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Vermont Board of Pharmacy News

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Letter From Executive Officer Robert Enos

I would like to take this opportunity to introduce myself as the new executive officer for the Vermont Board of Pharmacy. It is an honor for me to be able to assume this role on behalf of all our patients and providers throughout the state.

I have been a resident of Vermont for 35 years. I live in Hartland, VT, with my wife, Caren, a native of Randolph, VT, who herself has over 30 years' experience in the pharmacy profession.

In my 40 years as a pharmacist, I have been involved in hospital pharmacy, outpatient/retail pharmacy operations, management, clinical pharmacy practice, and clinical trials. I have acted as preceptor for students and residents, and I am currently employed at the Norris Cotton Cancer Center North in St Johnsbury, VT, on a per diem basis.

Throughout my career, I have had the opportunity to work alongside numerous excellent practitioners. I, like you, have seen the tremendous impact that our pharmacists and pharmacy technicians have on patient care. In my role with the Board, I will continue to support and advocate for a growing role in patient care.

I am already at work with the Board on some important initiatives. Over the next few months, we will be conducting inspections of all sterile compounding pharmacies in the state. We will be working in collaboration with the National Association of Boards of Pharmacy® to assess compliance with United States Pharmacopeia Chapter <797> guidance standards. We will also be addressing the need for inspections of institutional pharmacies, per Vermont Pharmacy Rules, Part 9.16. We will continue to work on updating our Pharmacy Rules and planning a comprehensive review and update of the Pharmacy Rules, recognizing the need to keep pace with the evolving practice of pharmacy and to have rules that are more receptive to end user needs.

Successful completion of these initiatives will require extensive dialogue among all stakeholders. Everyone's input will be vital.

Regulation of the practice of pharmacy as it continues to evolve is certainly a complex undertaking. The mission of the Board, however, is very simple and can be summed up in two words: public protection. This is the basis behind all that we will do.

I am confident that we have a dedicated and very committed professional staff at the Vermont Office of Professional Regulation and on the Board. I believe we can be progressive and proactive rather than reactive, and be real leaders in our profession.

I look forward to working with all of you to continue to improve the health of the people of Vermont. Please do not hesitate to reach out to me.

Robert Enos, RPh
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Administrative Rules Update

The Board thanks all those who questioned and commented during the rulemaking process. The Board submitted its final "Proposed Rules" to the Vermont Legislative Committee on Administrative Rules in July 2015. At the time this article was drafted, the rules were on the Committee's agenda for review on August 13. If accepted, the last stage is to file the final "Adopted Rules" with the Vermont Secretary of State. The new rules would take effect 15 days after that filing.

You may visit the Board's web page, *https://www.sec.state.vt.us/professional-regulation/profession/pharmacy.aspx,* to see the rules as they stand now.

Important Information From the VDH: Help Make Naloxone Available

The rise in heroin use and overdoses in Vermont prompted the legislature to ask the Vermont Department of Health (VDH) to create a responsive program. The VDH launched a pilot program to distribute the drug naloxone to individuals at risk for fatal overdose. Distribution occurs via community-based programs, treatment centers (methadone clinics), syringe exchanges, and recovery centers. Naloxone may be prescribed to a drug user/abuser, patients with acute or chronic pain managed by opiates/opioids, and their friends or family members who may be in a position to respond to an overdose.

Vermont pharmacies can help individuals avoid potentially fatal overdoses with naloxone. 26 V.S.A. §2080 required the Board to adopt a protocol for "pharmacists to dispense or otherwise furnish naloxone hydrochloride to patients who do not hold an individual prescription for naloxone hydrochloride." Vermont pharmacists have the opportunity to:

- Provide overdose prevention education and response (administration of naloxone) to those who may be in a position to save a life.
- Educate patients and concerned individuals on the importance of careful and responsible use of opioids and the risks of misuse.

Under the Board protocol, a Vermont pharmacist may dispense an Overdose Rescue Kit to a person 12 years of age or older who is at risk of experiencing an opiate/opioid overdose, or to a family member, friend, or other person in a position to help such a person, as follows.

1) Each kit dispensed must contain two doses of naloxone with two nasal atomizers.
2) The kit may only be dispensed with the VDH brochure "Overdose Rescue Kit – How to give nasal naloxone for suspected opioid overdose" and instructions on how to store the kit until use *(www.healthvermont.gov/adap/treatment/naloxone/index.aspx#kit)*.
3) Billing and payment information: For transactions other than free distribution or purchases where the consumer has paid for the naloxone kit in full, the pharmacist only needs to obtain information sufficient to permit third-party reimbursement.

At this time, Vermont has a limited supply of rescue kits for free distribution. Medicaid will pay for a person filling a prescription for naloxone. Under the protocol, a pharmacist may dispense naloxone

continued on page 4

Counterfeit Botox Found in the United States, FDA Warns

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox® was found in the United States and may have been sold to doctors' offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug's manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients' health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA's Office of Criminal Investigations. More information is available on the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm443217.htm*.

One way pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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. *Email: ismpinfo@ismp.org.*

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP *National Pharmacy Compliance News* readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled "Offer" in Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an "offer" to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, "Do you have any questions?" or told to "Please sign here." They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit *www.ismp.org/communityRx/tools/ambulatoryhighalert.asp.* ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat

muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm*.

New FDA Drug Info Rounds Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- In "NDC Directory," pharmacists demonstrate how to use this quick, easy, online resource.
- In "FAERS," pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications' drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

- MUCINEX FAST-MAX Night-Time Cold & Flu;
- MUCINEX FAST-MAX Cold & Sinus;
- MUCINEX FAST-MAX Severe Congestion & Cough; and
- MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for safe disposal, is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm444028.htm*.

Pharmacists Are Performing More Patient Care Activities, National Survey Indicates

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the *2014 National Pharmacist Workforce Survey*. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACP website, *www.aacp.org*.

Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL

INTERPOL has issued a global alert for a drug known as 2.4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The "Orange Notice" warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at *www.interpol.int/News-and-media/News/2015/N2015-050*.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, "Pathways to Safer Opioid Use," also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at *http://health.gov/hcq/training.asp#pathways*.

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continued from page 1

without a prescription, but the cost will be out of pocket. The state is looking for additional funding sources for Overdose Rescue Kits.

In the meantime, be aware of the protocol. It is available on the Board web page at *https://www.sec.state.vt.us/professional-regulation/profession/pharmacy.aspx* under "Statutes & Rules."

You are urged to do whatever you can do to make the naloxone kits available in your community.

Prospective Drug Review

As a general reminder, the Board would like to outline requirements relating to the obtaining and recording of patient health information and associated provisions for computer software.

Pharmacy Rules relating to prospective drug review read as follows:

10.30 Prospective Drug Review

(a) A pharmacist shall review the patient record and each prescription drug order presented for dispensing for purposes of promoting therapeutic appropriateness by identifying:
  (1) Over-utilization or under-utilization;
  (2) Therapeutic duplication;
  (3) Drug-disease contraindications;
  (4) Drug-drug interactions (including serious interactions with non-prescriptive or over-the-counter drugs);
  (5) Incorrect drug dosage or duration of drug treatment;
  (6) Drug-allergy interactions; and
  (7) Clinical abuse or misuse.

(b) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the practitioner.

10.26 Allergy and Health Information. The Pharmacist or pharmacy technician or intern shall make a reasonable effort to ascertain from the patient or the patient's representative the patient's known allergies, drug reactions, idiosyncrasies, chronic conditions, or disease states and current use of other drugs which may relate to prospective drug review. The information shall be recorded in the patient profile. It shall be updated periodically, but not less than once per year.

A valid prospective drug review is dependent on thorough, accurate, and up-to-date patient health records. The pharmacist must make a reasonable effort to obtain this patient health information and it shall be done not less than once per year. A patient drug utilization review shall include all prescription and nonprescription drugs, regardless of the pharmacy from which the medications are being obtained. This information shall be obtained from the patient or the patient's agent. To rely solely on information obtained through the patient's insurer is insufficient. The patient health information shall be entered into the patient record, and shall be updated as conditions and medications change.

Per Pharmacy Rules, Part 12, pharmacy software systems must be capable of flagging or warning of allergies and medication interactions. Since the patient record may include medications obtained from other pharmacies, the software implemented must be capable of warning of medication interactions based on all medications in use as reflected by the patient record, regardless of the dispensing source, and not solely reviewing the in-house dispensing record of a pharmacy.

The expectation of the Board is that all pharmacies will achieve full compliance by updating patient records, and also ensuring that the software systems utilized are capable of warning of allergies and medication interactions based on all medications being used by the patient, regardless of the dispensing source.

For questions regarding this matter, please contact Dan Vincent, field investigator, at daniel.vincent@sec.state.vt.us or 802/279-1232.

Vermont Prescription Monitoring System

The Vermont Prescription Monitoring System (VPMS) Rule identifies certain minimum legal requirements that apply for each aspect of the system that makes controlled substances (CS) available to patients. It specifies when pharmacists or others who dispense CS must make reports to the VPMS. For prescribers of CS (including those prescribers who dispense), it sets forth requirements for when VPMS must be queried before prescribing or dispensing. Some of the requirements come directly from existing law, but some are new. For instance, there are now circumstances in which the requirements apply to urgent care settings. In addition, there are now some circumstances in which VPMS must be queried before prescribing opioids for acute pain. The VPMS Rule may be found at *http://healthvermont.gov/regs/documents/vpms_rule.pdf.*

Prescribing Opioids for Chronic Pain

The Rule Governing the Prescribing of Opioids for Chronic Pain provides minimum legal requirements for prescribing opioids for treatment of chronic pain. These minimum legal requirements may not meet the standard of care in all cases; they are established as the minimum that must be done to help manage the risks of misuse, abuse, diversion, addiction, and overdoses. The rule sets forth requirements for the clinician, including the requirement to document the consideration of non-opioid and non-pharmacological treatment options, as well as documentation of an assessment of the risks for the patient associated with use of opioids. The rule may be found at *http://healthvermont.gov/regs/documents/opioids_prescribing_for_chronic_pain_rule.pdf.*

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