



Nevada State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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NPLEx

This is a reminder that participation in the National Precursor Log Exchange (NPLEx) system for the electronic tracking of pseudoephedrine (PSE) purchases became mandatory on September 3, 2014, as the result of AB 39 during the last legislative session. Please refer to NRS 639.430 through 639.450 and to the letter sent to all pharmacies from the Nevada State Board of Pharmacy office on June 16, 2014, for details. Hopefully this statewide, real-time, electronic PSE monitoring program will help curtail illegal PSE purchases and prevent “home brewed” methamphetamine production.

‘Red Flags’ Video

The Board, in conjunction with the National Association of Boards of Pharmacy® and the Anti-Diversion Industry Working Group, has released and linked to its website (<http://bop.nv.gov>) a new educational video entitled “Red Flags” for pharmacists and pharmacy technicians to help them identify the warning signs of prescription drug abuse and diversion. Please take a few minutes and watch the video at <http://bop.nv.gov/resources/PrescriptionDrugAbusePreventionVideo>.

Pharmacy Technicians

It is your responsibility to maintain your in-service training records (continuing education) at the primary pharmacy of your employment. Board inspectors will

ask to inspect those records, far too often finding nothing to inspect; then you and your pharmacy manager get reprimanded. Do not expect to provide your CPE Monitor® login to the inspector for review. Please keep those records in a file in the pharmacy.

Tramadol Goes Schedule IV

All regulatory requirements applicable to Schedule IV controlled substances apply to tramadol as of August 18, 2014, when the Drug Enforcement Administration (DEA) final rule placing tramadol in Schedule IV became effective. Tramadol was first approved for use in the United States by Food and Drug Administration (FDA) in 1995, under the trade name Ultram®. Subsequently, FDA has approved generic, combination, and extended release tramadol products distributed in various forms (tablets, capsules, liquid).

The abuse of tramadol has increased over the past several years during our country’s prescription drug abuse epidemic, being substituted for other opioids. The Board has begun the process of changing its regulations to include tramadol in Schedule IV and bring state law into compliance with federal law.

Hydrocodone Products Go Schedule II

On Friday, August 22, 2014, DEA published in the *Federal Register* the final rule moving hydrocodone products from Schedule III to the more restrictive Schedule II. This final rule went into effect 45 days thereafter.

The abuse of hydrocodone is well known and documented in our country, with hydrocodone usually being ranked as the number one opiate of abuse in most states. Likewise, the Board has begun the process of changing its regulations to include hydrocodone products in Schedule II to mirror federal law.

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DEA Reschedules Hydrocodone Combination Products as Schedule II

Drug Enforcement Administration (DEA) has published its final rule rescheduling hydrocodone combination products from Schedule III to Schedule II in the *Federal Register*. The change imposes Schedule II regulatory controls and sanctions on anyone handling hydrocodone combination products, effective October 6, 2014. DEA first published the proposed rules in March 2014 in response to a Food and Drug Administration (FDA) recommendation. DEA received almost 600 public comments regarding the proposed rules after they were published, with a small majority of the commenters supporting the change, DEA notes in a press release, which is available at www.justice.gov/dea/divisions/hq/2014/hq082114.shtml.

The announcement is available on the *Federal Register* website at <https://federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule>.

The mL-Only Standard for Liquid Dosing Gathers Steam

 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. E-mail: ismpinfo@ismp.org.

ISMP first reported on the confusion of teaspoonfuls and milliliters (mL) in its newsletter in 2000, and in 2009, issued a call for practitioners to move to sole use of the metric system for measuring over-the-counter and prescription oral liquid doses, but mix-ups have continued to result in the serious injury of children and adults. Use of the metric system alone when prescribing, dispensing, and administering medications would prevent mix-ups because there would only be one method used to communicate and measure doses.

The health care industry is beginning to acknowledge the risk of confusion when using non-metric measurements, especially with oral liquid medications. The National Council for Prescription Drug Programs (NCPDP) just released a white

paper entitled *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications*, which is available at www.ismp.org/sc?id=337. The white paper supports mL as the standard unit of liquid measure used on prescription container labels for oral liquid medications. It also calls for dosing devices with numeric graduations, and for units that correspond to the container labeling to be easily and universally available, such as including a device each time oral liquid prescription medications are dispensed. NCPDP also reiterates that dose amounts should always use leading zeroes before the decimal point for amounts less than one, and should not use trailing zeroes after a decimal point on labels for oral liquid medications.

The white paper comes as welcome news and is well-aligned with the *ISMP 2014-15 Targeted Medication Safety Best Practices for Hospitals*, Best Practice 5, which calls for organizations to use oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale. The white paper also comes at a time when the Centers for Disease Control and Prevention, ISMP, the Consumer Healthcare Products Association, the United States FDA, the US Metric Association, and the American Academy of Pediatrics have initiatives in place that will help guide health care organizations to commit to metric measurements.

ISMP recommends the following actions to help prevent errors:

- ◆ Use only metric units, not teaspoon or other non-metric measurements, for all patient instructions, including those listed in prescribing and pharmacy computer systems. This should cover directions incorporated into computer system mnemonics, speed codes, or any defaults used to generate prescriptions and prescription labels.
- ◆ Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters.
- ◆ Coach patients on how to use and clean measuring devices; use the “teach back” approach and ask patients or caregivers to demonstrate their understanding.

DEA Classifies Tramadol a Controlled Substance

Under a final rule published in the *Federal Register*, the pain reliever tramadol is now classified as a Schedule IV controlled substance. As of August 18, 2014, DEA requires manufacturers to print the “C-IV” designation on all labels that contain 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol (tramadol), including its salts, isomers, and salts of isomers. The agency notes that every “DEA registrant who possesses any quantity of tramadol on the effective date of this final rule must take an inventory of all stocks of tramadol on hand as of August 18, 2014, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11 (a) and (d).” In addition, all “prescriptions for tramadol



or products containing tramadol must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of August 18, 2014.”

The announcement is available on the *Federal Register* website at www.federalregister.gov/articles/2014/07/02/2014-15548/schedules-of-controlled-substances-placement-of-tramadol-into-schedule-iv.

FDA Lowers Recommended Starting Dose for Lunesta Due to Risk of Morning Impairment

FDA has lowered the recommended starting dose of the sleep drug Lunesta® (eszopiclone) from 2 mg to 1 mg. Patients who are currently taking 2 mg and 3 mg doses of eszopiclone should contact their health care provider to ask for instructions on how to continue to take their medication safely at a dose that is best for them, FDA advises. The dose change came after findings from a study of 91 healthy adults found that the medication was associated with impairment to driving skills, memory, and coordination for as long as 11 hours after the drug is taken, FDA notes.

More information is available in an FDA news release at www.fda.gov/newsevents/newsroom/pressannouncements/ucm397453.htm.

Lidocaine Should Not Be Used to Treat Teething Pain in Children, FDA Warns

FDA is recommending that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain, and is now requiring a new boxed warning to be added to the drug label to highlight this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death, indicates FDA in a June 2014 Safety Announcement. FDA advises health care providers not to prescribe or recommend this product for teething pain. FDA is also requiring the “Warnings” and “Dosage and Administration” sections of the drug label to describe the risk of severe adverse events and to include additional instructions for dosing when the drug is prescribed for approved uses.

In 2014, FDA reviewed 22 case reports of serious adverse reactions, including deaths, in infants and young children who were either given lidocaine for treatment of mouth pain, or who accidentally ingested the medication.

More information is available in the safety announcement on FDA’s website at www.fda.gov/Drugs/DrugSafety/ucm402240.htm.

FDA Reiterates Warning Against Using NuVision Pharmacy Products

Health care providers should not use or distribute compounded drugs marketed as sterile produced by Downing Labs, LLC, of Dallas, TX, also known as NuVision Pharmacy,

warns FDA. Inspection results issued on July 16, 2014, indicate that FDA observed unsanitary conditions resulting in a lack of sterility assurance of sterile drug products produced by the company, which may put patients at risk, FDA notes in the safety announcement. “The inspection revealed sterility failures in 19 lots of drug products intended to be sterile, endotoxin failures in three lots of drug products, and inadequate or no investigation of these failures,” states FDA in the announcement.

In 2013, the agency issued several similar warnings following NuVision’s refusal to recall all sterile products. In April 2013, NuVision recalled methylcobalamin injection and lyophilized injection products, citing concerns about sterility in the wake of adverse event reports. Health care providers and consumers may report adverse events or quality problems associated with NuVision products to FDA’s MedWatch Safety Information and Adverse Event Reporting Program.

Additional information is available in the safety announcement, available on FDA’s website at www.fda.gov/Drugs/DrugSafety/ucm405940.htm.

JCPP Releases New Patient-Care Document to Promote Consistency

The Joint Commission of Pharmacy Practitioners (JCPP) has released a resource document aimed at promoting consistency in the pharmacists’ process of patient care service delivery. “Pharmacists’ Patient Care Process” was developed by examining key source documents on pharmaceutical care and medication therapy management. The document describes the process in five parts: collect, assess, plan, implement, and follow-up.

JCPP brings together the chief executive officers and elected officers of national pharmacy associations, including the National Association of Boards of Pharmacy®, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice.

The document can be downloaded online at www.pharmacist.com/sites/default/files/JCPP_Pharmacists_Patient_Care_Process.pdf.

CPE Credit Offered for FDA Course on Misleading Prescription Drug Promotion

To raise awareness about the risks associated with false or misleading prescription medication marketing, FDA, in partnership with Medscape, is offering an online, one-hour continuing education course through its Bad Ad Program. Pharmacists may receive continuing pharmacy education (CPE) credit by taking this course. Learning objectives, faculty information, and other information is available on the course’s website at www.sigmatech.com/BadAd. There is no registration fee for the course. Upon completion, pharmacists will receive one Accreditation Council for Pharmacy Education-accredited CPE hour (0.1 continuing education unit).

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Now the question arises as to the handling of refills indicated on hydrocodone prescriptions dated before October 6. The Board will mirror the language in the *Federal Register's* final rule by allowing pharmacists to honor those refills for up to six months.

Attention Pharmacies

Claims Adjudication Process to Validate OPR Practitioners

In order for Medicaid to reimburse for services or medical supplies that require a provider's order, prescription, or referral, the Affordable Care Act (42 CFR Parts 405, 447, 455, 457, and 498) requires that the ordering, prescribing, or referring (OPR) provider be enrolled in Medicaid. Compliance with this requirement necessitates **future** changes to Nevada Medicaid claims and provider enrollment processes. The Nevada Department of Health and Human Services Division of Health Care Financing and Policy is actively working on the implementation of this new requirement, which is anticipated to occur in fourth quarter 2014.

How Will This Affect You?

The practitioner writing a prescription for a Medicaid Fee-for-Service recipient needs to be enrolled as a full Medicaid service provider or an OPR-only provider by the **last quarter of 2014**.

To comply with these provisions, Nevada Medicaid, with the implementation of the OPR claims adjudication process, will verify both the presence of a valid practitioner National Provider Identifier (NPI) and the practitioner's enrollment in Nevada Medicaid as either a full Medicaid service provider or an OPR-only provider. Pharmacy claims will post an edit informing the billing provider if the NPI for the prescriber is not present. If the prescriber does not have prescriptive authority, or is not enrolled as either a full Nevada Medicaid service

provider or an OPR-only provider, the edit will result in a claim denial.

Every prescriber must include his or her personal NPI on each prescription. Every pharmacy must accurately submit this prescriber NPI with each prescription claim. If a provider intentionally submits a claim with a prescriber NPI that he or she knows to be inaccurate, he or she is committing a fraudulent act, and may be subject to administrative, civil, and/or criminal actions.

For more information about the changes to billing and the new OPR provider enrollment category, call the Catamaran Technical Call Center at 866/244-8554.

And Finally. . .

Pharmacy technicians, your license renewal deadline is October 31!