June 2013

Vermont Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

Vermont Secretary of State, Office of Professional Regulation, Board of Pharmacy
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Issuance of Paper License

The Office of Professional Regulation is no longer issuing paper licenses upon successful renewal. Everyone (individual licensees and entities) will be able to print their own licenses once the renewal has been processed. You will need the user ID and password provided in your renewal notice to log on and print your paper copy. This also gives you the ability to print your license/registration at any time throughout the renewal cycle. If you need your user ID and password, you may e-mail Aprille Morrison at Aprille.Morrison@sec.state.vt.us and provide your name or company name, license number, and verify information currently on file. Your user ID and password will then be e-mailed to you.

Renewal Notices

Vermont pharmacy licenses will be expiring July 31, 2013. Renewal notices will be mailed the week of June 17. Your renewal notice will contain your user ID and password for renewing online as well as printing your paper license. If you do not receive your renewal notice by June 26, please contact the renewal clerk either by e-mail at renewal_clerk@sec.state.vt.us or 802/828-1505.

Preceptor Registrations

The Vermont Board of Pharmacy is no longer issuing separate registration for a preceptor. The information as to whether you hold a Vermont preceptor registration will be listed on your actual pharmacist license. In order for you to have a preceptor endorsement on your application you will need to have held a Vermont pharmacist license in good standing for a minimum of one year. If you previously held a preceptor registration, and have let it lapse, you will need to file a new registration application to add this endorsement to your current unencumbered license. The form can be printed from the Board's Web site, *www.vtprofessionals.org/opr1/pharmacists/,* or you can e-mail Aprille Morrison at Aprille.Morrison@sec.state.vt.us.

Pharmacist Immunizations

The Board continues to receive questions regarding pharmacist authorization to administer vaccines and specifically to administer the Zostavax® vaccine to your patients. At this time, Board rules require that pharmacists may only administer vaccines recommended by the Centers for Disease Control and Prevention. Pharmacists may administer the Zostavax vaccine only to adults 60 years of age and older.

All pharmacists who administer vaccines are reminded they must be immunization certified, have current training/certification in basic cardiac life support, and have a current collaborative practice agreement with a practitioner.

The applicable portion of the Administrative Rules of the Vermont Board of Pharmacy is reprinted below for your reference.

9.34 Immunizations

(a) A pharmacist may administer vaccines, if properly trained, to a patient 18 years of age or older and may administer only those vaccines recommended by the CDC (Center[s] for Disease Control and Prevention) for adult immunizations.

(1) A pharmacist must take an accredited training course on immunizations and keep proof of training on file in the pharmacy. The immunization course must, at a minimum, meet U.S. Center[s] for Disease Control and Prevention (CDC) Guidelines and be accredited by the Accreditation Council for Pharmac[y] Education (ACPE) or AMA (American Medical Association) Category I approval or a similar health authority or professional body, and include pre-administration education and screening, vaccine storage and handling, administration

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FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- Ambien®, Edluar™, and Zolpimist®: 5 mg for women, 5 mg or 10 mg for men
- Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at *www.fda.gov/Drugs/DrugSafety/ucm334033.htm.*

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of **reports** at a given organization, not the actual number of **events** or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting **reported** errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good reporting system, and thus what appears to be a high error "rate," may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (*www.nccmerp.org*), states the "Use of medication error rates to compare health care organizations is of no value." The council has taken this position for the following reasons:

- Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at *http://verp.ismp.org/.*

Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- Ensure the correct strength is ordered.
- Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- Order 5% as "vinegar," which reduces the potential for confusion with glacial acetic acid.
- Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at *www.ismp.org/NAN/files/20130121.pdf.*

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as "acet" or "APAP." Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that "state boards of pharmacy prohibit the use of the abbreviation 'APAP' on prescription labels, and require that 'acetaminophen' be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity." The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist's role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers "estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation" of the recommendation to use the complete spelling of acetaminophen on prescription labels. "This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines," states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at *www.ncpdp.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf,* developed for pharmacists that summarizes some of NCPDP's key recommendations regarding acetaminophen. In addition, the white paper, available for download at *www.ncpdp.org/ind_WP.aspx,* includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at *www.ncpdp.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.*

Pharmacists Rated High for Honesty and Ethical Standards in Gallup's 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at *www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx*.

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of medication, record-keeping, emergency response and reporting of adverse reactions.

(2) A pharmacist must maintain current training in **Basic Cardiac Life Support.**

(3) A pharmacist may administer a vaccine pursuant to a written protocol including emergency measures e.g., epinephrine and/or diphenhydramine based on a collaborative practice agreement or a patient-specific prescription from a licensed prescriber.

Advanced Practice Registered Nurses and Pharmacy

A couple of questions that have come into the Board office address the interactions between pharmacists and advanced practice registered nurses (APRNs). As they are general knowledge questions, they are reprinted here for your reference.

Question:

Is it appropriate and acceptable for an APRN with prescriptive authority to write a prescription for oral buprenorphine (Suboxone® or Subutex®)?

Answer:

No. Under the Drug Addiction Treatment Act of 2000 (DATA 2000), waivers to permit the prescription of Schedule III, IV, or V medications for opioid addiction treatment are available only to "qualifying physicians." The term "qualifying physician" is specifically defined in DATA 2000 as a "physician who is licensed under State law," has Drug Enforcement Administration (DEA) registration to dispense controlled substances (CS), has the capacity to refer patients for counseling and ancillary services, will treat no more than 30 such patients at any one time, and is qualified by certification, training, and/or experience to treat opioid addiction.

Qualified physicians must receive specific training prior to prescribing oral buprenorphine, and must meet guidelines set by the Substance Abuse and Mental Health Services Administration and the DATA 2000 before receiving a special DEA license number amendment.

Question:

Is it appropriate and acceptable for an APRN with prescriptive authority to write a prescription for a CS for his or her own use or for an immediate family member?

Answer:

According to the Vermont Board of Medical Practice:

> . . . it is unacceptable medical practice and unprofessional conduct to prescribe Schedule II, III, and IV controlled substances for his or her own use. It is also unacceptable medical practice and unprofessional conduct for a licensee to prescribe Schedule II, III, and IV controlled substances to a member of his or her immediate family, except in a bona fide emergency of short term and unforeseeable character.

Immediate family includes the following: a spouse (or spousal equivalent), parent, grandparent, child, sibling, parent-in-law, son/daughter-in-law, step-parent, step-child, step-sibling, or any other person who is permanently residing in the same residence as the licensee.

The *Vermont Board of Pharmacy News* is published by the Vermont Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, 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 the Foundation or the Board unless expressly so stated.

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