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To Compound or Not to Compound . . .

By Mitch G. Sobel, BS Pharm, RPh, MAS, FASHP, CPGx, contributing editor, Board member

The New Jersey State Board of Pharmacy has rules regarding what a pharmacist may or may not compound in a pharmacy. These rules are listed under N.J.A.C. 13:39-11.25 Prohibited Compounding, N.J.A.C. 13:39-11A.3 Prohibited Compounding, and N.J.A.C. 13:39-11A.4 Compounding Commercially Available Products.

The intent of these rules is to use commercially available products instead of compounding them, in order to protect public safety and health. Commercially available products follow stringent federal guidelines, effective and established standard operating procedures, and consistent and documented quality performance indicators. In the Food and Drug Administration (FDA) guidance document related to compounding and commercially available drug products, FDA defines a drug product as commercially available if it is a marketed drug product. For more information on FDA guidances, visit *https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/guidances/default.htm.*

A pharmacist shall not compound any commercially available product or any preparations that contain drug products on FDA's *List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness,* codified in Title 21 Code of Federal Regulations (CFR) 216.24.

However, a pharmacist may compound a commercially available product if, in the professional judgment of the prescriber, the product is modified to produce a significant difference between the compounded product for the patient and the comparable commercially available product.

Additionally, a pharmacist may dispense a compounded commercially available product if the product is not available from normal distribution channels in a timely manner to meet the patient's needs. The dispensing of the compounded product must be approved by the prescriber and the patient.

If a pharmacist does compound a commercially available product due to unavailability or a significant difference or modification approved by the prescriber, there shall be documentation of the reason for such compounding.

Safe and Secure!

By Mitch G. Sobel, BS Pharm, RPh, MAS, FASHP, CPGx, contributing editor, Board member

There are rules and regulations regarding the security of pharmacies and pharmacy departments. This is a review of N.J.A.C. 13:39-4.15 Security of Pharmacies and Pharmacy Departments. It is important for the pharmacist-in-charge (PIC), pharmacy permit holder, and pharmacy personnel to observe and practice the rules to keep the pharmacy safe and secure.

A pharmacy or pharmacy department permit holder and the PIC shall ensure that:

- All entrances to the pharmacy or pharmacy department are capable of being locked.
- The pharmacy is connected to a monitored security system that transmits an audible, visual, or electronic signal warning of intrusion.
- The security system shall be equipped with a backup mechanism to ensure notification or continued operation if the security system is tampered with or is disabled. **Note:** It is important to inspect and become familiar with the alarm system when entering a new workplace or receiving new or revised security equipment.

Only the PIC shall be responsible for the security of the keys and the security system access code to the pharmacy or pharmacy department.

If theft, diversion, or significant loss of prescription legend drugs, devices, or controlled substances (CS) is reported to the PIC, the PIC shall notify the pharmacy or pharmacy department permit holder of the report.

In the case of theft, diversion, or significant loss, the PIC and the pharmacy or pharmacy department permit holder shall ensure that:

- A written report is filed with the Board upon the discovery of theft, diversion, or significant loss of prescription legend drugs or devices.

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National Pharmacy Compliance News

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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 Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP $AWAR_XE$® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the $AWAR_XE$ program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

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- A written report is filed with the federal Drug Enforcement Administration upon discovery of theft, diversion, or significant loss of CS.
- A copy of such report shall be filed with the New Jersey Drug Control Unit.

The PIC and holder of the pharmacy or pharmacy department permit will ensure that:

- There is a secure area for receiving packages known to contain prescription legend drugs, devices, and/or CS.
- No prescription drug shall be accepted during the hours that the pharmacy or pharmacy department is closed unless adequate security for the storage of such shipments has been provided.
- If a drop-off device is utilized for prescriptions, it is of a one-way, irretrievable, and secure design.
- The pharmacy department is constructed to enable the closing off and securing of the department from the main store area. The department shall be separated from the main store area by a secured barrier or partition extending from the floor or fixed counter to the ceiling of either the department or main store.
- All medications requiring pharmacist supervision, including dispensed medication, remain within the confines of the department when the pharmacist is not in the pharmacy department.

The pharmacist(s) on duty in all pharmacies, including pharmacy departments, shall be responsible for:

- keeping the pharmacy or pharmacy department closed and the security system turned on at all times when he or she is not present within the permitted premises of a pharmacy or pharmacy department, except as provided in N.J.A.C. 13:39-6.4 Meal or Restroom Breaks;
- determining if, in the case of a pharmacy or pharmacy department that has been issued an institutional permit, that based on his or her professional judgment, if the security of prescription legend drugs, devices, and CS will be maintained in the pharmacist's absence, pharmacy technicians may remain within the permitted premises when the pharmacy or pharmacy department is closed and secured;
- ensuring that the security of the prescription dispensing area and its contents are maintained at all times, including the restriction of persons unauthorized by the pharmacist on duty from being present in the prescription dispensing area; and
- for reporting all theft, diversion, or any significant loss of prescription legend drugs, devices, and CS to the PIC or the pharmacy permit holder upon discovery. When determining whether a loss of prescription legend drugs, devices, or CS is significant, the following factors shall be considered, consistent with Title 21 CFR 1301.74(c):
  - ◊ the actual quantity of prescription legend drugs, devices, or CS that is missing in relation to the type of business;
  - ◊ the specific prescription legend drug, device, or CS that is missing;
  - ◊ whether the loss of the prescription legend drugs, devices, or CS can be associated with access to those drugs, devices, or CS by specific individuals;
  - ◊ whether the loss can be attributed to unique activities that may take place involving the drugs, devices, or CS;
  - ◊ a pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses;
  - ◊ whether the specific prescription legend drugs, devices, or CS are likely candidates for theft or diversion; and
  - ◊ local trends and other indicators of potential theft or diversion of the missing prescription legend drug, device, or CS.

Security and safety are everyone's responsibility in a pharmacy; if you see something, say something!

Requirements for Continuing Education

By Mitch G. Sobel, BS Pharm, RPh, MAS, FASHP, CPGx, contributing editor, Board member

The following is a review of education requirements for pharmacists in New Jersey. Please see N.J.A.C. 13:39 Subchapter 3A Continuing Education, for full details.

Each pharmacist applicant for biennial license renewal shall complete a minimum of 30 credits of continuing education (CE) during the preceding biennial period. The following are requirements for CE.

- At least 10 of the CE credits shall be obtained through didactic instruction or be "live." **"Didactic instruction" means in-person instruction and may include telephonic or electronic instruction that is interactive but shall not include videotaped instruction.**
- At least three CE credits shall be on pharmacy law applicable to the practice of pharmacy in New Jersey.
- At least one CE credit shall be 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.
- Pharmacists with immunizer approval must have at least two CE credits on topics that cover immunizations.

CE credit hours are described in N.J.A.C. 13:39-3A.3 Continuing Education Credit Hour Calculations. Credit for CE shall be granted as follows for each biennial license period.

- Credit shall **not** be granted for programs or courses that are less than one contact hour in duration, which is

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defined as 50 minutes of actual attendance in a program or course of study.

- One half credit shall be granted for each 30-minute segment of a program or course that is more than one contact hour in duration.
- Successful completion of graduate coursework related to the practice of pharmacy at an accredited college or university, beyond that which is required for professional licensure, shall be granted three CE credits for each course credit awarded.
- Teaching and research appointments related to the practice of pharmacy shall be granted three CE credits for each **new program** or course taught or subject matter researched by a licensee, for a maximum of six credits.
- Participation as a preceptor in an externship program, upon prior approval by a college of pharmacy, shall be granted three CE credits per student to a maximum of six credits.
- Participation as a preceptor in an internship program shall be granted three CE credits per 160 hours of work performed by the intern(s) and supervised by the licensee, to a maximum of six credits.
- Publication of an article related to the practice of pharmacy in a peer-reviewed, professional journal shall be granted three CE credits per article, to a maximum of six credits.
- The Board **shall not** grant credit for, or approve as a component of a CE program, participation in the routine business portion of any meeting of a pharmaceutical organization or any presentation that is offered to sell a product or promote a business enterprise.

A licensee shall maintain all documentation concerning the completion of CE requirements for a period of **five years** from the completion of the credit hours and shall submit such documentation to the Board upon request. See N.J.A.C. 13:39-3A.4 Continuing Education Credit Hour Reporting Procedure, for exact details of these requirements.

The Board may waive CE requirements on an individual basis for reasons of military service, hardship, illness, or disability. According to N.J.A.C. 13:39-3A.5 Waiver of Continuing Education Requirements:

- A licensee seeking a waiver of CE requirements shall apply to the Board in writing and set forth with specificity the reasons for requesting the waiver.
- The licensee shall also provide the Board with such additional information as the Board may request in support of the application for the waiver.
- A waiver of CE requirements, once granted, shall be effective only for the biennial period in which such waiver is granted.
- If the condition(s) that necessitated the waiver continue into the next biennial period, a licensee shall apply to the Board for a renewal of such waiver for the new biennial period.

There are plenty of educational programs that meet Board requirements that are available through professional organizations and online. Please be sure to utilize CPE Monitor®, a service provided through the collaborative efforts of National Association of Boards of Pharmacy®, Accreditation Council for Pharmacy Education (ACPE), and ACPE providers, for the easiest way to track and record your CE credits. Log in to *https://nabp.pharmacy/cpe-monitor-service* for more information regarding monitoring and storing continuing pharmacy education credits. Please note that in accordance with N.J.A.C. 13:39-3A.7 Monitoring of Continuing Education Programs or Courses, a Board member or a Board representative may monitor an approved program or course without giving prior notification to the CE sponsor.

Who Are You? We Really Want to Know!

By Mitch G. Sobel, BS Pharm, RPh, MAS, FASHP, CPGx, contributing editor, Board member

The following is a clarification and correction of information regarding identification of pharmacy personnel. This can be found under N.J.A.C. 13:39 Subchapter 6 Pharmacist-in-Charge; Pharmacy Personnel, and specifically, N.J.A.C. 13:39-6.3 Identification Tag.

All personnel working at any pharmacy practice site, except personnel engaging in the compounding of sterile preparations consistent with the requirements of N.J.A.C. 13:39-11, shall wear an identification tag, which shall include at least the person's first name, first initial of the last name, and job title. It is **not** necessary to have the pharmacy worker's full last name on an identification badge; just the first initial of the last name is required.

In addition, the identification tag of any employee in training shall reflect the status of the employee as a trainee. It is important for the public to know whether the pharmacy worker is a pharmacist, pharmacy technician, or other pharmacy personnel. It is also important to know whether that employee is in training or is working in full capacity.

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