



New Jersey State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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

Long-Term Care Facilities and Central Fill Agreements

By Linda Witzal

Long-term care facilities and assisted living facilities are regulated by the New Jersey Department of Health, and there are specific regulations related to the provision of pharmacy services for the residents who reside in these facilities. Pharmaceutical services needed for these populations tend to be a cross between hospital and retail services. When a service such as infusion or compounding is needed to fill a prescription or medication order for these entities and the retail pharmacy is not equipped to supply infusion medications, a contract with an infusion or compounding pharmacy is established by a central fill agreement.

N.J.A.C. 13:39-4.19 Procedures for Centralized Prescription Handling allows two or more pharmacies to share the responsibility for preparing a prescription and ensures accountability by the entities. (New Jersey State Board of Pharmacy regulations can be found on the New Jersey Division of Consumer Affairs website at www.njconsumeraffairs.gov/regulations/Chapter-39-State-Board-of-Pharmacy.pdf.)

The four component functions of handling a prescription are intake, processing, fulfillment, and dispensing.

- ◆ An intake or originating pharmacy is a pharmacy that receives the patient's or prescribing practitioner's request to fill or refill a prescription.
- ◆ A central processing pharmacy is a pharmacy that engages in prescription review by performing functions that may include, but are not limited to, data entry, prospective drug review, refill authorizations, interventions, patient counseling, claims submission, claims resolution, and adjudication. A central processing pharmacy or a central fill pharmacy may be considered the intake or originating pharmacy if the prescription was transmitted by the prescribing practitioner directly to the centralized pharmacy or if the patient requested the refill from that pharmacy.
- ◆ A central fill pharmacy is a pharmacy engaging in central prescription handling by filling and/or refilling prescriptions, which includes the preparation and packaging of the medication.
- ◆ A dispensing pharmacy is a pharmacy that receives the processed prescription and/or the filled or refilled prescription for dispensing to the patient or to the patient's authorized representative and that offers patient counseling regarding the dispensed medication.

Two or more of the pharmacies delineated may engage in central prescription handling, provided any or all of the pharmacies participating in central prescription handling have a contractual agreement to provide such services or have the same owner. Prior to engaging in central prescription handling, all pharmacies that are parties to the central prescription handling must obtain Board approval. If a participating pharmacy is located outside the state of New Jersey, the pharmacy shall have registered with the Board pursuant to N.J.A.C. 13:39-4.20. The pharmacies shall make a single application to the Board, delineating the scope of practice of each pharmacy.

An audit trail must be maintained that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s), or extern(s) and the component function(s) performed by each, at the time the functions are performed, for each step of prescription handling that is required to be performed by a pharmacist, pharmacy technician, intern, or extern pursuant to the requirements of this chapter. All steps performed by a pharmacy technician, intern, or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern, or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in the component functions of prescription handling, the unique and secure user identifier(s) of the pharmacist(s) responsible for the accuracy and appropriateness of each component function(s) shall be recorded in the audit trail.

All pharmacies that are to engage in central prescription handling must maintain a common policies and procedures manual that designates who shall be responsible for each of the component functions of handling the prescription and for ensuring compliance with the Board rules. All pharmacies that are to engage in central prescription handling must share a common electronic file.

Please be sure to read and understand all aspects of a central fill agreement with respect to in-state and out-of-state pharmacies.

New Jersey Pharmacist-in-Charge Responsibilities

By Margherita Cardello and Mitch G. Sobel

In addition to the requirements all pharmacists must meet, the pharmacist-in-charge (PIC) has a specific set of additional responsibilities. Some of the responsibilities of the PIC are included here; for more complete information, please see N.J.S.A. 45:14 and N.J.A.C. 13:39.

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WHO Launches Global Patient Safety Challenge on Medication Safety

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at <http://who.int/mediacentre/news/releases/2017/medication-related-errors/en>.

Continuous Quality Improvement and Patient Safety Organizations

 *This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.*

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing

well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*.

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda*, which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit <https://www.pso.ahrq.gov/faq>.

NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at www.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf. Additional information for pharmacists about emergency preparedness is available on the NCPDP website at www.ncdp.org/Resources/Emergency-Preparedness.

FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efundex®, and

News to a particular state or jurisdiction can only be ascertained
such state or jurisdiction.

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm.

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm.

FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a “bulk drug substance” and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at www.fda.gov/Drugs/DrugSafety/ucm502075.htm, FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA’s website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf and www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf.

APhA Resource Guide Applies JCPP Pharmacists’ Patient Care Process to Immunization Services

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists’ Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists’ Patient Care Process to Immunization Services*. “[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation,” indicates the APhA guide. For more information, visit the APhA Immunization Center at www.pharmacist.com/immunization-center.

CPE Training on Older Adult Fall Prevention Available Online

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, “STEADI: The Pharmacist’s Role in Older Adult Fall Prevention,” visit the CDC website at www.cdc.gov/steadi/training.html for more information.

New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, “Combat Methamphetamine Epidemic Act,” pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

FDA Presents Series of CE Webinars for Students and Clinicians

FDA’s Division of Drug Information in the CDER presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA’s role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA’s website at www.fda.gov/DDIWebinars.

Every pharmacy must name a PIC who is to work full-time, at least 35 hours per week, and who is allowed to assume PIC responsibilities only for one pharmacy department at a time (exception: a health care facility permitted as an institutional and retail pharmacy). Whenever there is a change or absence of the registered PIC for more than 30 days, the registered PIC and the permit holder must notify the Board of the change, with the name of the incoming or interim PIC in writing, within 30 days, by completing a form provided by the Board.

An inventory of controlled dangerous substances (CDS) as defined in N.J.A.C. 8:65-10.1 through 10.5 shall be performed consistent with the requirements of N.J.A.C. 8:65-5.4 and 5.5 any time there is a PIC change. The controlled substances (CS) count shall include Schedule II and Schedule III through V CDS on separate documents and documentation that the count occurred at either the start or end of the business day, with date, time, and signature. Best practice recommends performing the count with a witness and documenting the aforementioned activity with the co-signature of another pharmacist.

Any suspected loss, theft, and/or diversion of CDS must be reported within 24 hours of discovery to the Board and to the federal Drug Enforcement Administration (DEA), per N.J.A.C. 13:39-4.15(b)2. A full investigation of suspected loss must be completed within 30 days of discovery, with the follow-up in writing, by completing forms provided by the Board and DEA. If local law enforcement is contacted regarding theft or loss of CDS, the New Jersey Department of Health must be contacted immediately.

A PIC must ensure the security of the prescription area and its contents at all times (per N.J.A.C. 13:39-4.15), that the prescription area is maintained in an organized manner, and that adequate staffing is present to satisfy the needs of the pharmacy. Policies must be put in place and enforced regarding accurate dispensing and labeling of prescriptions. The policy and procedure manual must be reviewed every two years, and documentation of the review shall be made available upon request by the Board.

All pharmacy personnel must comply with federal and state statutes, rules, and regulations governing the practice of pharmacy, including but not limited to record keeping and state and federal licensing of personnel. PICs must ensure that no misbranded, deteriorated, adulterated, improperly stored, or outdated drugs, or any drugs marked "sample," are present in the active stock of the pharmacy, per N.J.A.C. 13:39-6.2(f)7.

Registered PICs must ensure that only pharmacists and interns or externs under immediate personal supervision of a pharmacist provide professional consultation with patients and physicians; that only pharmacists, interns, or externs accept telephone prescriptions; and that only pharmacists, interns, externs, or pharmacy technicians consistent with the requirements of N.J.A.C. 13:39-6.6(b) accept renewal authorizations. All pharmacy personnel must have a name badge, which shall include at least the person's first name, first initial of their last name, and job title. The definitions of pharmacy extern, intern, and technician are as follows:

- ◆ A **pharmacy extern** is in the fifth or sixth (third or fourth professional) year of an Accreditation Council for Pharmacy Education (ACPE)-approved college of pharmacy assigned for practical experience.
- ◆ A **pharmacy intern** must be a graduate of an ACPE (or equivalent)-approved college of pharmacy within two years or seeking a reciprocal licensure; has not practiced for 1,500 hours within two years preceding application; must register with the Board; and needs 1,440 hours of practical experience.

- ◆ A **pharmacy technician** is registered with the Board and works under the immediate personal supervision of a pharmacist.

When pharmacy technicians and pharmacy technician applicants are engaged in any permitted activities, the pharmacist(s) shall be responsible for all the activities of the pharmacy technicians and the pharmacy technician applicants – meaning, supervision is not just solely the PIC's responsibility.

The PIC's name and the hours that the pharmacy department is open must be posted in plain view at all consumer entrances to the department, as well as in all access points to the premises, including drive-through windows. The PIC is ultimately responsible for all activities that occur in his or her pharmacy, including any mistakes or violations.

New Jersey Board of Pharmacy Application Tips

By Anthony Rubinaccio

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 Board 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. Using Internet Explorer, submit your Pharmacist's Application by "Examination/Score Transfer" online 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 April 30, 2019). 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 your application, the Board office 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 profession within the New Jersey Division of Consumer Affairs**, the Board office may be able to "resubmit" your fingerprints that are on file to facilitate a criminal history background check.
8. The Board office will mail you a deficiency letter indicating any missing items required to complete the process. Please address all correspondence to the address in the deficiency letter, as this is the most effective way to ensure the Board office will receive your information.

Authorized 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 the following two items from you:

1. Your application.
2. 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 people to test and retrieves test scores through the National Association of Boards of Pharmacy® (NABP®) e-Profile Connect system. Please contact NABP directly regarding any NAPLEX/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 **many** applications. Each application needs to be reviewed as part of the processing.
2. Applications are processed in the order in which they are received.
3. You can help by submitting all required documentation in as few mailings as possible.
4. Please log in to the website to review the status of your application. If you have not noticed a change in your information within 10 business days, please email the Board office requesting an application status:

◆ **Email address:** NJPharmacist@dca.lps.state.nj.us

◆ **Subject Line:** STATUS REQUEST: <last name>, <first name> Pharmacist Applicant Number <applicant>

After receipt of your email, Board office staff will reach out to you shortly with an update.

5. Applications may take additional time to review if any of the following conditions apply:
 - ◆ You are delinquent in repaying your student loans,
 - ◆ You are in arrears on your child support payments,
 - ◆ There are issues with your citizenship,
 - ◆ Your answer to one or more questions on your application requires additional documentation, or
 - ◆ Your criminal history background check indicates that you have been arrested at any time in the past.

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

Review of Security Requirements for a Pharmacy

By Mitch G. Sobel

The following is a synopsis of N.J.A.C. 13:39-4.15 Security of Pharmacies and Pharmacy Departments.

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 department. The security procedures and plans should be clearly delineated in your policy and procedure manual.

In the case of a pharmacy or pharmacy department that has been issued an institutional permit, pharmacy technicians may remain within the permitted premises when the pharmacy or pharmacy department is closed and secured, if the pharmacist determines, based on his or her professional judgment, that the security of prescription legend drugs, devices, and CS will be maintained in the pharmacist’s absence.

The holder of a pharmacy or pharmacy department permit and the PIC of the pharmacy or pharmacy department shall ensure that all entrances to the pharmacy or pharmacy department are capable of being locked and are 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 back-up mechanism to ensure notification or continued operation if the security system is tampered with or disabled. It is a good idea to perform testing each month to ensure that the security system is working properly. Only the PIC shall be responsible for the security of the keys and the security system access code to the pharmacy or pharmacy department.

In addition, there is a secure area for receiving packages known to contain prescription legend drugs and devices and CS. No prescription drug shall be accepted during the hours the pharmacy or pharmacy department is closed unless adequate security for the storage of such shipments has been provided; and, if a drop-off device is utilized for prescriptions, it must be of a one-way, irretrievable, and secure design.

The pharmacy department is constructed so as 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 supervision of a pharmacist, including dispensed medication, remain within the confines of the department when the pharmacist is not in the pharmacy department.

Finally, the holder of a pharmacy or pharmacy department permit shall comply with any law and/or ordinance of the municipality in which the pharmacy or pharmacy department is located, requiring the placement of a security key box on the exterior of the pharmacy or the premises in which the pharmacy department is located, for purposes of permitting emergency access to the premises.

For losses of drugs and CDS, the PIC must be notified and the PIC must notify the pharmacy permit holder. The Board must be contacted by the PIC and permit holder in writing regarding the significant loss of drugs and CDS. See Title 21 Code of Federal Regulations 1301.74(c) for a definition of significant loss of CDS. In the case of significant loss of CDS, DEA must be contacted immediately, regardless if the full investigation has not been completed. DEA Form 106 is filled out online and a copy is sent to the Board. All subsequent amendments are also sent to the Board.

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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.

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