

January 2019

News



New Hampshire Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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<https://www.oplc.nh.gov/pharmacy>

Board Office Updates

The pharmacist renewal period ended December 31, 2018. Everyone should have their updated permits as of this date. The New Hampshire Board of Pharmacy is working diligently to streamline the new database with each renewal season. The Board thanks everyone for their patience and understanding during the renewal process. When the renewal season begins each year, the Board puts all the instructions in the email that is sent to you. Please read those instructions carefully. Most of your questions can be answered there, without calling the office.

The Board website, www.oplc.nh.gov/pharmacy, is updated two to three times per week, on average, to keep everyone informed of the most current activity. Please visit the Board website first before calling the Board office. On the home page, “[Important Notices and Updates](#)” is a key place to find information. Information can also be found by selecting your profession in “[Licensing](#),” or under “[Laws, Rules & Procedures for Reporting Changes](#).”

When the Board sends out renewal notices to licensees, all the instructions needed for renewing are included. Many of the calls to the Board office during renewal time include questions that can be answered by reading renewal instructions. The Board office has a small staff of three and desires to be helpful to everyone. The Board staff requests that before calling with a renewal question, you first fully read the instructions in the renewal notice, as many answers to questions are found there. Reducing the number of phone calls during the renewal period allows staff the time needed to complete each renewal in a timely manner, so everyone may receive their license renewals on time.

Pharmacist-in-Charge Exam

For scheduling or questions email elsa.croteau@oplc.nh.gov. Study materials for the exam can be found on the Board website under “[Laws and Rules](#),” including Revised Statutes Annotated (RSA) 318; RSA

318-B; and Pharmacy Rules 100 – 2000, Administrative Rules.

Registered and Certified Pharmacy Technicians

There is an application process to follow for a person to move from a registered pharmacy technician to a New Hampshire certified pharmacy technician. It has come to the attention of the Board that many individuals are achieving national certification status and then beginning to practice as a certified pharmacy technician in New Hampshire without notifying the Board. An individual cannot practice in New Hampshire as a certified pharmacy technician or use the CPhT designation without first submitting the application to the Board and then receiving a Board-issued certified technician registration. Additional information on the process can be found on the Board website at www.oplc.nh.gov/pharmacy. Go to the right-hand side of the page, select “[Licensing](#),” then “[Pharmacy Technician License](#),” and open the document called “[Laws, Rules and Procedures for Reporting Changes](#).” Follow the instructions in part (d) on how to become a New Hampshire certified pharmacy technician. Please keep in mind, this requirement is established in RSA 318:26-a, which includes status of employment under the types of changes that require notifying the Board within 15 days of the change.

Again, if anyone has any questions about this information, please do not hesitate to contact the Board office.

The Board hopes everyone had an enjoyable and happy holiday season.

An Interview With Michael D. Bullek

Michael D. Bullek, BSP, RPh, is the administrator/chief of compliance at the Board. The following interview is excerpted from the November/December 2018 issue of the National Association of Boards of Pharmacy® (NABP®) monthly newsletter, *Innovations*®.

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National Pharmacy Compliance News

January 2019



NABPF
National Association of Boards
of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- ◆ *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- ◆ *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Con-

trolled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The “ASHP Guidelines on Preventing Medication Errors in Hospitals” are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy*, the guidelines are available at www.ajhp.org/content/75/19/1493. ASHP's October 2, 2018 press release can be found in the News section at www.ashp.org.

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities*. In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities*. This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at <https://againstopioidabuse.org>.

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added

biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- ◆ generic substitution is recommended as part of the pharmacist's dispensing role;
- ◆ pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- ◆ a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at www.fip.org in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes*, will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit <http://fdapasediabetes.e-paga.com>.

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.

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Michael D. Bullek

How long have you served as administrator/chief of compliance of the New Hampshire Board of Pharmacy? What was your role prior to working with the Board?

I have held the position of administrator/chief of compliance for one and a half years. Previously, I was a commissioner on the Board for seven years and also worked in the retail setting.

ously, I was a commissioner on the Board for seven years and also worked in the retail setting.

What is one of the most significant challenges or issues your Board addressed in the past year or so?

Our Board is responsible for all licensing concerning pharmaceuticals, both in-state companies and companies that ship into New Hampshire, the Prescription Drug Monitoring Program (PDMP) and all compliance and inspections involved, and inspecting all providers' offices for medication-related issues. Last April, the Board had a legislative audit performed involving the PDMP and our compliance unit, verifying our processes to current statutes and rules. We have developed new guidelines, as well as a strategic plan, to move forward on recommendations stated in the audit.

What actions were taken by the Board to address the issue?

The Board reviewed and updated all our inspection policies and procedures and started the process of developing software to access our databases to streamline the process. We also looked at how the PDMP was operating and made changes to programs to meet the audit requirements for outcomes management information we send to our providers.

What other key issues has the Board been focusing on?

The Board has moved to a paperless system, with all pharmacy demographics, licensing, inspection, and investigations performed through the state computer system.

What insights do you have for other states that may be facing similar challenges?

New Hampshire is unique in how it has integrated the PDMP into normal Board operations as well as into inspections of providers' offices to state and federal drug laws. These programs would not be successful without reaching out to various boards and investigators from other states, as well as to NABP, for guidance.

New Hampshire Board of Pharmacy

Number of Board Members: 6 pharmacist members and 1 public member

Number of Compliance Officers/Inspectors: 3

Rules and Regulations Established by: Board of Pharmacy

Number of Pharmacist Licensees: 2,572

Number of Pharmacies: 310 (in-state)

Number of Wholesale Distributors: 1,305 (including manufacturers)

Violations and Inspections – What to Expect

Violation notices issued during an inspection are reviewed by the Board during non-public meetings to protect the reputation of each of the businesses or individuals who received a violation notice per RSA 91-A. Board actions related to a violation notice, or as a result of an investigation related to a complaint, may include dismissal, issuing a letter of concern, issuing an administrative fine, or requesting an administrative hearing.

1. A dismissal occurs when members of the Board review a violation or investigation and agree that it does not merit further action, so the Board will vote for dismissal and close the file.
2. A letter of concern occurs when the Board agrees that the action is of concern, and that the business or individual should be notified of that concern. However, it is non-disciplinary. The letter of concern will be placed in the business' or individual's file for future reference or in the event that additional information becomes known to the Board that warrants it to reopen the case.
3. An administrative fine occurs when the Board agrees that the action rises to a level that warrants discipline. An administrative fine is **not** reported to the NABP Clearinghouse. When a business or individual receives a Board-issued administrative fine, there are two actions available to the party:
 - a. Sign a settlement agreement and pay the fine. In this case, the settlement agreement goes into the party's file, and the Board will close the case.
 - b. Contest the fine and request a public hearing before the full Board. In this situation, the Board will issue a notice of hearing, and a date and time for the party to appear before the Board so it can hear why the party should not be issued the administrative fine. After the hearing, the Board may elect to dismiss the case, retain its original decision, or modify the original decision, including notice to NABP.

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The party will be notified of the Board's decision within 30 days.

4. A disciplinary hearing occurs when the Board agrees that the action rises to a level that warrants discipline that requires a hearing. The Board sends the responsible party a notice of hearing that includes which RSA or Administrative Rules warranted issuing the notice, along with a date and time to appear before the Board. The injured party will appear before the Board to hear why the Board should not take the proposed action outlined in the notice of hearing. After the hearing, the Board may elect to dismiss the case, retain its original decision, or modify the original decision. In the event that the Board does not dismiss the case and elects to retain its decision or modify the original decision, actions taken will be sent to NABP. The party will be notified of the Board's decision within 30 days.

Technician Renewals and CE Requirements

The renewal period for technicians opens on February 1, 2019, and closes on March 31, 2019. All registered and certified technicians will be emailed detailed instructions on how to renew their registrations. The Board asks that before calling with a question, individuals carefully read the instructions in the notice as most answers to questions can be found there. A technician cannot practice with an inactive/expired registration. Once inactive, you would then have to follow the reinstatement procedures noted on

the Board's website to make your registration active again.

Certified technicians are included in the automated, random 10% audit of their continuing education (CE). The 2018 audit identified several certified technicians who failed to comply with the CE requirement and were notified by the Board. Individuals identified in 2019's audit as non-compliant are subject to disciplinary action by the Board.

Stay Up to Date on Important News From the Board

As a reminder to all licensees/registrants, the Board posts important updates and advisories on its Facebook and Twitter pages. Be sure to follow the Board on these services at <https://facebook.com/nh.pharmacy.board> and https://twitter.com/nh_pharmacy_brd.

Additionally, if you ever have questions on any Board-related matter, please visit its website at www.oplc.nh.gov/pharmacy, which is updated daily with the latest notices, advisories, and other news from the Board. You can also call the Board office at 603/271-2350, Monday through Friday, between 8 AM and 3:30 PM.

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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.

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