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New Hampshire Board of Pharmacy News

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Board Changes

House Bill (HB) 615 was introduced last fall, passed the New Hampshire House of Representatives and the New Hampshire Senate, and is heading to Governor Chris Sununu, who is expected to sign it.

Key provisions of the bill include:

- Deleting the position of New Hampshire Board of Pharmacy treasurer, which leaves the officer positions of president, vice president, and secretary. The Board is now part of the New Hampshire Office of Professional Licensure and Certification (OPLC), which handles Board finances.
- Prohibiting a third party from completing or signing a Board application for a license or permit.
- Changing license and permit renewals to every two years.
  - **Even years** are manufacturers, wholesalers and distributors, research organizations, reverse distributors, drug distribution agents as third-party logistics providers, brokers, and pharmacists.
  - **Odd years** are pharmacy technicians, 503B facilities, interns, in-state pharmacies, nonresident pharmacies, and limited retail drug distributors (all three types).
- Allowing a registered nurse or physician assistant to reconstitute or dilute a medication following manufacturer-specific directions (package insert).
- Repealing the following New Hampshire Revised Statutes Annotated (RSAs), some of which have been on the books since 1921.
  - **RSA 318:45:** "This chapter shall not prevent the sale of the following: alum, blue vitriol, borax, camphor gum, copperas, epsom salts, glauber salts, castor oil, oil of turpentine, sulphur, cottonseed oil, saltpetre, household ammonia, flavoring extracts, and unofficial chlorinated solutions."
  - **RSA 318:46:** "The pharmacist in charge of a pharmacy shall at all times keep in the pharmacy a record book in which shall be entered all sales of the following, other than sales to physicians, dentists and veterinarians, and sales made upon a prescription of a physician, dentist, veterinarian, or advanced practice registered nurse: arsenous acid (arsenic trioxide), mercuric chloride, hydrocyanic acid, potassium cyanide, cyanide mixture, strychnine and its salts except in proper dosage in pill or tablet form."
  - **RSA 318:47:** "The record required by RSA 318:46 shall show in parallel columns the date of sale, name of article sold, quantity of article sold, purpose for which it is to be used, the name or initials of the dispenser with the signature and address of the purchaser, and shall at all times during business hours be open for inspection by any police officer, sheriff, city or town representative, or any representative of the board; and shall be preserved for a period of not less than 2 years from the date of the last entry made therein."
  - **RSA 318:47-e:** This statute relates to dispensing emergency contraception.
  - **RSA 318:51-a, V(b)(4):** This statute relates to the names, addresses, and titles of new corporate officers, partners, or owners.

Fines: The Good, the Bad, and the Ugly

Over the past several months, the Board has issued several hundreds of dollars in fines to pharmacists and technicians for failing to notify the Board of changes. Unfortunately, the word is not getting around about actions taken by the Board regarding failures of notifications.

RSA 318:26-a is a law, not a rule, thus it **cannot** be waived by the Board. The law states that any pharmacist or technician who changes his or her name, place or status of employment, or residence **shall** notify the Board in writing within 15 days of the change. Failing to report such a change to the Board in 15 days means that the Board may suspend the pharmacist's license or the pharmacy technician's registration. In the event of a suspension, reinstatement shall be made only upon payment of a reasonable fee as established by the Board.

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National Pharmacy Compliance News

July 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.

FDA Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a Drug Safety Communication, provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

"Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse," the agency said in the communication. "Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances."

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the News and Events section of the FDA website.

DEA Warns of Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a DEA press release, this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of legitimate investigation or legal action is made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- maintaining quality manufacturing compliance,
- strengthening and refining regulations on compounding from bulk drug substances,
- finalizing the agency's memorandum of understanding with the states, and
- issuing revised draft guidance for compounding by hospital and health systems.

"We've worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs," then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a statement published on the FDA website. "We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . ."

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a press release from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

"Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis," Senate Minority Leader Chuck Schumer said in the press release. "We must hold China accountable for their role in the fentanyl trade. China's new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers."

In a December meeting with President Donald Trump, China's President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be "the largest source of illicit fentanyl and fentanyl-like substances" in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a press release posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy® (NABP®) Drug Disposal Locator Tool, available in the AWAR$_X$E® Prescription Drug Safety section of the NABP website, *www.nabp.pharmacy/initiatives/AWARxE.* With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at *https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine.*

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In addition to RSA 318:26-a, Board rules related to Pharmacy Rule (Ph) 704.12 Termination of the Pharmacist-in-Charge Notice and Ph 704.13 Termination of the Pharmacist-in-Charge Inventory have lightened the wallet of several pharmacists. It is the responsibility of the pharmacist-in-charge (PIC) to notify the Board in writing of the date when he or she ceases performing as the PIC. The PIC remains responsible for compliance to all federal and state laws governing the pharmacy until the Board receives notification from the PIC. The Board office has received notifications from third parties, which does not comply with Ph 704.12, as the rule requires the PIC to notify the Board.

Ph 704.13 requires the new PIC to take an inventory within three days of becoming the PIC, of all controlled substances located within the pharmacy where he or she is the PIC. A record of the inventory is required to be retained in the pharmacy for a minimum of two years. The Board has issued fines of up to $500 for noncompliance to Ph 704.12 and Ph 704.13.

Ph 805 requires a pharmacy technician to register with the Board within 15 days of employment, and Ph 808.01(5) requires a registered pharmacy technician to seek Board certification within 15 days of employment as a certified pharmacy technician. Per Ph 704.11(b)(11), the PIC is responsible for ensuring all personnel involved in the preparation and dispensing of prescriptions are properly licensed or registered with the Board. The Board has issued several fines to PICs for failing to comply with this rule.

The failure to monitor temperature logs has triggered several fines. Ph 702.02, Ph 1002.01(5), and Ph 1002.01(6) require daily monitoring of thermometers for both refrigerators and the room to ensure drugs are appropriately stored per manufacturer package inserts.

Sterile Syringe and Needle Access in New Hampshire Community Pharmacies

The Board seeks to enhance awareness and participation among pharmacists and pharmacy technicians to help prevent the transmission of HIV, hepatitis C virus (HCV), and other blood-borne infections among people who inject drugs (PWID). By stocking and selling new, sterile syringes and needles to PWID, they reuse and share syringes less frequently, decreasing not only blood-borne viral infections, but also bacterial infections related to syringe reuse and unsafe injection practices. **Increased access to sterile equipment does not increase drug use but does increase access to treatment.**

Injection drug use currently accounts for one-third of all new United States AIDS cases and approximately 60% of HCV infections. HCV is the major cause of end-stage liver disease, the need for transplantation, and liver cancer. Nationally, 50% of new HIV infections occur among intravenous drug users and their sex partners. HIV outbreaks among PWID have occurred in Massachusetts recently, which are largely preventable through sterile syringe access.

The Centers for Disease Control and Prevention (CDC) recognizes pharmacies as critically important in helping intravenous drug users reduce their injection-related risks. **The CDC strongly promotes increased access to sterile syringes through pharmacy sales.**

With your help, we can prevent new blood-borne infections, reduce the negative consequences of injection drug use, ensure safe disposal of syringes, and facilitate entry into drug treatment. **Together we can protect the health of all New Hampshire residents and communities.**

The Board encourages you to print and distribute the syringe disposal half sheet to patients with every sterile syringe purchase. It includes required information on syringe disposal, syringe exchange programs, and referral to treatment resources. The handout is available on the Board website for adults over 18 years old.

Fast Facts

- **Anyone over the age of 18** can purchase **any quantity** of syringes in New Hampshire.
- **No** prescription, insurance, or identification card is necessary.
- All pharmacy staff members (pharmacists, interns, technicians) are allowed to complete the sale.
- Pharmacy staff are not required to obtain any information from the patient at the point of sale.

Here Is Why

- When safe, sterile syringe and needle access is limited, **PWID are more likely to share and reuse.**
- Sharing and reusing syringes and needles increases the risk and spread of infections such as HCV and HIV.
- **Infections and costly hospitalizations among PWID can be prevented by selling sterile syringes and needles at community pharmacies.**

Best Practice

- Stock syringes and needles in an organized, convenient location to allow for faster and easier transactions.
- Store items below the counter for easy staff access.
- **Familiarize yourself** and your staff with common needle sizes and be sure to always have them in stock (eg, 30G 1cc ½ inch).
- **Per New Hampshire state law,** you must also distribute information regarding safe disposal and treatment options.

Safe Disposal and Treatment Options

- New Hampshire's Department of Health and Human Services resource center
- New Hampshire Alcohol and Drug Treatment Locator
- Substance Abuse and Mental Health Services Administration National Helpline for free treatment referrals: 1-800/662-HELP
- Locate local safe syringe disposal

New Hampshire, First in the Nation

In October 2018, the Board endorsed the creation of a license for a licensed pharmacist assistant. HB 463 was

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introduced in the New Hampshire House of Representatives, with public hearings before its Executive Departments and Administrative Standing Committee. The bill left the committee with unanimous support and passed the full House without debate.

During public testimony before the Senate's Executive Departments and Administrative Standing Committee, the name of the license was changed to licensed advanced pharmacy technician. With the change, the bill left the Senate committee with unanimous support and passed the full Senate without debate.

The bill was signed by Governor Sununu on June 5, 2019, and became law on July 1, 2019. The law requires the Board to write rules regarding the requirements for licensure, renewing the license, and the duties allowed to be performed by new licensees.

Board Commissioner John Genovese, RPh, will be leading a group of stakeholders to begin work on drafting rules that will govern this newly created category of licensure. Key objectives of this work group will be to define the requirements for licensure, including education, experience, training, and examination; and make a recommendation to the Board on what duties should be allowed to be performed by these licensees.

The law allows the Board to assign any duty or function allowed by federal and state law, including verifying products, processing refills, verifying repackaged drugs, completing final checks, and any other task not specifically required to be performed by a pharmacist. A licensed advanced pharmacy technician may perform duties that either a certified or registered pharmacy technician are allowed to do. The only functions the law specifically prohibits are:

- interpreting or evaluating a prescription or drug order;
- verifying or validating a compounded drug or medication; and
- counseling or advising an individual on the clinical use of a medication.

Employing a licensed advanced pharmacy technician by a pharmacy is voluntary. However, should a pharmacy elect to employ such a person, the pharmacy is required to provide clinical services in addition to dispensing prescriptions. A pharmacy owner shall provide resources necessary to the pharmacist to safely provide clinical services as determined by rules adopted by the Board, and when a pharmacy does employ a licensed advanced pharmacy technician, a pharmacist must be physically on the premises to provide supervision.

A key factor in establishing this new category of licensure is that the licensee will be held accountable to the Board for duties allowed by the Board and not the pharmacist on duty. This is comparable to a licensed practical nurse who works under the supervision of a registered nurse. The licensee will be required to have liability insurance.

Individuals interested in participating in the stakeholder work group should contact Commissioner Genovese at jrgrph@gmail.com.

PDMP on the Move

A bill heading to Governor Sununu for signing is Senate Bill (SB) 120, regarding the controlled drug prescription health and safety program, commonly referred to as the prescription drug monitoring program (PDMP).

When the PDMP was created in 2012, there was no OPLC, so the PDMP was structurally placed within the Board. Over the years, the PDMP became viewed as a Board program and not a program associated with and governed by all the licensing health boards, such as the medical, dental, nursing, and veterinarian boards. SB 120 structurally moves the program to oversight by OPLC and all the health licensing boards.

SB 120 retains the Advisory Council, but it makes changes to the composition of its membership and limits the time someone may serve on it. Advisory Council membership shall include a member from each of the medical, pharmacy, dental, nursing, and veterinary licensing boards; representation from the associations and societies of medicine, pharmacy, nursing, dental, veterinary, and hospital; and members from the Office of the Attorney General, Department of Health and Human Services, law enforcement, and the Senate and House of Representatives. A member may not serve for more than five years, and any current member serving six or more years will not be eligible to serve.

The program administrator shall make a report, at least annually, beginning November 1, 2019, to the Senate president, the speaker of the House of Representatives, the Oversight Committee on Health and Human Services, the Advisory Council, and licensing boards of all the professions required to use the PDMP. The report shall focus on the effectiveness of the PDMP.

Duties and responsibilities of the Advisory Council shall be:

- making recommendations to OPLC relating to the design, implementation, and maintenance of the PDMP, including rules, legislation, and sources of funding;
- reviewing the PDMP's annual report;
- making recommendations to OPLC regarding PDMP operations;
- providing ongoing advice regarding changes in technology and best practices; and
- developing a mission statement and strategic goals for the PDMP.

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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