October 2018 News



New Hampshire Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Board Licensing Update

As many of you are aware, the New Hampshire Board of Pharmacy has moved to online license renewals for all license and registration types regulated by the Board. For pharmacist renewals, the renewal period is from November 1 through December 31. Pharmacy Rule (Ph) 401.02(c) of the Board's Administrative Rules states that you must have your renewal filed with the Board no later than December 15. Further, if you do not renew by the December 31 deadline, then your license will turn to an inactive status, and you cannot practice with an inactive/expired license. You would then have to follow the reinstatement procedures noted in Ph 401.06 to make your license active again, which include retaking the New Hampshire Multistate Pharmacy Jurisprudence Examination®.

The online renewal procedures the Board emails out to each pharmacist at the start of the renewal period contain very detailed instructions to ensure the process is as clear and concise as possible. Please read those instructions carefully before beginning to renew your license. There is an automated, random 10% continuing education (CE) audit that is emailed out in February to those pharmacists randomly selected by computer and due back in March. Please check your email regularly, and ensure the Board is updated whenever your email address changes. Email is the first line of communication **from** our office, and it is also the best way to reach our office.

For pharmacy technicians, the renewal period opens on February 1 and closes on March 31. Again, the Board emails every technician very detailed instructions to ensure the process is as clear and concise as possible. Please read those instructions carefully before beginning to renew your registration. If you do not renew before the March 31 deadline, then your registration will turn to an inactive status. You cannot practice with an inactive/expired registration. Once inactive, you would 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 CE. The email to inform the 10% being audited this year went out August 16, 2018, and was due back by September 6, 2018.

All licensees are required to submit any demographic/license changes to the Board within 15 days of the change, as outlined in the following state law:

New Hampshire Revised Statutes Section 318:26-a Change in Name, Employment, or Residence.

Any pharmacist or pharmacy technician who changes his or her name, place or status of employment, or residence shall notify the board in writing within 15 days. For failure to report such a change within 15 days, the board may suspend the pharmacists license or the pharmacy technician's registration. Reinstatement shall be made only upon payment of a reasonable fee as established by the board.

This includes email address changes, home/mailing address changes, employment changes, phone number changes, or legal name changes. Please visit the Board's website at www.oplc.nh.gov/pharmacy and select Licensing from the column on the right, then select Report License Changes to Board from the top of the next page. Once you select that, you will see a Personal License Update Form. Please complete this fillable pdf form and submit it to the Board's office according to the instructions on the form itself.

The Board has a new licensing database that can track when changes are entered. It is therefore vital that licensees submit updates within 15 days of the change in order to comply with state law. Licensees who fail to do so are subject to disciplinary action by the Board.

Passing of Former Board Member Vahrij Manoukian, RPh



New Hampshire recently lost an influential and dynamic pharmacist, Dr Vahrij Manoukian. He served on the Board from 2003 to 2013 with enthusiasm and passion for the profession, and he was Board president from 2011 to 2013. Vahrij was instrumental in the passing of legislation to implement the New Hampshire Prescription Drug Monitoring Program, which has successfully reduced prescriptions for

opioids since its implementation.

Vahrij, a well-known Hollis, NH, resident; pharmacist; and selectman; passed away on August 16, 2018, at the age of 66 after a courageous battle with cancer. Born in Beirut, Lebanon, in 1952, Vahrij was one of four children of the late Nazareth and Anouch Manoukian. He immigrated to the United States in 1977 and resided in Boston before moving to New Hampshire in 1980.

continued on page 4

NH Vol. 25, No. 4 Page 1

National Pharmacy Compliance News



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NABPF
National Association of Boards
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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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants, which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at www.samhsa.gov.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act, will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and

♦ respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at www.fda.gov/newsevents/ newsroom/fdainbrief/ucm607339.htm.

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at www.ema.europa.eu.

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, www.hhs.gov/opioids, with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at www.surgeongeneral.gov.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services, describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at www.cdc.gov/dhdsp/ pubs/guides/best-practices/index.htm.

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability, FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at www.fip.org/news_publications.

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 Morbidity and Mortality Weekly Report, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016-September 2017," can be accessed at http:// dx.doi.org/10.15585/mmwr.mm6709e1.

continued from page 1

Vahrij was a graduate of Northeastern University, completed his residency at Massachusetts General Hospital, and received an honorary doctorate from the Massachusetts College of Pharmacy and Health Sciences. Vahrij established the Hollis Pharmacy and General Store, which he owned and operated for the past 33 years. Vahrij was very active in his community, and the town of Hollis adopted him as a native.

For more than 15 years, Vahrij was a senior selectman for the town of Hollis; was a member of the Hollis Brookline Rotary Club; served as president of the Board; played a major role in the Armenian Pharmacy Association of New England; and was a board member of the Child Advocacy Center. Additionally, Vahrij was the chairman of the Republican Party of Hillsborough County and a member of the Legal Ethics Committee of New Hampshire. He was the recipient of the Town of Hollis Citizen of the Year award in 2015. In addition, he received the Citizen of the Year award for the state of New Hampshire from the Veterans of Foreign Wars. He was a major advocate for the veterans of this country.

Vahrij was very proud of his Armenian/Lebanese heritage and was fluent in five languages. He loved the US; was a true patriot; and loved the freedom, peace, and opportunity of this great country. His store became a mandatory stop and landmark for all presidential candidates. In his leisure time, he enjoyed spending time with family and friends and had a passion for cars, motorcycles, and the New England Patriots. Additionally, he tirelessly fought to put an end to the opioid crisis and implement the New Hampshire Controlled Drug Prescription Health and Safety Program.

Welcome, New Board Member Nicole Harrington, RPh



A 1994 graduate of the University of Rhode Island College of Pharmacy, Nicole is employed by CVS Health. Nicole was appointed by Governor Chris Sununu on August 22, 2018.

As senior director of pharmacy services for CVS, Nicole leads a team that is dedicated to ensuring that the level of pharmacy practice exhibited by their retail pharmacy

team meets or exceeds the standards and expectations set by government regulators, payers, business partners, and most importantly, their patients.

Nicole's team is also responsible for the Safer Communities Programs at CVS, which include:

- ♦ Pharmacists Teach: One Choice Changes Everything An education and prevention program called "One Choice Changes Everything" that allows pharmacists to educate high school students about the dangers of prescription drug abuse.
- ♦ Safer Communities Drug Disposal Program In addition to more than 750 drug disposal kiosks installed in stores, CVS Pharmacy has teamed up with the Partnership for Drug-Free Kids at https://drugfree.org to create an innovative community donation program through which local police departments can apply to receive a drug collection

unit to help their communities safely dispose of unwanted medications, including controlled substances.

Nicole has been employed at CVS Health since 1994. Her prior roles have included intern, pharmacist, pharmacy manager, and pharmacy supervisor with responsibility for multi-unit operations in the state of New Hampshire. She also served on the Board of Directors for the Partnership for Successful Living, which had oversight of seven nonprofits focused on mental illness, human immunodeficiency virus/acquired immunodeficiency syndrome, and homelessness. Nicole received her bachelor of science degree in pharmacy at the University of Rhode Island.

Board Licensee Statistics

Active Licensees as of September 2018

Active Licensees as of September 2018		
Pharmacists	2,754	
Registered Pharmacy Technicians	2,106	
Certified Pharmacy Technicians	941	
Pharmacy Interns	345	
Prescription Drug Manufacturers, Wholesalers, Distributers	1,122	
Nonresident Pharmacies	707	
In-State Pharmacies	314	
Retail (Direct to Patient) Medical Gas/Prescription Device Distributors	271	
Public Health Clinics	17	
Methadone Clinics	9	
Bulk Sterile and Nonsterile Compounders	43	
Pharmaceutical Research Organizations	2	
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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://twitter.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, or call the office at 603/271-2350, Monday through Friday, between the hours of 8 AM and 3:30 PM.

Page 4 – October 2018

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