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Vermont Board of Pharmacy News

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Pharmacist Manager Changes and CS Inventory Requirements

That magic moment in your life has arrived and you have been appointed/promoted to pharmacist manager (pharmacist-in-charge (PIC)) of a pharmacy. After the celebration is over, there are two important things you need to do for the Vermont Board of Pharmacy.

1. Notify the Board, in writing, of your appointment and advise your predecessor that he or she needs to notify the Board of his or her status change. This must be done within five days of the appointment.
2. Conduct a controlled substances (CS) inventory. This inventory must have a definite cutoff time that is clearly indicated on the inventory. This means the inventory must be conducted after the business closes for the day or before it opens for business. Ideally, the inventory is taken by both the incoming and outgoing pharmacist managers, both of whom sign and date their signatures on the inventory. In the event either the incoming or outgoing pharmacist manager is unavailable to conduct the CS inventory, please provide an explanation of same to the Board. A copy of the CS inventory must be sent to the Board office along with the Application to Change Pharmacist Manager.

For your reference, the applicable portion of the Administrative Rules of the Vermont Board of Pharmacy is reprinted below.

6.7 Change of Pharmacist-Manager When a pharmacist-manager changes employment or responsibilities, he or she shall do the following:

(a) Within 5 days, the outgoing and incoming pharmacist-managers shall notify the Board, in writing, regarding his or her change in employment.
(b) The outgoing pharmacist-manager shall conduct a physical written inventory of all controlled drugs, explain any discrepancies in full, certify the inventory as true and correct, and retain a copy for his or her records.
(c) The inventory shall be certified as true and correct, by the incoming pharmacist-manager, and filed with the permanent records of the drug outlet.
(d) The inventory shall be signed by both the incoming and outgoing pharmacist-managers, and a copy submitted to the Board as an attachment to the forms provided.
(e) A new license, indicating the name of the new pharmacist-manager will be issued upon approval.

Loss of CS

Every month, the Board receives several Drug Enforcement Administration Report of Theft or Loss of Controlled Substances forms. On an average of once a month, the Board receives one of these forms that reports the loss of a 100-count bottle of a Schedule II CS.

Most often, the reason cited by the pharmacist manager for this loss is that the bottle was accidentally thrown out in the trash or swept into the garbage as the counter was cleaned. Other reasons most often cited include accidentally dispensing an extra 100 tablets when filling a prescription, and an inability to count the bottles of drugs on the shelf and add/subtract properly when doing the perpetual inventory.

The Board is very concerned about these losses and considers such losses to be unacceptable. The Board reminds pharmacist managers (PICs) of their responsibility for all aspects of the pharmacy operation, and this includes security and policies and procedures that prevent the loss of CS, as well as up-to-date maintenance of a perpetual Schedule II CS inventory. For your reference, the applicable portion of the Administrative Rules of the Vermont Board of Pharmacy is reprinted here.

10.33 Perpetual Inventory A perpetual inventory shall be maintained for at least two years for all Schedule II controlled substances. Electronic versions may be permitted if they provide a secure audit trail of entries.

10.34 Schedule II Inventory All Schedule II controlled substances must be physically inventoried and documented at least once every thirty (30) days.

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National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Comp
and can only be ascertained by examini

New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled "Red Flags," encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described "red flags" as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARERX.ORG/pharmacists*.

Root Causes: A Roadmap to Action

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.*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for car**bam**azepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of car**bam**azepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient's medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child's car**bam**azepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.[i]

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy.* The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event.**

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event.** For more information and to access the **free** workbook, visit *www.ismp.org/tools/rca/.*

[i] *http://pediatrics.aappublications.org/content/113/2/406.abstract*

FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety*.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- The millimeter (mL) should be used as a standard unit of measurement.
- Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.
- Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* is available for download from the NCPDP website at *http://ncpdp.org/Education/Whitepaper*.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum,* and may currently be viewed on the USP website at *www.usp.org/usp-nf*. Comments were accepted until July 31, 2014.

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In the future, the Board intends to more thoroughly review such loss reports and may consider initiation of administrative action for unprofessional conduct against both the pharmacy and the pharmacist manager (PIC). The Board may also direct that there be further investigation of the loss and/or a CS audit of the pharmacy to determine if there are other shortages of CS. Such audits would be conducted by the Board's designee or agent.

Fifty-Year Pharmacists

The Board congratulates the following pharmacists who have been licensed for 50 or more years. The Board thanks you for your service to the people of Vermont.

- Edward A. Fausel, Essex Junction, VT
- Robert J. Murphy, Ogunquit, ME
- Alvin M. Sandberg, Cleveland, TN
- David B. Van Etten, Lake Katrine, NY

Automatic Counting Machines

If your pharmacy utilizes an automatic counting machine to assist the pharmacist in dispensing drugs, the Board expects appropriate records to be kept. Systematic documentation should be established to ensure:

1. All CS dispensed using such a system are accounted for. In the event of a CS shortage, a "counting machine error" will not be accepted as the reason for the shortage. There should be, at a minimum, quarterly documentation that verifies by actual count against the machine of quantities most commonly dispensed.
2. Drugs are maintained in a clean and sanitary environment and stored in accordance with current United States Pharmacopeia standards and in accordance with manufacturer labeling. There should be a policy and procedure, as well as documentation, to ensure that delivery chutes and cassettes are maintained in a clean manner.
3. Drugs stocked in the counting machine are tracked by lot number and expiration date, and the cassette is labeled with the following information:
   A. Name of drug,
   B. Strength of drug, if applicable,
   C. Dosage form of drug, and
   D. The lesser of the manufacturer's expiration date or expiration date of one year from date of transfer of drug from manufacturer's container to cassette.
4. Schedule II CS should not be transferred into or dispensed from an automatic counting machine.

Disciplinary Actions

At its regularly scheduled meeting on June 25, 2014, the Board took the following actions.

Brandon Cigana, pharmacist, Whitehall, NY. Summary suspension.

Jeff L. Cohen, pharmacist, Warren, VT. Decision setting forth reinstatement prerequisites and conditions should pharmacist license be reinstated.

John Walters, pharmacist, Rutland, VT. Indefinite suspension of privilege to seek reinstatement of pharmacist license that has expired.

At its regularly scheduled meeting on May 28, 2014, the Board took the following actions.

Corner Drug Company, Inc, pharmacy, White River Junction, VT. Stipulation and consent order approved.

Crown Laboratories, pharmacy, Johnson City, TN. Preliminary denial decision reversed. Registration as wholesale drug outlet issued.

At its regularly scheduled meeting on April 30, 2014, the Board took the following action.

Corner Drug Company, Inc, pharmacy, White River Junction, VT. Stipulation and consent order rejected.

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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