July 2019

New Jersey State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

PO Box 45013 • 124 Halsey St, 6th Floor • Newark, NJ 07101 • *www.njconsumeraffairs.gov/phar*

Board Application Tips

Congratulations, new graduates! You have passed all your coursework, graduated, and received your diploma – now let's get licensed to practice in New Jersey! But where do you start?

Follow these steps, and the New Jersey State Board of Pharmacy office will get you licensed as quickly as possible.

1. Scan any documents required with your application to separate files (eg, photo, birth certificate, legal document indicating a change of name).
2. Use Internet Explorer to submit your pharmacist's application by examination or score transfer at *www.njconsumeraffairs.gov/phar/Pages/applications.aspx.*
3. During the submission of your initial application, upload the documents you scanned. If you upload the documents, you do not need to mail these documents to the Board office.
4. Answer each question completely and honestly.
5. Toward the end of the process, you will be asked to pay the application fee of $125 via credit card. Make sure you pay by credit card. Without payment of the application fee, your application will not exist in the Board's licensing database.
6. Print out and mail the checklist (as your cover letter) to the Board office to continue your application processing. Using one staple, attach any additional required documentation from the checklist (including any required documents that you did not upload), along with a license fee of $140 (for the current biennial license cycle ending on April 30, 2021). You may pay using a check or money order made out to N.J. Division of Consumer Affairs.
7. As soon as the Board office receives the application that you submitted online, it will mail you fingerprinting instructions. Please read and follow the directions on this multipage document completely. If you have been licensed after 2008 by any professional board within the New Jersey Division of Consumer Affairs (DCA), the Board office may be able to resubmit your fingerprints that are on file to facilitate a criminal history background check (eg, if you previously held a pharmacy technician registration). The fee for resubmission is currently $18.75.
8. The Board office will also mail you a deficiency letter indicating any missing items required to complete the application process. Please address all correspondence to the address in the deficiency letter, as this is the most effective way to ensure that the Board office will receive your information.

Please Note

- Copies of passports or driver's licenses are **not** acceptable for your photo requirement.
- If your last name differs from what is on your birth certificate, submit proof of a legal name change.
- If your birth certificate is not in English, submit a certified translated copy.
- Be sure to include any apartment or floor numbers in your address.

Authorization to Test

Before the Board office can authorize you to take the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®), the Board office will need to receive **and** process your pharmacist application and a copy of your **official** transcript from your college of pharmacy. **If the transcript does not display your date of graduation and degree conferred, you will not be authorized to test.**

The Board authorizes applicants to test and retrieves test scores through the National Association of Boards of Pharmacy® (NABP®) e-Profile system. Please contact NABP directly regarding any NAPLEX or MPJE testing policies and procedures that need to be followed.

"I've sent everything in; why hasn't the status of my application changed?"

Things to remember:

1. **Please be patient.** The Board office receives **a large volume of applications at this time of year.** Each application needs to be reviewed as part of the processing.
2. Applications are processed in the order that they are received.

Continued on page 4

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.*

Continued from page 1

3. You can help by submitting all required documentation in as few uploads/mailings as possible.

Please log in to the website to review the status of your application. If you have not noticed a change in your information after 10 business days, please email the Board office requesting an application status at **NJPharmacist@dca.lps.state.nj.us** using the subject line **STATUS REQUEST: <last name>, <first name> - Pharmacist Applicant Number <applicant>.**

Board office staff will reach out to you shortly after receiving your email with an update. Applications may take additional time to process if any of the following situations apply.

- You are in arrears on your child support.
- There are issues with your citizenship.
- Your answer to one or more questions on your application requires additional documentation.
- Your criminal history background check indicates that you have been arrested at any time in the past.

The Board office staff members understand how important it is to license applicants in a timely manner and will do their best to process your application as efficiently and quickly as possible!

Narcan Distribution Day

Overdose deaths in New Jersey rose to over 3,000 in 2018. In recognition of this ongoing public health emergency, New Jersey Department of Human Services (DHS), New Jersey Cares, and DCA requested and received Board approval of a pilot program under New Jersey Statutes Annotated 45:14-48(b)(10). This pilot program allows for the distribution of opioid antidotes to anonymous recipients at no cost, at pharmacies that have obtained naloxone standing orders from the New Jersey Commissioner of Health or a New Jersey-licensed physician. The first Narcan® distribution day occurred on June 18, 2019, and the approved pilot program allows for additional distribution days over the next 12 months, as DHS advises. The opioid antidotes will be made available through state and/or federal funding and be administered by DHS. Participating pharmacies will be required to have a valid standing order and must agree to specific conditions set forth in the pilot program, including but not limited to separating the opioid antidotes provided for the program from regular pharmacy drug stock, having a process for the anonymous distribution of opioid antidotes, record keeping, and counseling obligations for participating pharmacists and pharmacies.

View the press release at *https://www.state.nj.us/humanservices/news/press/2019/approved/20190607.html.*

Summer Temperatures Are Here

The Board reminds pharmacists-in-charge (PICs) that prescription medications must be stored, filled, dispensed, transported, and/or delivered to the patient, agent of the patient, or facility or health care provider providing care to the patient to ensure and maintain the integrity and stability of the prescription drug or chemical at the temperatures specified by the drug manufacturer. If the drug manufacturer has not specified the appropriate temperature, the prescription drug or chemical shall be thermostatically maintained between 20° and 25° Celsius (68° and 77° Fahrenheit).

A pharmacy shall monitor and record the temperature of the pharmacy-permitted area and refrigerator and, if applicable, the freezer, no less than twice daily with an interval between checks of at least eight hours. Appropriate manual, electromechanical, or electronic temperature recording equipment and/or logs shall be utilized to document the proper storage of prescription drugs and chemicals. A pharmacy shall maintain documentation of the recorded temperatures for two years.

In the event of a temperature excursion (any deviation from the manufacturer's specifications or, in the absence of manufacturer specifications, applicable United States Pharmacopeia standards) at a permitted pharmacy practice site lasting 24 hours or more, the PIC shall immediately notify the Board. The notification shall be made so that notice is received by the Board within 48 hours of becoming aware of the temperature excursion. If that temperature excursion lasts for 72 hours or more, a pharmacist shall not dispense any prescription drug or chemical unless the pharmacist verifies with the manufacturer of the prescription drug or chemical that the drug or chemical has not been adulterated, it is safe and efficacious, and its stability has not been adversely affected.

More detailed information on this topic may be found by reviewing New Jersey Administrative Code (N.J.A.C.) 13:39-5.11 Control and Monitoring of Temperature of Prescription Drugs and Chemicals.

'Don't Hesitate to Educate!'

Counseling is vitally important for the health and welfare of our patients and communities that take medications and use medical devices. The following rules are paraphrased from N.J.A.C. 13:39-7.21 Patient Counseling.

Before dispensing a new medication, a pharmacist shall make reasonable efforts to counsel the patient or the patient's caregiver. The offer to counsel may be made by pharmacy personnel. However, counseling shall be performed only by a pharmacist, or by a pharmacy intern or pharmacy extern under the immediate personal supervision of a pharmacist.

If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document accompanying the prescription. A written offer to counsel shall be in bold print, easily read, and include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population.

A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such counseling. At the time of dispensing, the pharmacist shall document by obtaining the signature of the patient or caregiver that counseling was provided or refused.

Continued on page 5

Continued from page 4

The aforementioned requirements shall not apply to a pharmacist who dispenses any drug to an inpatient at a hospital or a long-term care facility in which the resident is provided with 24-hour nursing care.

In the case of a medication that was used in the hospital and is now dispensed to the patient for discharge, refer to N.J.A.C. 13:39-9.12 Drug Disbursement; Oral Orders, which is summarized below.

The pharmacist may release to the patient at discharge any remaining medication in a multiple dose container (for example, inhalers, multiple dose injectable medications such as insulin, topical preparation, drops, ointments, and topical irrigation solutions), and a limited supply of other medications.

However, per N.J.A.C. 13:39-7.12; 2, the pharmacist must label the medications for outpatients, counsel the patient prior to discharge from the hospital or medical facility, and ensure that discharge orders contain the attending physician's authorizations to dispense the remaining doses of the prescription or the limited supply of other medications to the patient or guardian.

Counseling includes the following:

- the name and description of the medication
- the dosage form, dosage, and route of administration
- the duration of drug therapy
- special directions and precautions for preparation, administration, and use by the patient
- common adverse or severe side effects or interactions and contraindications that may be encountered, including how to avoid such side effects, interactions, and contraindications, and the action required if they occur
- techniques for self-monitoring drug therapy
- proper storage
- prescription refill information
- action to be taken in the event of a missed dose

It is the duty of pharmacists to protect the health of their patients. Counseling and education are paramount for promoting wellness and improving compliance. Your patients will appreciate the interaction and their professional pharmacist's personal touch and care.

Reminders for the PIC

The following are reminders for the PIC adapted from N.J.A.C. 13:39-6.2 Pharmacist-In-Charge. The PIC is responsible for keeping up with rules and regulations governing pharmacy practice in the state of New Jersey. New Jersey pharmacy laws, statutes, rules, and regulations can be found on the Board website at *https://www.njconsumeraffairs.gov/phar/Pages/regulations.aspx.*

The PIC shall be a full-time employee, in good standing, employed for a minimum of 35 hours per week, and shall be physically present in the pharmacy or pharmacy department for that amount of time, which is necessary to supervise and ensure that:

- The pharmacy is staffed by sufficient, competent personnel in keeping with the size, scope, and complexity of the pharmaceutical services provided by the pharmacy.
- Accurate records of all prescription medication received and dispensed are maintained.
- Security of the prescription area and its contents are maintained at all times.
- The prescription area is maintained in an orderly and sanitary manner.
- There are written policies and procedures to ensure the proper storage and delivery of all prescription drugs and chemicals.
- Policies are in place regarding accurate dispensing and labeling of prescriptions and those policies are followed. The policy and procedures manual shall be reviewed, at a minimum, once every 24 months and shall be updated on a continuous basis to reflect current practice. Exceptions to the 24-month review of policies are policies and procedures for automated medication systems (N.J.A.C. 13:39-10.4 Written Policies and Procedures of Operation) and immunizations (N.J.A.C. 13:39-4.21 Procedures for Physician Ordered or Government Sponsored Immunizations Performed by Pharmacists), which shall be reviewed annually. The best practice is to review and update all policies and procedures annually. Documentation of the review shall be made available to the Board upon request. The pharmacy and all pharmacy personnel must provide pharmaceutical services in accordance with acceptable professional standards and comply with all federal and state statutes, rules, and regulations governing the practice of pharmacy.
- No pharmacy shall operate without a PIC for more than 30 days. If the PIC is absent from the pharmacy for more than 30 days, the PIC and the permit holder shall notify the Board of the name of the pharmacist who shall act as the interim PIC. Whenever a pharmacist assumes or terminates duties as a PIC of a pharmacy, both the outgoing and incoming PIC and the permit holder shall so advise the Board in writing within 30 days by completing a form provided by the Board.

The PIC is a very im portant responsibility and requires knowledge of the laws, rules, and regulations designed to protect patient welfare and safety. If you have questions, please stay up to date with the regulations, and contact the Board for assistance.

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

New Jersey State Board of Pharmacy – State News Editor
Mitch G. Sobel, BS Pharm, RPh, MAS, FASHP, CPGx – Contributing Editor
Carmen A. Catizone, MS, RPh, DPh – National News Editor & Executive Editor
Amy Sanchez – Communications Manager