



New Jersey State Board of Pharmacy

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Requirement for the Proper Display of Licenses and Permits

The New Jersey State Board of Pharmacy would like to remind all pharmacists-in-charge (PICs) and permit holders that they are responsible for ensuring compliance with the following regulations regarding the display of licenses and permits in licensed facilities.

N.J.A.C. 13:39-3.1 Authorization to Practice; display of license

- a) An applicant who has successfully satisfied all Board requirements for licensure and has been approved by the Board to be licensed shall receive an authorization signed by the Executive Director of the Board granting the applicant the right to practice pharmacy in the State of New Jersey until such time as an initial license may be issued. The licensee shall maintain such authorization on his or her person at all times while engaging in the practice of pharmacy until the initial license is issued.
- b) Upon issuance of a license, the current biennial renewal license shall be conspicuously displayed in the pharmacist's principal place of employment.
- c) A pharmacist who is employed by more than one pharmacy in the State shall maintain the wallet-sized license issued by the Board on his or her person when he or she is working at a location where his or her current biennial renewal license is not on display.

N.J.A.C. 13:39-3.6 Reproduction of license prohibited

The biennial license or wallet-sized license issued by the Board to any pharmacist shall not be reprinted, photographed, photostated, duplicated or reproduced by any other means either in whole or in part, except as provided in N.J.A.C. 13:39-3.2.

N.J.A.C. 13:39-4.3 Display of permits

The current permit issued by the Board for the operation of a pharmacy shall be conspicuously displayed.

N.J.A.C. 13:39-6.7 Authorization to practice as a pharmacy technician; display of registration

- a) An applicant for registration as a pharmacy technician who has successfully satisfied all Board requirements for registration and has been approved by the Board to be registered shall, upon payment of the initial registration fee set forth in N.J.A.C. 13:39-1.3, receive an authorization signed by the Executive Director of the Board granting the applicant the right to practice as a pharmacy technician in the State of New Jersey until such time as an initial registration may be issued. The registrant shall maintain such authorization on his or her person at all times while engaging in the practice of pharmacy as a pharmacy technician until the initial registration is issued.
- b) Upon issuance, the current biennial renewal registration shall be conspicuously displayed in the registered pharmacy technician's principal place of employment.
- c) A registered pharmacy technician who is employed by more than one pharmacy in the State shall maintain the wallet-sized registration issued by the Board on his or her person when he or she is working at a location where his or her current biennial renewal registration is not on display.

N.J.A.C. 13:39-9.3 Licensure of institutional pharmacies

- a) Any institutional pharmacy as defined under N.J.A.C. 13:39-9.2 shall be registered with and possess an institutional permit issued by the Board. The permit shall be conspicuously displayed in the facility's pharmacy. The institutional pharmacy is subject to and shall be conducted in accordance with all existing State and Federal rules and regulations.

Pharmacist License Renewal – April 2015

License renewal for all pharmacists licensed to practice pharmacy in New Jersey will occur in April 2015. The state will begin to mail renewal notices approximately 60 days prior to the license expiration date for each pharmacist and each immunizing pharmacist. The current expiration date is April 30, 2015. Licensees who have moved since the last license renewal in 2013, and have not yet notified the Board of their new

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DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.

System-Based Causes of Vaccine Errors

 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.

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter (www.ismp.org/sc?id=307), ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis

adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

- 1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
- 2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
- 3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
- 4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
- 5) Preparing and administering the vaccine immediately after verification, and
- 6) Documenting the vaccine on the patient's medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous



review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm.

PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at www.ptcb.org.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at <http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full>.

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access.

Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at www.njconsumeraffairs.gov/press/05012013.pdf.

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, www.rxpatrol.com, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc. of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at www.fda.gov/Safety/Recalls/ucm412431.htm.

address should do so immediately in order to avoid a delay in the renewal of their license.

A total of **30** continuing education (CE) credits must be completed before your license expires. As a part of your required 30 CE credits, **three** CE credits must be in pharmacy law and **10** CE credits must be in live or didactic instruction. (“Didactic instruction” means in-person instruction, and may include telephonic or electronic instruction that is interactive, but shall not include videotaped instruction.) **If a pharmacist is also approved to perform immunizations, two** of the 30 CE credits must be related to immunization training.

A pharmacist granted authorization to engage in **collaborative drug therapy management** shall complete a minimum of **10** credits of CE every biennial renewal period in each disease(s) or condition(s) covered by the collaborative practice agreement(s) to which he or she is a party, consistent with the requirements of N.J.A.C. 13:39-3A. However, to the extent that a pharmacist may enter into collaborative practice agreements to treat patients with co-existing or interrelated conditions or diseases, a pharmacist need only complete a total of 10 credits in interrelated conditions or diseases.

CE credits completed between May 1, 2013 through April 30, 2015, will be accepted as part of your biennial pharmacy license renewal requirements. You may carry over a maximum of **10** CE credits to be counted toward your 2015 renewal if the CE credits were earned during the last **six** months of the 2013 biennial renewal period (November 1, 2012 through April 30, 2013) and the CE credits were **not** previously reported to the Board.

The current pharmacist biennial license renewal fee is \$140. There is no fee for the renewal of your immunization approval, but you must renew this registration separately online through the “MyLicense Online Licensing for the New Jersey Division of Consumer Affairs” website. If you currently are approved to enter into collaborative practice agreements for specific disease states or conditions, you will receive a separate renewal correspondence from the Board with instructions regarding the renewal of your approval(s).

The NJPMP Continues to Improve

As of December 2014, New Jersey Prescription Monitoring Program (NJPMP) user enrollment has increased from less than 10,000 health care providers to over 35,500 within the last year. This number represents 56% of the total eligible registrants.

For 2015, the program looks to continue improving the usefulness of the system as the NJPMP pursues data sharing with New York State through the NABP PMP InterConnect® hub, incorporating user enrollment with license renewal, and working to improve the timeliness of the information uploaded to the database.

As part of these efforts, the program will be enhancing database capacity and moving toward requiring daily uploading of prescription records during the first quarter of 2015. The NJPMP thanks you for your participation and looks forward to the new year.

Compounding Sterile and Nonsterile Preparations in Retail and Institutional Pharmacies

The substantially modified N.J.A.C. 13:39-11 (Compounding Sterile and Non-Sterile Preparations in Retail and Institu-

tional Pharmacies) is now in effect, and can be accessed in the updated “Pharmacy Regulations” hyperlink at www.njconsumeraffairs.gov/pharm/phar_rules.htm, which was last revised on June 3, 2013. The new regulation divides the subchapter into sterile compounding (N.J.A.C. 13:39-11.1-24) and nonsterile compounding (N.J.A.C. 13:39-11A.1-15), and brings New Jersey regulations into agreement with the practice standards established by the United States Pharmacopeia General Chapter 797 (Pharmaceutical Compounding of Sterile Preparations) and General Chapter 795 (Pharmaceutical Compounding of Nonsterile Preparations). The Board urges all licensees to become familiar with the new regulation.

This is the seventh and last article of the series summarizing critical changes in the new regulation and will cover N.J.A.C. 13:39-11.21-24 of the sterile compounding regulations, which describes labeling, handling, packaging, and delivery of sterile compounded products; required contents of policy and procedures manuals; and components of a quality assurance program.

- ◆ **N.J.A.C. 13:39-11.10 is being amended and recodified as N.J.A.C. 13:39-11.21.** This section sets forth the information that is required to appear on a prescription label.
 - ◇ **N.J.A.C. 13:39-11.21(a)** has been amended to clarify that the section relates to sterile preparations.
 - ◇ **N.J.A.C. 13:39-11.21(a)5** is being amended to require that the label of a compounded sterile preparation now indicates the strength of all active ingredients, as well as the name and volume of the diluent, vehicle, and base solution(s) if applicable.
 - ◇ **N.J.A.C. 13:39-11.21(a)7** is being amended to require that labels contain the phrase “use by” followed by the preparation’s use-by date.
 - ◇ **N.J.A.C. 13:39-11.21(a)9** replaces the term “cytotoxic products” with the terms “antineoplastic agents and other hazardous substances.”
 - ◇ **N.J.A.C. 13:39-11.21(a)11** is a new provision requiring that preparations prepared by a retail pharmacy not dispensed pursuant to the requirements of N.J.A.C. 13:39, Subchapter 9 contain the prescription number.
 - ◇ **N.J.A.C. 13:39-11.21(b)** is a new subsection relating to the labeling of a compounded sterile preparation when not administered by the person who prepared it, or its administration was not witnessed by the person who prepared it.
- ◆ **N.J.A.C. 13:39-11.12 is being amended and recodified as N.J.A.C. 13:39-11.22.** This section relates to a pharmacy’s responsibilities in the proper handling, packaging, and delivery of compounded sterile preparations. The Board proposes to amend this section to clarify that the rule relates to sterile preparations, that the PIC must ensure that tamper-evident packaging is used, and that delivery must be made to the patient or patient care location within a reasonable time.
- ◆ **N.J.A.C. 13:39-11.13 is being amended and recodified as N.J.A.C. 13:39-11.23.** This section sets forth the topics that must be covered by a pharmacy’s policy and procedures manual.
 - ◇ **N.J.A.C. 13:39-11.23(a)** is being amended to require that a pharmacy’s policy and procedures manual set forth in detail the pharmacy’s standard operating procedures with respect to compounded sterile preparations. The

- existing rule requires the PIC to maintain a policy and procedures manual that relates to the licensee's standard operating procedures regarding compounded sterile preparations.
- ◇ **N.J.A.C. 13:39-11.23(b)** is being amended to make several non-substantive changes to language for clarity.
 - ◇ **N.J.A.C. 13:39-11.23(b)1** is being amended to require that pharmacies' risk management programs require that the PIC report all incidents of confirmed contamination to the Board within 48 hours of becoming aware of such incidents.
 - ◇ **N.J.A.C. 13:39-11.23(b)17** is being amended to specify that the policy and procedures manual must contain protocols and procedures to maintain the integrity of the interior work area of laminar airflow workbenches, compounding aseptic isolators, compounding aseptic containment isolators, and biological safety cabinets used to compound sterile products. The existing rule applies only to laminar flow hoods.
 - ◇ **N.J.A.C. 13:39-11.23(c)** is being amended to require review of the policy and procedures manual at a minimum of once every 24 months, and to require updating the manual on a continuous basis to reflect current practice. The existing rule requires the PIC to review the manual at least once every two years and to amend the manual as needed.
 - ◆ **N.J.A.C. 13:39-11.14 is being amended and recodified as N.J.A.C. 13:39-11.24.** This section sets forth the requirements for a pharmacy's quality assurance program. **The Board is proposing to delete existing Subsection (a) in its entirety. Existing Subsection (a) states that the section applies to both commercially available sterile drug products that are dispensed to patients without compounding or other manipulation, and to sterile preparations that have been repackaged, reconstituted, diluted, admixed, blended, or otherwise manipulated.**
 - ◇ **N.J.A.C. 13:39-11.24(a) 1 through 10** set forth the minimum requirements for a pharmacy's quality assurance program.
 - ◇ **N.J.A.C. 13:39-11.24(b)1** has been recodified as **N.J.A.C. 13:39-11.24(a)1**. It has been amended to delete a reference to a "dispensing pharmacist" and refers only to a "pharmacist" because "dispensing pharmacist" is an old term, and all pharmacists can dispense.
 - ◇ **N.J.A.C. 13:39-11.24(a)2** no longer sets forth examples of the phases of sterile compounding, and requires the quality assurance program to encompass all phases of sterile compounding for each unique type of compounded sterile preparation dispensed.
 - ◇ **N.J.A.C. 13:39-11.24(a)3** is a new paragraph, requiring inspection after preparation of every admixture.
 - ◇ **N.J.A.C. 13:39-11.24(a)4** is a new paragraph, requiring that all pharmacists, pharmacy technicians, interns, and externs involved in compounding sterile preparations have their aseptic technique tested consistent with N.J.A.C. 13:39-16.
 - ◇ **N.J.A.C. 13:39-11.24(a)5** specifies under what conditions high-risk level compounded sterile preparations are required to be tested to ensure that they are sterile before being dispensed or administered. This paragraph also sets forth the methods of verification that may be used.
 - ◇ **N.J.A.C. 13:39-11.24(a)5i** is a new subparagraph that sets forth the quality assurance procedure to be followed when high-risk level compounded sterile preparations are dispensed before receiving the results of the sterility tests outlined in proposed N.J.A.C. 13:39-11.24(a)5.
 - ◇ **N.J.A.C. 13:39-11.24(a)5ii** is a new subparagraph that requires that all high-risk sterile preparations, except those for inhalation and ophthalmic administration, be tested to ensure that they do not contain excessive bacterial endotoxins.
 - ◇ **N.J.A.C. 13:39-11.24(a)6** is being amended to require that air and surface sampling for microbial organisms in ISO Class 5 primary engineering controls, such as laminar airflow workbenches, compounding aseptic isolators, compounding aseptic containment isolators, and biological safety cabinets, and all other ISO-classified areas be done once every six months and at any time when microbial contamination is suspected. The existing rule refers to laminar hoods and ISO Class 6 cleanrooms, and requires cleaning to be done twice annually.
 - ◇ **N.J.A.C. 13:39-11.24(a)7** is a new paragraph, setting forth requirements for pressure differential monitoring and documentation.
 - ◇ **N.J.A.C. 13:39-11.24(a)8** is being amended to refer to laminar airflow workbenches, compounding aseptic isolators, compounding aseptic containment isolators, and biological safety cabinets instead of laminar flow hoods, and to require that these primary engineering controls meet appropriate ISO classifications.
 - ◇ **N.J.A.C. 13:39-11.24(a)9** is being amended to delete references to ISO Class 6 cleanrooms and ISO Class 7 anterooms. **N.J.A.C. 13:39-11.24(a)9** requires that cleanrooms be certified every six months, or whenever the room or a primary engineering control in the room is relocated or altered, or whenever a major service to the facility is performed. The Board proposes to incorporate by reference procedures outlined in the Controlled Environment Testing Association Certification Guide for Sterile Compounding Facilities, as amended and supplemented. The Board proposes to delete the provision in the existing rule regarding the disposal of unused drugs and materials used in the compounding of sterile preparations because this requirement was incorporated into N.J.A.C. 13:39-11.2(a)10.
 - ◇ **N.J.A.C. 13:39-11.24(a)10** is a new rule, setting forth the procedure to be followed whenever test results indicate that a cleanroom or any primary engineering controls do not meet the standards established in N.J.A.C. 13:39-11.24.