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New Jersey State Board of Pharmacy News

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December 2017 Updates to Regulations

By Mitch G. Sobel, RPh, MAS, FASHP

The New Jersey State Board of Pharmacy regulations were updated and became effective in December 2017. The numerous updates affect all licensees: pharmacies, pharmacists, pharmacy technicians, interns, etc. Below is a brief overview of some of the changes.

These short descriptions are not intended to replace each licensee's and registrant's obligation to review and comply with all the regulations. The Board strongly suggests that all licensees and registrants review the regulations in their entirety for the complete details of all the updates. The following notices highlight some of the changes that have occurred:

- Pharmacies must notify the Board in writing within 48 hours of any temperature excursions.
- Pharmacies must notify the Board in writing within 48 hours of any cleanroom environmental sampling results that are out of compliance with the standards set forth in the Board's rules.
- Pharmacies must become compliant with United States Pharmacopeia General Chapter <800> on the date it becomes official, which is currently scheduled to be December 1, 2019.
- Pharmacies must transfer prescriptions within four hours of receiving a request to do so as outlined in the regulations.
- Acceptable methods to notify the Board when a change of ownership occurs for a pharmacy have been updated.
- When there is a change in a pharmacy's pharmacist-in-charge (PIC), both the outgoing and incoming PIC are required to conduct the controlled dangerous substances inventory.
- All applications submitted to the Board that are not completely processed within one year of submission will be administratively closed. Once closed, applicants who wish to continue with the application process must reapply by submitting a new application, along with the proper documentation, and all fees.
- Applicants who have failed the North American Pharmacist Licensure Examination® or Multistate Pharmacy Jurisprudence Examination® three or more times must now wait one year before each subsequent attempt to retake the respective examination.
- Commencing with the biennial renewal period that began on May 1, 2017, pharmacists renewing their license must complete at least one of the required 30 continuing education credits in educational programs or topics concerning prescription opioid drugs, including alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion.
- Within 90 days of the Board's approval of a pharmacy permit application, the pharmacy must notify the Board in writing that the pharmacy has opened for business. After 90 days, if the pharmacy has not notified the Board that it has opened for business or requested an extension, the Board will rescind the pharmacy permit.

The **complete Board regulations** can be found at *https://www.njconsumeraffairs.gov/regulations/Chapter-39-State-Board-of-Pharmacy.pdf.*

Closing a Pharmacy

By Mitch G. Sobel, RPh, MAS, FASHP

Here are the rules and regulations to follow when permanently or temporarily closing a pharmacy practice:

Permanently Closing a Pharmacy

Some reasons a pharmacy is closed or discontinued may include, but are not limited to: suspension or retirement of the permit holder, sale of the pharmacy, or insolvency and business failure. When this happens:

- The permit holder is required to immediately send written notification within 15 days prior to the anticipated closing to:
  - ◊ The Board
  - ◊ New Jersey Drug Control Unit
  - ◊ Drug Enforcement Administration (DEA)

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National Pharmacy Compliance News

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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.*

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- In the case of an unanticipated occurrence, such as the death of the permit holder, the permit holder's representative shall send written notification to the Board, New Jersey Drug Control Unit, and DEA as soon as possible, prior to the actual closing date.
- All medications, including prescription/legend and controlled drugs, should be transferred to the holder of a current pharmacy permit, a wholesaler, a reverse distributor, and/or a manufacturer.
- All medications not properly transferred shall remain on the pharmacy premises with all licenses and registrations in effect until such medications are disposed of in the manner prescribed by the Board, New Jersey Drug Control Unit, and/or DEA.
- Within 30 days of closing a pharmacy, the permit holder or his or her representative shall:
  - ◊ Remove all drug signs from both the inside and outside of the discontinued pharmacy.
  - ◊ Notify the Board in writing of the location of the previous five years of prescription and patient profile records.
  - ◊ Return the permit to the Board for cancellation.

When a pharmacy ceases operation as the result of a suspension, retirement, or death of the owner; sale; or other cause, including insolvency; the permit holder, or the one responsible for supervising the disposition of the practice, shall make every effort to notify patrons that they have the right to obtain copies of currently valid prescriptions and/or copies of their patient profile and the location of the prescriptions and patient profile for a one-year period following notice, using all of the following methods:

- Notifying the Board in writing
- Publishing a notice once weekly for two successive weeks in a newspaper with a circulation encompassing the geographic area where the pharmacy is located. The notice should advise patrons they have the right to obtain copies of their prescriptions and/or patient profile, and should inform them of the location of the prescriptions and patient profile for a one-year period following publication
- Placing a sign in the pharmacy location informing patrons they have the right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile

For a permitted pharmacy that uses social media that is specific to individually identified locations, the pharmacy shall post notice on all social media platforms used by the pharmacy informing patrons of the pharmacy closure, that they have a right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile.

In addition, the pharmacy shall discontinue and remove all commercial advertising from social media sites.

Upon a sale of assets or a change in ownership, both the new and former pharmacy permit holders shall ensure that there is access to patient prescription and profile records within 24 hours of the transfer of business assets, and that all telephone calls to the former pharmacy shall be forwarded to the new pharmacy.

Documentation indicating the personnel responsible for completing the required tasks, the name of the licensee who has agreed to accept the transfer of medications and patient records, copies of newspaper advertisements indicating the closing of the store, and other items may be requested by the Board.

Temporarily Closing a Pharmacy

A notice shall be conspicuously displayed on the exterior of any pharmacy to indicate any temporary changes in the opening or closing hours of the pharmacy, or to indicate a temporary closing of the pharmacy whenever such changes occur.

Any temporary closing of a pharmacy for more than 48 hours shall be reported to and approved by the Board. The notification to the Board shall include contingency plans for accessing patient records.

Any temporary closing of more than 48 hours without prior Board approval shall result in the pharmacy being deemed a closed or discontinued pharmacy.

If you have questions, please always contact the Board office. The goal is to communicate to the Board, ensure patient access to their medications, and ensure the security of drug inventory in a closed or discontinued pharmacy.

More details are available in the New Jersey Administrative Code 13:39-4, Pharmacy Permit Requirements, which can be found by following the link below and navigating to subchapter 4.

The **complete Board regulations** can be found at *https://www.njconsumeraffairs.gov/regulations/Chapter-39-State-Board-of-Pharmacy.pdf.*

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