December 2016

New Hampshire Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

121 S Fruit St, Concord, NH 03301-2412 • Tel: 603/271-2350 • Fax: 603/271-2856
www.nh.gov/pharmacy

Board Administrator Vacancy

Executive Director Michael R. Dupuis recently resigned from the New Hampshire Board of Pharmacy to pursue an opportunity at Frisbie Memorial Hospital. The Board wishes Mike the best and thanks him for his service. The Board will be posting this position soon, and interested applicants can visit the Board website once the Board officially posts for further information on the position and to print out an application. The Board will be moving quickly to fill this critical position, so all interested pharmacists are strongly encouraged to apply early.

Required Pharmacist Breaks

With the passage of Pharmacy Rule (Ph) 704.01 regarding pharmacist breaks, the Board has received a number of inquiries. There was some concern that the Board should have used "must" instead of "shall" in the language. "Shall" is the word preferred by legislative services and means "must" or that the action is required. Others have commented that they have received no direction from their superiors regarding implementation. While the Board understands it can take a little time to create signage, send communications to licensees, etc, the language in this rule was negotiated in good faith with permit holders as a result of direction from New Hampshire State Senator Sharon Carson during workload committee hearings. If the Board finds lack of cooperation in implementing this important step in addressing patient safety, it will go back to the legislature for more authority. Please feel free to keep the Board informed on the implementation of this rule.

Advanced Practice Pharmacy Technicians

The work group designing the rules for advanced practice pharmacy technicians (Ph 1800s) has made significant progress over the past few months. The Board anticipates having an initial document ready for public hearing early in 2017. Please keep an eye on the Board website and feel free to send your comments. All rules under consideration for updates or changes are listed on the Board website. Click on Laws and Rules on the left-hand side to view current and recently adopted rules and proposed rule changes.

Renewal Forms on Board Website

Renewals for 2017 will again be paper format, which are available for printing from the Board website, *www.nh.gov/pharmacy.*

The New Hampshire Office of Professional Licensure and Certification, the agency that the Board is now a part of because of state agency consolidations, is expecting to have online renewals available midway through 2017. This means pharmacist, in-state pharmacy, nonresident pharmacy, and pharmacy technician registrations will be manually filed again this year. Remember to make sure your contact information (as well as your technicians') is current. RSA 318 requires all licensees to notify the Board within 15 days of a change of address or employment. Communications are done through email, and many times Board communications are returned as undeliverable because of licensees not providing correct/updated email or mailing addresses. All applications are available on the Board website under the Licensing tab, then by selecting your profession. It is the licensee's responsibility to print out a license renewal form from the Board website and ensure that he or she files the application on time with the Board office. Because of the volume of licenses up for renewal this time of year and limited staffing at the Board office, walk-ins and same-day issuance of renewed licenses are not possible. The turnaround time from submission to the point you receive your renewed license is two weeks, so please be sure you renew no later than December 15 to ensure you receive your 2017 license in time.

Check the Board Website for Important Updates!

On the Board website, *www.nh.gov/pharmacy,* you will also find a current listing of Board members, Board office staff contact information, all the Board's laws/rules,

continued on page 4

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.

continued from page 1

rulemaking proposals, Board work groups/subcommittees, up-to-date rosters of all the Board's current licensees, and other timely notices and advisories from the Board. Please bookmark the site and refer to it frequently, as it is updated daily.

Find Us on Facebook and Twitter

The Board also continuously updates its Facebook and Twitter pages so those who subscribe/like the Board's pages with either service can receive automatic updates and notifications on all Board matters and also contact the Board directly from these sites.

Facebook: *www.facebook.com/NH.Pharmacy.Board*

Twitter: *www.twitter.com/NH_Pharmacy_Brd*

New Board Initiatives

At the time of publication, there are three Board initiatives that are moving along and will soon begin the process toward approval and implementation. They are the new advanced practice pharmacy technician (Ph 1800s), continuous quality improvement (potentially Ph 1700), and collaborative practice rules. Collaborative practice and advanced practice pharmacy technician are both either rule changes or proposed new rules. The rules process allows the Board to submit these new rules/changes to the New Hampshire Office of Legislative Services for review of language and authority, and at that time a public hearing will be scheduled for each of these. Proposed rules are posted on the Board website, and the Board encourages all licensees to read these documents and send comments to the Board. These comments could be in support of the new rule or in opposition to the rule. You can also comment on any area within the rule, again in opposition or suggesting a correction. At the end of the process, the more participation received allows for the best possible outcome with the language and content of the rule. The Board anticipates having public hearings on both of these rules in early spring 2017. Remember, you do not have to appear at the public hearing to have your voice heard. Communicating to the Board via mail or email will get your comments on the record and considered. You just need to be willing to sign your name to the submission.

The continuous quality improvement initiative will follow a longer path. The Board will need the statutory authority to create the program and then the authority to write rules to implement. With this in mind, the Board will be seeking sponsors for this bill during the upcoming legislative session. The Board will also be introducing a bill to allow interns to administer vaccines. The Board again asks that if you support either of these initiatives, please contact your representative and senator expressing your support. Many times these conversations can lead to educating your representatives in an area with which they may not be familiar. In addition, these communications can create long-term relationships that lead them to using you as a resource when pharmacy issues come up in the future. Pharmacy professionals all need to play a role in shaping our future. Please get involved either personally or through one of the professional associations; they have been very involved the last few years in moving the profession forward.

The *New Hampshire Board of Pharmacy News* is published by the New Hampshire 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.

Open Position - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Amy Suhajda - Communications Manager