

On November 27, 2013, President Barack Obama signed into law the Drug Quality and Security Act (DQSA) primarily as the result of the New England Compounding Center (NECC) compounding fiasco that killed many and injured hundreds of patients. The act is intended to ensure the integrity of the prescription drug supply chain and includes the compounding of pharmaceuticals. As background, pharmacies are licensed by boards of pharmacy to fill prescriptions, and manufacturers are licensed by FDA to manufacture drugs. NECC, which was licensed as a pharmacy and hence not inspected by FDA, was clearly manufacturing compounded medications and shipping them all over the country. The DQSA consequently has added a business class now referred to as "outsourcing facilities," defined as a facility that is engaged in the compounding of sterile drugs; has registered with the FDA as such; and complies with Section 503B of the new law. 503B requires outsourcing facilities to comply with current Good Manufacturing Practices; be inspected by the FDA; and report adverse events with their products among other requirements.

Pharmacies may still compound prescriptions on a patient-specific basis and a practitioner is still prohibited from dispensing an "office use" compounded product to his or her patients.

Pharmacy Technician In-Service Training Reminders

A topic always inquired about by the Board's licensed technicians is their in-service training hours. Many technicians refer to them as CE, which, if accepted by their managing pharmacists, the Board, in turn, will accept them as meeting the requirement of 12 hours every two years. A few reminders:

- In-service hours are to be maintained at the pharmacy in which the technician is employed.
- Certificates will be checked upon the inspection of the pharmacy and **must** be readily available to the inspector.
- Do **not** expect to provide your CPE Monitor login to the inspector for review. He or she will check certificate copies.
- One hour in an approved Nevada law program is required for both technicians **and** technicians-in-training **prior** to renewal of licensure (October 31 – even-numbered years). As a courtesy, the Board provides a link on the CE page for the only online approved program, and it is **free** to Board licensees.
- The 12 hours are counted starting from the date of hire and can be calculated at 0.5 hours per month. Though hours are not required monthly, inspectors will review them to ensure that hours are being completed and not ignored. For example, if the hire date is January 1, and the pharmacy is inspected in June of that same year, the inspector will look for some hours to have been completed. If no hours have been completed within that six-month period, then plan for the inspector to make note of it.
- The Board does not dictate which in-service programs are to be completed for the other 11 hours required. Please see your managing pharmacist for appropriate programs to best serve your patients.

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™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

Larry Pinson, PharmD - State News Editor

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

Deborah Zak - Communications Manager