



Ohio State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

77 S High St, Room 1702 • Columbus, OH 43215-6126 • Tel: 614/466-4143

Fax: 614/752-4836 • www.pharmacy.ohio.gov

New Board Member Welcome

The Ohio State Board of Pharmacy is pleased to welcome new Board Member Fred M. Weaver, BS, RPh. Mr Weaver, of Elyria, OH, is a professional pharmacist member of the Board and was appointed by Governor John R. Kasich, with his first term ending June 30, 2016. He graduated from the University of Toledo in 1989 with a bachelor of science in pharmacy. His professional practice of pharmacy has included a variety of practice settings, including health system outpatient pharmacy, hospital pharmacy, mail-order, and a correctional institution. He currently is a pharmacy manager for Giant Eagle Pharmacy, where he has practiced for 14 years. Mr Weaver is a member of the following professional associations: Ohio Pharmacists Association, American Pharmacists Association, and the Northern Ohio Academy of Pharmacy.

Corresponding Responsibility and New Ohio Legislation

With the increased attention to Ohio's prescription drug abuse epidemic, the Ohio General Assembly has enacted a number of laws to address this pressing public health crisis. The Board continues to receive a number of questions regarding the role of pharmacists in these newly enacted laws.

For example, House Bill (HB) 314 (effective September 17, 2014) requires prescribers to obtain informed consent from a parent or guardian prior to initial issuance of a prescription for an opioid pain medication to a minor. While this new law primarily impacts prescribers, both Ohio laws and rules and federal laws and regulations place a corresponding responsibility on the pharmacist to use his or her professional judgment to determine if a prescription has a legitimate medical purpose and is compliant with all state and federal laws.

Pharmacists should be aware of the unique role they play in preventing addiction and misuse of prescription drugs by minors. For example, if a minor meets any of the exemptions in the law, then the pharmacist can safely assume, using professional judgment, that no informed consent by the prescriber is required. However, it is recommended that pharmacists check for informed consent if presented with a prescription where a lack of parental consent could create a patient safety issue. For example, if a 16-year-old patient

presents an initial opioid pain medication prescription with no parent or guardian present and does not meet any of the exemptions in the law, the pharmacist should verify with the prescriber that a consent form was completed (or was not required) prior to dispensing.

The Board recognizes that, as a pharmacist, you are presented with a number of different scenarios involving patient care. A pharmacist should use his or her professional judgment to ultimately decide what is in the best interest of the patient, and the lack of informed consent does **not** preclude a pharmacist from dispensing an opioid prescription to a minor.

Another new law enacted by the General Assembly, HB 341, requires a prescriber, prior to issuing a prescription for an opioid analgesic or benzodiazepine, to query the Ohio Automated Rx Reporting System (OARRS) database. It also requires **all** pharmacists to register with OARRS by September 15, 2015. While there are new mandatory requirements for prescribers to check OARRS, pharmacists should also be aware that they have a corresponding responsibility to check the system. Ohio Administrative Code (OAC) 4729-5-20 requires a check of OARRS in any of the following instances:

- (1) Receiving reported drugs from multiple prescribers;
- (2) Receiving reported drugs for more than 12 consecutive weeks;
- (3) Abusing or misusing reported drugs (eg, overutilization; early refills; appears overly sedated or intoxicated upon presenting a prescription for a reported drug; or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks);
- (4) Requesting the dispensing of reported drugs from a prescription issued by a prescriber with whom the pharmacist is unfamiliar (eg, prescriber is located out-of-state or prescriber is outside the usual pharmacy geographic prescriber care area); or
- (5) Presenting a prescription for reported drugs when the patient resides outside the usual pharmacy geographic patient population.

In conclusion, the pharmacist – not an employer, supervisor, or a fellow employee – is the one held accountable for making an independent judgment to ensure that a prescription

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).

presented at the pharmacy is legitimate. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, a pharmacist who deliberately looks the other way when there is reason to believe that the purported prescription had not been issued for a legitimate medical purpose risks the loss of his or her professional license and may be prosecuted criminally. If you have any questions regarding corresponding responsibility, please contact the Board directly by visiting www.pharmacy.ohio.gov/contact.aspx.

Board Releases Guidance Documents on Law and Rule Changes

The ‘Take-Back Rules’

Authorized entities are permitted to engage in the collection of pharmaceutical drugs from ultimate users if they comply with Drug Enforcement Administration (DEA) and Board regulations. To assist in the implementation of these new rules, the Board has developed the following guidance document, located at www.pharmacy.ohio.gov/takeback.

HCPs Are Now Schedule II

Effective October 6, 2014, all hydrocodone combination products (HCPs) will be classified as Schedule II controlled substances (CS) pursuant to a rule adopted by the United States DEA on August 22, 2014. The Board created a guidance document to assist in complying with this rule change. The document can be accessed at www.pharmacy.ohio.gov/hydrocodone.

The Board has also developed guidance documents regarding new rule changes and one upcoming law change. Please take the time to review the following documents.

- ◆ **CS Inventory Rule Change (www.pharmacy.ohio.gov/inventory):** Effective January 1, 2015, OAC Rule 4729-9-14 requires each prescriber or terminal distributor of dangerous drugs to take inventory of all stocks of CS on hand every year following the date on which the initial inventory is taken. This is a change from the previous version of the rule that required a CS inventory every two years.
- ◆ **Drugs Compounded in a Pharmacy Must Adhere to US Pharmacopeial Convention (USP) Chapters <795> and <797> (www.pharmacy.ohio.gov/USP):** Effective January 1, 2015, OAC Rule 4729-9-21 requires drugs compounded in a pharmacy to adhere to USP Chapters <795> for nonsterile compounded drugs and <797> for sterile compounded drugs. Additionally, all compounded prescriptions must also adhere to Section 503A of the Federal Food, Drug, and Cosmetic Act.
- ◆ **Informed Consent for Opioids Prescribed to a Minor (www.pharmacy.ohio.gov/HB314):** Effective September 17, 2014, HB 314 requires all prescribers (physicians, physician assistants, advanced practice registered nurses, optometrists, dentists, and podiatrists) to obtain explicit informed consent, in the absence of a medical emergency or other specified circumstances (see the guidance document), if they intend to prescribe to minors CS containing opioids. The guidance document also outlines a pharmacist’s corresponding responsibility regarding this new law change.
- ◆ **Non-Self-Injectable Drugs (www.pharmacy.ohio.gov/SB230):** Effective September 17, 2014, Senate Bill 230 prohibits pharmacists and pharmacy interns from dispensing

certain non-self-injectable cancer drugs by delivering them or causing them to be delivered directly to the patient, the patient’s representative, or the patient’s private residence. The dispensing prohibition does not apply when the patient’s private residence is an institutional or health care facility or if certain notifications have been provided (see the guidance document) when the patient is a hospice patient or home health agency client.

OARRS Updates

OARRS is committed to providing the best service possible to improve patient care and reduce prescription abuse. Thus, the Board has updated the OARRS registration process to allow new accounts to be created completely online. Registration now includes answering a series of security questions to validate that the applicants truly are who they say they are. Upon completion of the process, a username is generated and you select your own password. No more forms to print; no more notarized signatures.

This same validation process will allow for online password resets, thus facilitating better patient care on evenings and weekends. No more being “locked out” of OARRS due to password entry errors, and no need to call the OARRS office for a password reset.

Additionally, with the passage of HB 341, all pharmacists who are dispensing prescriptions will be required to have an OARRS account as a condition of pharmacist license renewal. Get your account established now.

Disciplinary Actions

Anyone having a question regarding the license status of a particular practitioner, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The professional licensing agency websites listed below may include disciplinary actions for their respective licensees.

State Dental Board	614/466-2580 www.dental.ohio.gov
State Medical Board	614/466-3934 www.med.ohio.gov
State Nursing Board	614/466-3947 www.nursing.ohio.gov
State Optometry Board	614/466-5115 www.optometry.ohio.gov
State Pharmacy Board	614/466-4143 www.pharmacy.ohio.gov
State Veterinary Medical Board	614/644-5281 www.ovmlb.ohio.gov
Drug Enforcement Administration	800/882-9539 www.deadiversion.usdoj.gov

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

Eric A. Griffin - State News Editor
Carmen A. Catizone, MS, RPh, DPH - National News Editor
& Executive Editor
Deborah Zak - Communications Manager