



Virginia Board of Pharmacy

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Pharmacist and Pharmacy Technician Renewal

Current pharmacist licenses and pharmacy technician registrations expire at midnight on December 31, 2014. Please note that practicing on a lapsed license or registration is unlawful and constitutes grounds for disciplinary action by the Virginia Board of Pharmacy. Renewal notification letters will be mailed in early November to your address of record. If your address of record has changed since the last renewal, please update the address by e-mailing your current address to pharmbd@dhp.virginia.gov.

After the renewal notification letters have been mailed, pharmacists and pharmacy technicians may renew their license or registration via the online renewal process on the Board's web page using a personal identification number (PIN). Either an established login and password from a previous renewal cycle may be used to gain access or licensees may use the license number and PIN provided in the renewal letter. Licensees are encouraged to renew online. If you are unable to renew online, the notification letter will include instructions for obtaining a paper renewal form that may be mailed to the Board. Fees for renewals received by the Board by December 31, 2014, are as follows: pharmacist current active license – \$90; pharmacist current inactive license – \$45; and pharmacy technician registrations – \$25. If you desire to change your pharmacist license status from active to inactive, submit a written request to the Board providing your license number and the \$45 fee. You are encouraged to renew early, as an additional late fee of \$30 for current active pharmacist licenses, \$15 for current inactive pharmacist licenses, and \$10 for pharmacy technicians must be submitted for renewals received by the Board after December 31, 2014.

Renewals are processed the next business day following receipt; however, it may take seven to 10 business days following renewal to receive the license

or registration by mail. Holidays may further delay processing and receipt by mail. To avoid delays in receiving your license or registration, please renew as early as possible. If you do not receive your license or registration within 14 days of submitting the renewal, please contact the Board at 804/367-4456 or by e-mail at pharmbd@dhp.virginia.gov.

In addition to submitting the renewal fee, each current active pharmacist or pharmacy technician must attest to having successfully obtained all necessary continuing education (CE) hours during the 2014 calendar year. Each year, pharmacists are required to obtain 15 contact hours of qualifying CE per calendar year and pharmacy technicians must obtain five contact hours of qualifying CE per calendar year. Individuals who have not obtained the appropriate amount of CE during 2014 may request a one-time extension for no cause shown. Any subsequent extension requests will be granted for good cause only. Such requests must be made in writing and **prior** to renewing the license. Any individuals who request an extension will have their CE audited the following year and be required to submit the original CE documents as proof of compliance. Refer to Guidance Documents 110-4 and 110-42 at www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm for more information related to CE.

New Board Appointments and Board Meetings

This year, the Board had five members with expiring terms. The Board is pleased to announce that Jody H. Allen and Ellen B. Shinaberry have been reappointed by Governor Terry McAuliffe for a second full term, which will expire on June 30, 2018. Additionally, three new Board members were recently appointed by Governor McAuliffe: Michael I. Elliott, Lynchburg, VA; Melvin L. Boone, Sr, Chesapeake, VA; and Sheila Kay Wilson Elliott, Portsmouth, VA. In addition to welcoming these

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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).

new members, the Board would like to extend its gratitude to R. Crady Adams, Robert M. Rhodes, and Pratt P. Stelly for their dedication, leadership, and professionalism during their tenure on the Board. For a complete list of Board members, please visit www.dhp.virginia.gov/pharmacy/pharmacy_board.htm.

The next meeting of the full Board will take place on December 9, 2014, beginning at 9 AM. Dates for the 2015 full Board meetings are as follows: March 24; June 16; September 29; and December 1. Additionally, tentative dates for Regulation Committee meetings in 2015 are May 11 and November 3.

Sale of Dextromethorphan to Minors

Effective January 1, 2015, it is unlawful for any pharmacy or retail distributor to knowingly or intentionally sell or distribute a product containing dextromethorphan to a minor under the age of 18. It is also unlawful for any minor to knowingly or intentionally purchase a product containing dextromethorphan. The pharmacy or retail distributor, through its employee or agent, must obtain a federal, state, or local government-issued photo identification that contains the birth date of the purchaser that shows the purchaser to be at least 18 years of age, unless the employee or agent is able to reasonably presume by outward appearance that the purchaser is 25 years of age or older. The civil penalty for violation of §18.2-265.20 subsections A, B, and C of the Code of Virginia is \$25. The provisions of this section shall not apply if the product is obtained pursuant to a valid prescription order written by a practitioner while acting in the course of his or her professional practice as authorized in the Drug Control Act.

Transitioning Security Systems From 2G to 3G or 4G

Many wireless security systems communicate via cellular networks using 2G, 3G, and 4G technology. Some of these security systems were installed with a 2G-compatible Global System for Mobile communications device that can only communicate via the 2G wireless network. Therefore, when the 2G sunset occurs by January 1, 2017, these security systems will no longer be able to communicate alarm signals.

Pharmacies with older alarm systems may still be operating on a 2G frequency and may have received notifications from their alarm company regarding the need to upgrade their system from 2G to 3G or 4G technology. The amount of work necessary to upgrade the security system will depend on the security system in place, and could involve only a minor modification, but may require a significant modification or possibly a replacement of the security system. Pharmacists practicing in an environment using cellular technology must contact their alarm company directly to determine

what actions, if any, will be necessary to upgrade the pharmacy's security system. Per Board guidance, if the upgrade requires only a change to the circuit board, then a remodel application will not need to be submitted to the Board office. However, please be aware that if the upgrade involves any other type of action, to include replacement of the alarm panel, then a remodel application must be submitted to the Board office along with the appropriate fee, as the modified or new alarm system must be reinspected. Additionally, the Board advises pharmacists to maintain documentation on file that indicates if 3G or 4G technology is currently being used, if and when an upgrade was performed, and what action was necessary to upgrade the security system. This documentation should be readily available for review by an inspector. At all times, the security system shall comply with Regulation 18VAC110-20-180.

DEA Publishes Final Rule Rescheduling HCPs

On August 22, 2014, the United States Drug Enforcement Administration (DEA) published a final rule in the *Federal Register* placing hydrocodone combination products (HCPs) into Schedule II effective October 6, 2014. DEA first published the proposed rules in March 2014 in response to a Food and Drug Administration recommendation. DEA received almost 600 public comments regarding the proposed rules after they were published, with a small majority of the comments supporting the change. The DEA press release is available at www.justice.gov/dea/divisions/hq/2014/hq082114.shtml. Additionally, frequently asked questions sent to the Board may be downloaded as a Word document at www.dhp.virginia.gov/Pharmacy/news/FAQsOnReschedulingHCPs092014.doc.

Electronically Transmitting Prescriptions for Schedule II-V

On June 1, 2010, the DEA final rule for electronic prescriptions for controlled substances (CS) became effective, allowing prescriptions for drugs in Schedule II through V to be electronically transmitted. The electronic applications used by both the pharmacy and the prescriber must comply with the requirements of the DEA rule. There are some pharmacies and prescribers that may have the capabilities to transmit and receive these prescriptions electronically at this time. Information about this DEA rule is available at www.deadiversion.usdoj.gov/ecomm/e_rx/index.html.

Multiple Prescriptions for a Schedule II Drug

On December 19, 2007, DEA passed a federal regulation allowing a prescriber to provide individual patients with multiple prescriptions for the same Schedule II

CS to be filled sequentially. The combined effect of these multiple prescriptions is to allow the patient to receive, over time, up to a 90-day supply of that CS. Frequently asked questions on how to comply with this rule may be accessed at www.deadiversion.usdoj.gov/faq/mult_rx_faq.htm.

Transmitting a Schedule II Prescription via Facsimile or Verbally

Prescriptions for Schedule II drugs may only be faxed for informational purposes and may not serve as the original written prescription authorizing dispensing, except for orders to be administered to patients residing in a long-term care facility and home infusion patients, in accordance with §54.1-3408.01 B of the Code of Virginia, and except for prescriptions written for a Schedule II narcotic substance for patients residing in a hospice certified by Medicare under Title XVIII or licensed by the state, which may include home hospice. The prescriber shall note on the prescription if the patient is a hospice patient, and the prescription shall meet all requirements for a written prescription, including the prescriber's signature. Details of this may be found in Regulation 18VAC110-20-280.

Additionally, prescribers may directly communicate via telephone an emergency prescription for a Schedule II drug to a pharmacist; however, the quantity must be limited to a supply to cover the emergency period, the pharmacist must make a good faith effort to ensure the validity of the identity of the prescriber, and a written prescription must be obtained within seven days of dispensing from the prescriber. If a prescription is unable to be obtained within seven days, the pharmacist shall notify DEA and the Board.

Partial Filling of Schedule II Prescriptions

Partial filling of Schedule II prescriptions is allowable if the adequate quantity is not available; however, the remainder of the quantity must be dispensed within 72 hours of initial dispensing. If this cannot be done, the quantity dispensed must be notated on the face of the prescription and the prescriber must be notified of the quantity dispensed. No further quantity may be dispensed after the 72 hours without first obtaining a new prescription.

Additionally, orders for Schedule II drugs for patients in long-term care facilities may be dispensed in partial quantities for no more than 60 days from the date of issuance as long as the total quantity dispensed does not

exceed the amount prescribed. More information may be found in Regulation 18VAC110-20-310, available under the "Regulations" section at www.dhp.virginia.gov/Pharmacy/pharmacy_laws_regs.htm.

Board Website

The Board website includes a variety of information that may be helpful in your practice. The main page, available at www.dhp.virginia.gov/Pharmacy, includes information about current issues as well as links to other areas of the website; eg, guidance documents, inspections, *Newsletters*, presentations, meetings, and minutes.

The link to "Guidance Documents" provides information or guidance of general applicability to the staff or public to interpret or implement statutes or the Board's regulations. The guidance documents should be reviewed frequently for additions and changes. Guidance Document 110-9 "Pharmacy Inspection Deficiency Monetary Penalty Guide" provides valuable information about pharmacy inspections. Guidance Document 110-35 "Guidance on Virginia Prescription Requirements" provides an overview of prescription requirements for written, oral, faxed, and electronically transmitted prescriptions. Guidance documents regarding CS and their prescribing, record keeping, and storage include Guidance Document 110-41 "Changes a Pharmacist May Make to a Prescription Written for a Schedule II Controlled Substance;" Guidance Document 110-8 "Information on prescriptive authority in Virginia;" Guidance Document 110-11 "Proof of Identity when Dispensing Schedule II Drugs;" and Guidance Document 110-40 "Storage of Schedule II Drugs in a Pharmacy."

The "Inspections" link provides access to the current inspection reports that include the criteria used when a facility is subject to an inspection. The "Newsletters & Presentations" link includes the current and past *Newsletters*, as well as recent presentations provided by the Board. The "Meetings & Minutes" link provides access to minutes currently dating back to 2002.

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