December 2014

News

Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

1199 Shoreline Lane, Suite 303 • Boise, ID 83702

Changes Pharmacists May Make to Schedule II Prescription Drug Orders

The Idaho State Board of Pharmacy supports a Drug Enforcement Administration (DEA) statement whereby a pharmacist may use his or her professional judgment in addressing a prescription drug order for a Schedule II controlled substance (CS) that is incomplete or deemed incorrect, pursuant to the following updated Board policy. A pharmacist may change or add the dosage form, drug strength, drug quantity, and directions for use only after consultation with and agreement of the prescriber. After consultation with and agreement of the prescriber, a pharmacist may also add a missing date or change an obvious prescriber's error when writing the date, such as the prior year when a new year has just begun, but a date may never be changed to circumvent an expiration date or to provide a dispensing earlier than a prescriber has authorized when issuing multiple Schedule II prescription drug orders. Additionally, to satisfy the requirements of Section 37-2725(6), Idaho Code, which requires an alpha and numeric quantity on Schedule II prescription drug orders, after consultation and agreement with the prescriber, a pharmacist may add or change the alpha and/or numeric quantity. Also, a patient's address and a prescriber's DEA registration number may be added to a prescription drug order or corrected without consulting the prescriber after verifying from another reliable source. Finally, the patient's name may be corrected, such as changing a maiden name to a married name or correcting a misspelled name, but the patient's name, the physician's name, and the drug name may otherwise never be added or changed.

Hydrocodone Combination Products Rescheduled as Schedule II

On October 6, 2014, all hydrocodone combination products (HCPs), including products such as Vicodin®, Lortab®, Norco®, and Tussionex®, were rescheduled federally into Schedule II. HCPs are the number one prescribed opioid in the United States; nearly 137 million prescriptions were dispensed in 2013. As the Board did not object to this federal rescheduling, these products are also now Schedule II CS in Idaho, and codification into written Idaho code is expected to be approved by the 2015 Idaho Legislature. Each registrant who had these products in his or her possession was to inventory the products on October 6, 2014, pursuant to Board Rule #206.05 and federal law. HCPs are now subject to the more stringent Schedule II record-keeping requirements, and must be distributed pursuant to a DEA Form 222. Any legitimate prescription drug orders for HCPs that were issued before October 6, 2014, that authorize refills may be dispensed if such dispensing occurs before April 8, 2015. Prescription drug orders issued after October 6, 2014, may not be refilled; however, a prescriber may issue multiple prescriptions authorizing up to a 90-day supply in total, according to Board Rule #113.02 and federal law.

CS Registration Renewal for Non-Pharmacists

CS registrations for all persons except pharmacists expire December 31, annually. The renewal fee is $60. Renewal postcards were mailed to the mailing address on file on October 27, 2014. If you have not received the renewal notice (8" x 5" yellow postcard) or you are unable to log into the online renewal system, please contact the Board office for a personal identification number at info@bop.idaho.gov or call 208/334-2356.

Fee Exemption. The fee requirement for registration renewal will be waived (fee exempt) if:

- **DEA Exemption:** Pursuant to Idaho Administrative Rule IDAPA 27.01.01.20.05 – Fee Exemption for Controlled Substance Registrations, "Persons or drug outlets exempt pursuant to federal law from fee requirements applicable to controlled substance registrations issued by the DEA are also exempt from fees applicable to controlled substance registrations issued by the Board."
- **Military Exemption:** Pursuant to Idaho Code 67-2602A, any licensee serving in the armed forces of the US is exempt from the payment of license fees during any period of military service. If the military exemption applies, please indicate the branch of service and provide proof of military service.

Late Renewal. If you have continued to practice in Idaho after December 31, 2014, you can renew late until January 31, 2015. All registrants, including those that are "fee exempt," are subject to a late fee of $50.

Reinstatement. If you have continued to practice in Idaho after December 31, 2014, and did not renew by January 31, 2015, the online renewal system will not be accessible. Please use the following link to access the Board website and complete the paper Idaho Controlled Substance Registration Reinstatement Application: *www.bop.idaho.gov/renew/index.html.* All registrants, including those who are "fee exempt," are subject to late and reinstatement fees. The fee for reinstatement is $185, or $125 if "fee exempt."

New Board Inspector

The Board has hired a new inspector for northern Idaho: Wendy Shiell. Ms Shiell holds an associate of science degree in radiologic sciences, has managed within a medical center and a larger mercantile store that contains a pharmacy, and has been employed as a pharmacy technician. Please join us in welcoming Ms Shiell.

New DEA Number Series

DEA announced that the Department of Defense personal service contractors will be issued a new DEA registration "number" that begins with the letter "G." This new first character will be in addition to the current first characters A, B, and F of the DEA registration for practitioners. The "G" series DEA registration number will be listed in the database and available on the DEA website validation query system. A review of the registrant type (first letter of DEA number) follows.

- **A/B/F/G** – Hospital/Clinic/Practitioner/Teaching Institution/Pharmacy
- **M** – Mid-Level Practitioner (NP/PA/OD/ET, etc)

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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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- **P/R** – Manufacturer/Distributor/Researcher/Analytical Lab/Importer/Exporter/Reverse Distributor/Narcotic Treatment Program

Recent Board Discipline

M.T., PharmD: $500 fine and six additional continuing pharmacy education (CPE) hours for misfilling a prescription.

B.D., PharmD: $1,000 fine and six additional CPE hours for misfilling a prescription and failing to offer counseling.

V.B., RPh: $200 fine for allowing an unregistered technician to work in the pharmacy.

W.D., RPh: $200 fine for allowing an unregistered technician to work in the pharmacy.

S.N., Pharmacy Technician: $100 fine for working unregistered in a pharmacy.

K.L., PharmD: License and CS registration revoked for diversion.

D.G., Certified Technician: Registration revoked for a lack of fitness for professional practice and intoxication, impairment, or consumption of drugs while on duty.

K.F., Certified Technician: Registration revoked for theft of CS.

J.D., PharmD: License and CS registration revoked pursuant to voluntary surrender.

D.H., NP: Due to diversion, CS registration restricted as to not order, handle, administer, or dispense CS for two years.

S.W., NP: Due to diversion, CS registration restricted as to not order, handle, administer, or dispense CS or issue verbal orders for CS for two years.

H.C., DDS: CS registration restricted as to not order, handle, administer, or dispense CS for two years.

B.Z., PA: Amended original Board order restricting Schedule II privileges to no longer include a restriction of hydrocodone prescribing privileges.

E.H., DDS: Amended original Board order to reinstate Schedule II privileges.

E.C., NP: CS registration revoked for not maintaining appropriate records of CS.

S.S., DO: CS registration restricted pursuant to State of Idaho Board of Medicine order.

L.A., OD: CS registration restricted as to not order, handle, administer, or dispense CS for two years.

T.C., DDS: CS registration restricted as to not order, handle, administer, or dispense CS for two years.

D.A., RPh: Six additional continuing education units (CEUs) and a $150 fine for failing to obtain required CEUs.

H.A., PharmD: Six additional CEUs and a $150 fine for failing to obtain required CEUs.

J.B., PharmD: Four additional CEUs and a $100 fine for failing to obtain required CEUs.

G.D., RPh: Twelve additional CEUs and a $300 fine for failing to obtain required CEUs.

S.D., PharmD: Two additional CEUs and a $50 fine for failing to obtain required CEUs.

P.E., RPh: Fourteen additional CEUs and a $350 fine for failing to obtain required CEUs.

W.E., RPh: Two additional CEUs and a $50 fine for failing to obtain required CEUs.

C.E., PharmD: Eighteen additional CEUs and a $450 fine for failing to obtain required CEUs.

D.H., RPh: Two additional CEUs and a $50 fine for failing to obtain required CEUs.

M.H., RPh: Twelve additional CEUs and a $300 fine for failing to obtain required CEUs.

J.J., PharmD: Fifteen additional CEUs and a $375 fine for failing to obtain required CEUs.

B.J., RPh: Four additional CEUs and a $100 fine for failing to obtain required CEUs.

S.L., PharmD: Two additional CEUs and a $50 fine for failing to obtain required CEUs.

N.M., PharmD: Twenty-three additional CEUs and a $575 fine for failing to obtain required CEUs.

J.P., PharmD: Ten additional CEUs and a $250 fine for failing to obtain required CEUs.

Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns/externs, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them filed in your pharmacy, preferably in your *Idaho Pharmacy Law Book,* for future reference.

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

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