



Oregon State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

800 NE Oregon St, Suite 150 • Portland, OR 97232

No. 541: Controlled Substance Transfers

The rescheduling of medications serves as a good time to go back to the basics regarding transfers of a controlled substance (CS) prescription. Prescription transfers are not mandated federally or by the state of Oregon. However, in the event of transferring a CS, would you be able to answer the following questions?

- ◆ Do you obtain the physical address of the pharmacy to which you transfer?
- ◆ What is the process for voiding the prescription in the eyes of Drug Enforcement Administration (DEA)?
- ◆ What additional information is required for a CS transfer versus a non-controlled transfer?

Verify that the procedure performed at your pharmacy is up to date and meets the federal law below.

§1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.

- (a) The transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.
- (b) Transfers are subject to the following requirements:
 - (1) The transfer must be communicated directly between two licensed pharmacists.
 - (2) The transferring pharmacist must do the following:
 - (i) Write the word "VOID" on the face of the invalidated prescription; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record.
 - (ii) Record on the reverse of the invalidated prescription the name, **address**, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record.
 - (iii) Record the date of the transfer and the name of the pharmacist transferring the information.

- (3) For paper prescriptions and prescriptions received orally and reduced to writing by the pharmacist pursuant to §1306.21(a), the pharmacist receiving the transferred prescription information must write the word "transfer" on the face of the transferred prescription and reduce to writing all information required to be on a prescription pursuant to §1306.05 and include:
 - (i) Date of issuance of original prescription.
 - (ii) Original number of refills authorized on original prescription.
 - (iii) Date of original dispensing.
 - (iv) Number of valid refills remaining and date(s) and locations of previous refill(s).
 - (v) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.
 - (vi) Name of pharmacist who transferred the prescription.
 - (vii) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled. . .

- (c) The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill. (**Note: Oregon law requires record keeping for three years.**)
- (d) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferal.
- (e) The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing State or other applicable law.

The complete rule language is available at www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_25.htm.

No. 542: Cultural Competency

The Oregon State Board of Pharmacy is charged with preserving and protecting the health of our state's citizens in the delivery of pharmacy-related health care. Oregon's population is growing increasingly diverse, and inequities in access to quality health care are apparent, according to the Oregon Health Authority's Office of Equity and Inclusion (OEI). The OEI has determined that some racial and ethnic populations; lesbian, gay, bisexual, and transgender communities; low literacy level individuals; and rural

continued on page 4



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).

continued from page 1

Oregonians experience health disparities. The Board believes that increasing understanding and awareness of the necessity to provide culturally competent health care is a patient safety priority.

The National Institutes of Health (NIH) speaks to the critical importance of health care practitioners' awareness and competency in equal care given to patients across cultural lines. The NIH provides the following background to define cultural competence.

Culture is often described as the combination of a body of knowledge, a body of belief and a body of behavior. It involves a number of elements, including personal identification, language, thoughts, communications, actions, customs, beliefs, values, and institutions that are often specific to ethnic, racial, religious, geographic, or social groups. For the provider of health information or health care, these elements influence beliefs and belief systems surrounding health, healing, wellness, illness, disease, and delivery of health services. The concept of cultural competency has a positive effect on patient care delivery by enabling providers to deliver services that are respectful of and responsive to the health beliefs, practices and cultural and linguistic needs of diverse patients.¹

Cultural competency continuing education (CE) is a lifelong process of examining values and beliefs while developing and applying an inclusive approach to health care practice in a manner that recognizes the context and complexities of provider-patient interactions and preserves the dignity of individuals, families, and communities. CE in cultural competency should teach attitudes, knowledge, and skills to care effectively for patients from diverse cultures, groups, and communities. The OEI states that such training enables health care providers to work effectively in cross-cultural situations.

The Board recommends and encourages licensees to pursue ongoing CE opportunities for cultural competency. For purposes of maintenance of licensure, the Board considers CE in cultural competency to be relevant to the current practice of all licensees, and licensees may use this type of CE toward satisfying the required CE hours for license renewal. The Board will document licensees' voluntary participation in cultural competency CE through the license renewal process beginning in 2015.

In order for Oregon to achieve the triple aim of improving health, improving care, and lowering cost, providers must be responsive to the needs of diverse populations. Cultural competency training for health care providers is one method for helping Board licensees adapt to the needs of Oregon's socially and culturally diverse communities.

¹www.nih.gov/clearcommunication/culturalcompetency.htm

No. 543: Fifty-Year Pharmacists

The Board is pleased to acknowledge the pharmacists who have been licensed in Oregon for 50 years. The Board recognizes their many years of service and contributions to the profession and to the health and well-being of the citizens of Oregon. These distinguished individuals should be proud of their accomplishments, and they deserve the recognition and acknowledgement of their profession. The following is a list of pharmacists who reached this milestone in 2013 and 2014.

David Andersen Gresham, OR	David Foster Woodland Hills, CA
William Baily Lake Oswego, OR	George Freiberg Eugene, OR
David Beach San Diego, CA	Marie Haener Aurora, OR
Arlen Berger Happy Valley, OR	Rose-Ellen Hope Silverton, OR
Donna Caldwell Portland, OR	Wallace Muzzy John Day, OR
Bruce Carlson Umatilla, OR	Richard Parsons Salem, OR
Edward Cole Portland	Darrel Purkerson Saint Helens, OR
George Constantine Albany, OR	Keith Steele Ontario, OR
Lando Crittenden Lebanon, OR	Albert Takahashi San Jose, CA
Michael Dardis Portland	Charles Walters Shell Beach, CA
Raymond Elliott Kailua-Kona, HI	Donald Wiseley Coquille, OR

Page 4 – November 2014

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

Marc Watt, RPh - State News Editor

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

Deborah Zak - Communications Manager