December 2016

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
89 Main Street, Third Floor • Montpelier, VT 05620-3402 • *http://vtprofessionals.org*

Pharmacies and the Vermont Immunization Registry

Vermont law requires that all health care providers report all data regarding immunizations to the Vermont Immunization Registry (IMR). As of August 2016, 58 pharmacies in Vermont (34%) were sending immunization data to the IMR.

Pharmacies, like other health care providers, are required to submit immunization data to the IMR on a regular basis. The IMR is a consolidated source for immunization information. Whether a person received an immunization at a pharmacy, a hospital, or a provider office, the IMR holds that information. A comprehensive immunization record will reduce the possibility of adults receiving duplicate vaccines.

Pharmacies in Vermont that send data to the IMR currently send monthly batch files for import. With batch processing, it may take 30 days for the vaccine to be entered into the IMR.

Flu vaccines account for most of the immunizations administered at pharmacies and reported to the IMR. Pharmacists also administered the following vaccines: pneumococcal; tetanus, diphtheria, and pertussis; zoster (shingles); hepatitis A; hepatitis B; human papillomavirus; and others.

Increasing adult vaccination rates is a public health goal, and pharmacies can be an important partner in that endeavor.

The IMR is also able to provide assistance to immunizers at pharmacies in following schedule guidance and to check patient histories for previous immunizations.

Rules related to pharmacist administration of immunizations can be found in the Administrative Rules of the Vermont Board of Pharmacy, Part 10.35, found at *https://www.sec.state.vt.us/media/702345/5-RX-Rules-2015-Final-Adopted-August-24-2015.pdf,* and 18 V.S.A. §1129, found at *http://legislature.vermont.gov/statutes/section/18/021/01129.*

For more information, please contact Bridget Ahrens, IMR manager, at 802/951-4094.

USP Chapter <800>

United States Pharmacopeia (USP) Chapter <800> describes practice and quality standards for handling hazardous drugs (HDs). This standard applies to all health care personnel who handle HD preparations and includes, but is not limited to, receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile products and preparations.

This standard will be applicable to all pharmacies, not just "compounding" pharmacies, and will become enforceable by the Board on July 1, 2018.

The actual list of HDs is maintained by the National Institute for Occupational Safety and Health (NIOSH). The list includes antineoplastics, non-antineoplastics, and drugs that represent potential reproductive risks. Pharmacies will be required to maintain a list of any drugs on the list that are handled by the pharmacy and will be required to perform an assessment of risk for each of those items.

All pharmacists should review the *USP Compounding Compendium,* which contains the full text of USP Chapter <800> as well as Chapters <795> and <797>. The *Compendium* is available through the USP website at *www.usp.org/store/products/usp-compounding-compendium.* More information is also available at *http://education.usp.org.*

There are educational providers, such as CriticalPoint, LLC, that offer pharmacies opportunities to acquire a better understanding of HDs and other sterile and nonsterile compounding issues. More information may be found at *https://www.criticalpoint.info.*

Additional important resources for HDs that all pharmacists should be familiar with are:

- *OSHA [Occupational Safety and Health Administration] Technical Manual* Section VI: Chapter 2, Controlling Occupational Exposure to Hazardous Drugs. *https://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html.*
- NIOSH Alert: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings. Department of Health and Human Services (NIOSH) Publication No. 2004-165 and updates. *https://www.cdc.gov/niosh/docs/2004-165.*

FOUNDATION

National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

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.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

(1) Read and follow the label.
(2) Know which medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.

(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm*.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia,* a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online Item Writer Volunteer Interest Form available at in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at www.nabp.pharmacy, or contact CompAssess@nabp.pharmacy.

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
Mount Prospect, IL 60056

VERMONT BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

Vermont Pharmacy Technician Reminder

All pharmacy technicians are reminded that effective with the next biannual registration cycle, July 1, 2017, technicians will need to register as "pharmacy technicians" or "certified pharmacy technicians" per the Administrative Rules of the Vermont Board of Pharmacy, Part 5, found at *https://www.sec.state.vt.us/media/702345/5-RX-Rules-2015-Final-Adopted-August-24-2015.pdf.*

The details of the changes to pharmacy technician rules were outlined in the Board's March 2016 *Newsletter,* available at *https://nabp.pharmacy/wp-content/uploads/2016/06/VT032016.pdf.*

Changes Allowed to Written Controlled Drug Prescriptions

What actions may a pharmacist take when presented with a written prescription for a controlled drug when the information on the prescription is incomplete, inaccurate, or incorrect? What, if any, modifications may the pharmacist make to that prescription?

Board Administrative Rules do not specifically address this issue of controlled drug prescriptions. Pharmacists are required to comply with all Drug Enforcement Administration (DEA) regulations related to controlled substances (CS). The following is a summary of DEA policy on this issue.

The DEA describes those circumstances in which a pharmacist may make such changes in the DEA resource document on prescriptions, available at *www.deadiversion.usdoj.gov/faq/prescriptions.htm*.

For Schedule III-V CS prescriptions, the pharmacist may add or change the patient's address, the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted by the pharmacist on the prescription.

Guidance from DEA on Schedule II CS has been less direct.

In 2007, DEA published in the *Federal Register* a Final Rule, "Issuance of Multiple Prescriptions for Schedule II Controlled Substances" (72 FR 64921). The preamble of that rule contained information that was contradictory to previous DEA policy, which had permitted the same changes to a Schedule II prescription that a pharmacist may make to Schedule III-V CS prescriptions.

In follow-up correspondence sent as a letter from DEA to the National Association of Boards of Pharmacy® in August 2011, DEA provided clarification of its guidance on this topic. DEA advised that whether a pharmacist may make changes to a Schedule II prescription – such as adding the practitioner's DEA number or correcting the patient's name or address – varies case by case based on the facts present.

DEA stated: "DEA expects that when information is missing from or needs to be changed on a schedule II controlled substance prescription, pharmacists use their professional judgment and knowledge of state and federal laws and policies to decide whether it is appropriate to make changes to that prescription."

Pharmacists must always be aware of specific activities that violate the Controlled Substances Act (CSA). Per DEA, the following activities are always unlawful:

- Intentionally furnishing false or fraudulent material information, or omitting material information from documents required under CSA;
- Dispensing a CS prescription in violation of requirements for Schedule II CS prescriptions (21 USC 829); and
- Knowingly or intentionally using a registration number that is fictitious, revoked, suspended, expired, or issued to another person.

Pharmacists must also be mindful of the rule of "corresponding responsibility." Per regulation Title 21 Code of Federal Regulations §1306.04, the pharmacist filling a CS prescription has a corresponding responsibility to make sure the prescription was "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."

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.

Robert Enos, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Suhajda - Communications Manager