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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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Communicable Disease Reporting by Pharmacists

The Vermont Communicable Disease Regulations require pharmacists to report unusual or increased prescription requests, unusual types of prescriptions, or unusual trends in pharmacy visits that may result from bioterrorist acts, epidemic or pandemic disease, or novel and highly fatal infectious agents or biological toxins.

Here is the link to the reporting form: *http://healthvermont.gov/prevent/documents/CDR_unusual_rx_medication_request_pharmacist_report.pdf.*

Emergency Rules for Single Ingredient Hydrocodone Products

Dr Harry Chen, commissioner of the Vermont Department of Health, has issued an emergency rule to restrict how health care providers prescribe certain single active ingredient hydrocodone products such as Zohydro™ ER. The emergency rule was released on April 3, 2014, by the Vermont Department of Health. The following is an excerpt of the announcement:

> Joined by a contingent of Vermont mayors and Health Commissioner Harry Chen, MD, Gov. Peter Shumlin announced today that the Health Department has issued an emergency rule to tightly restrict how health care providers prescribe certain hydrocodones such as Zohydro, a high-dose narcotic painkiller approved last year in a form without abuse-deterrent formulation, in controversial decision by the Food & Drug Administration (FDA). The approved drug is manufactured without an abuse-deterrent formulation (ADF) or other tamper-proofing technology. ADFs make drugs less likely to be abuse or diverted.

Among other restrictions, the new rule requires prescribers to:

- Conduct and document a thorough medical evaluation;
- Conduct and document a risk assessment;
- Document in the medical record that the prescription of a hydrocodone medication without an ADF is required for the management of pain (ie, nothing else will effectively manage the severe pain);
- Receive a signed informed consent form including information from the drug insert;
- Receive from the patient a Chronic Controlled Substance Treatment Agreement that shall include conditions such as urine screening, pill counts, safe storage and disposal, and other appropriate conditions as determined by the prescriber;
- Query the Vermont Prescription Monitoring System;
- Determine a maximum daily dose or a "not to exceed value" for the prescription to be transmitted to the pharmacy; and
- Schedule and undertake periodic follow-up visits, evaluations, and referrals.

To read the complete text of the rule, visit *http://healthvermont.gov/regs/documents/hydrocodone_emergency_rule.pdf.*

Expiration Date Required on Prescription Label

Vermont law requires any medication that is dispensed and will expire in one year or less to have the exact expiration date on the prescription label. The applicable portion of the statute that addresses misbranded drugs is reprinted below for your reference.

> 18 V.S.A. §4064a. Misbranded drugs or devices sold by prescription
>
> **§ 4064a. Misbranded drugs or devices sold by prescription**
>
> (a) Except as provided in subsections (b), (c), and (d) of this section a drug or device which is sold or offered for sale by prescription including those transported or mailed into this state for use in this state although purchased elsewhere is misbranded:

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New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at *www.usp.org/support-home/frequently-asked-questions/compounding*. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

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 Error Reporting Program. Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

VESIcare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESIcare®** (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid®** (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESIcare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril **(Lotensin®)** and **Benadryl®** (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazapryl." The pharmacist who received the fax interpreted it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit *www.med-errs.com* and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations,* commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at *www.fda.gov/Safety/Recalls/ucm382076.htm.*

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.*

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- The preliminary application and first state transfer fee will increase from $350 to $375
- Each additional state transfer will increase from $50 to $75
- Change of states will increase from $50 to $75
- Time extensions will increase from $50 to $75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at *www.nabp.net.* Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.

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(1) if its labeling is false or misleading in any particular; or

(2) unless it is labeled with the following:

(A) the name of the patient or if the patient is an animal the name of its owner and the species of the animal;

(B) the expiration date of the drug where the date is required by law or has been determined by the manufacturer, board, or any agency of the state or United States government, if this date is less than one year from date of dispensing;

(C) the name or place of business of the dispenser;

(D) the serial number and the date the prescription was filled;

(E) directions for use as may be stated in the prescription and the name of the medical, dental, osteopathic, or veterinary professional prescribing the drug or device;

(F) the name and strength of the drug or its generic equivalent, if any, according to the latest official United States Pharmacopoeia, latest official homeopathic pharmacopoeia of the United States, or latest official national formulary, or any supplement to any of them;

(G) the name of the drug shall be the same as written by the prescriber, unless the prescription has been filled with a generic equivalent approved by the prescriber and the purchaser has been informed of the change.

(b) The labeling requirements of subdivisions (a)(2)(F) and (G) of this section shall not apply to a drug or device if the prescribing physician explicitly requests for medical reasons that such information shall be omitted.

(c) The labeling requirements of subsection (a) of this section shall not apply to a drug or device administered under the supervision of a licensed physician to patients within a hospital or nursing home.

(d) Nothing in this section shall be construed to limit the ability of a licensed physician to give, administer, or dispense any drug or device to a patient under his or her care. (Added 1971, No. 182 (Adj. Sess.), eff. July 1, 1972; amended 2007, No. 163 (Adj. Sess.), § 4.)

Statistics

Here are the current pharmacy statistics as of April 30, 2014.

- Total number of active registered technicians is **1,420** (1,326 resident, 94 nonresident).
- Total number of active licensed pharmacists is **1,338** (714 resident, 624 nonresident).
- Total number of active licensed tele-pharmacists is **103.**
- Total number of active licensed in-state pharmacies is **180** (all types of facilities).
- Total number of active licensed nonresident pharmacies is **546.**
- Total number of active licensed nonresident wholesale distributor facilities is **671.**

The *Vermont Board of Pharmacy News* is published by the Vermont 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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