



# New Jersey State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **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 Institutional Pharmacies) is now in effect, and can be accessed in the updated “Pharmacy Regulations” hyperlink at [www.njconsumeraffairs.gov/pharm/phar\\_rules.htm](http://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 New Jersey State Board of Pharmacy urges all licensees to become familiar with the new regulation. Accordingly, in this issue the Board *Newsletter* will begin a series of articles designed to summarize critical changes in the new regulation. This issue will cover N.J.A.C. 13:39-11.4-7 of the sterile compounding regulations, encompassing new spatial requirements and terminology.

- ◆ **N.J.A.C. 13:39-11.4** was recodified from the old N.J.A.C. 13:39-11.16 and amended to refer to “cleanrooms” instead of the old term “controlled environment for compounded sterile preparations.”
  - ◇ 13:39-11.4(a) sets forth the physical criteria that a cleanroom must meet to minimize airborne contamination from contacting critical sites.
  - ◇ 13:39-11.4(b) requires that all sterile compounding take place within the confines of a buffer area unless it meets one of the exceptions set forth in paragraphs (b)1 through 3.
  - ◇ 13:39-11.4(c)(4) is amended to add that 66°F is the ideal temperature for a cleanroom.
  - ◇ 13:39-11.4(d) requires a pressure indicator or air velocity meter to monitor the room for correct room pressurization or air velocity.

13:39-11.4 Cleanroom: Use, Access, Location; Temperature; Air Pressure

- (a) The pharmacy shall have a designated area for sterile preparation compounding, known as the “cleanroom.” A cleanroom shall be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites. Critical sites are locations that include any component or fluid pathway surfaces (for example, vial septa, injection ports, beakers), openings (for example, opened ampules, needle hubs), exposed and at risk of direct contact with air (for example, ambient room or HEPA-filtered), moisture (for example, oral and mucosal secretions), or touch contamination. A cleanroom shall include a buffer area and an ante area. The buffer area shall contain an ISO class 5 or better primary engineering control, such as a laminar airflow workbench, biological safety cabinet, compounding aseptic isolator, and/or compounding aseptic containment isolator, unless the buffer area has ISO class 5 or better air quality.
- (b) All sterile compounding shall take place within the confines of the buffer area, except for the following:
  1. Compounding in a compounding aseptic isolator or a compounding aseptic containment isolator pursuant to N.J.A.C. 13:39-11.8;
  2. Compounding in a laminar air flow workbench in an institutional pharmacy pursuant to N.J.A.C. 13:39-11.10; and
  3. Compounding immediate use compounded sterile preparations in an institutional pharmacy pursuant to N.J.A.C. 13:39-11.11.
- (c) A cleanroom shall be:
  1. Accessible only to designated personnel;
  2. Used only for the compounding of sterile preparations or such other tasks that require a cleanroom;

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## Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at [www.yourhealthathand.org/images/uploads/OTC\\_Trust\\_Survey\\_White\\_Paper.pdf](http://www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf).

## ISMP Study on Targeted Mandatory Patient Counseling

 This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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](http://www.ismp.org). ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at [www.ismp.org](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- ◆ Opioid-containing analgesics
  - ◇ fentanyl patches
  - ◇ hydrocodone with acetaminophen
  - ◇ oxycodone with acetaminophen
- ◆ Anticoagulants
  - ◇ warfarin
  - ◇ enoxaparin
- ◆ Antidiabetic drugs (insulin analogs)
  - ◇ Humalog® (insulin lispro)
  - ◇ NovoLog® (insulin aspart)
  - ◇ Levemir® (insulin detemir)
  - ◇ Lantus® (insulin glargine)
  - ◇ Apidra® (insulin glulisine)
- ◆ Antineoplastic drug (non-oncologic use)
  - ◇ methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at [www.ismp.org/AHRQ/default.asp?link=ha](http://www.ismp.org/AHRQ/default.asp?link=ha).

## Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow,



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encourage, or mandate pharmacists to substitute generics for brand-name drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book*, is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, will be available in the forthcoming June-July 2013 *NABP Newsletter*, which will be accessible in the Publications section of [www.nabp.net](http://www.nabp.net).

## **NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients**

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders; experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal; and the background to communicate relevant trends or issues to the patient.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancil-

lary supplies, and hazardous waste disposal assistance as well as access to nursing services.

3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders exactly as written within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements; be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system; and regularly review insurance payment information with patients, and provide unit cost information to help patients manage medication costs.

The full article regarding standards of care for hemophilia patients, including information on state implementation of such standards, will be available in the forthcoming June-July 2013 *NABP Newsletter*, which will be accessible in the Publications section of [www.nabp.net](http://www.nabp.net).

## **NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands**

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in NABPLAW® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. NABPLAW Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about NABPLAW Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at [www.nabp.net/programs/member-services/nabplaw/](http://www.nabp.net/programs/member-services/nabplaw/).



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3. Structurally isolated from other areas within the pharmacy by means of restricted entry or access; and
  4. Air conditioned to maintain a temperature of 59 to 77 degrees Fahrenheit with an ideal temperature of 66 degrees Fahrenheit.
- (d) A pressure indicator or air velocity meter shall be installed that can be readily monitored for correct room pressurization or air velocity, respectively, consistent with the following:
1. For compounding of non-hazardous drugs, if the buffer area and the ante area are physically separated through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02 inch to 0.05 inch water column shall be required. For buffer areas not physically separated from the ante area, the principle of displacement airflow shall be employed. Using displacement airflow, an air velocity of 40 feet per minute or more from the buffer area across the line of demarcation into the ante area is required.
  2. For compounding of antineoplastic agents and other hazardous substances in a cleanroom pursuant to N.J.A.C. 13:39-11.9, the primary engineering control shall be placed in an ISO class 7 buffer room that is physically separated from other preparation areas and has not less than 0.01 inch water column negative pressure to adjacent positive pressure ISO class 7 or better ante room, thus providing inward airflow to contain any airborne drug.
  3. For compounding of antineoplastic agents and other hazardous substances outside of a cleanroom pursuant to N.J.A.C. 13:39-11.8, if a compounding aseptic containment isolator is used outside of a buffer area, the compounding area shall be physically separated from other areas and shall maintain a minimum negative pressure of 0.01 inch water column and have a minimum of 12 air exchanges per hour.
- (e) No chewing gum, drinks, candy, or food items shall be brought into the cleanroom.
- ◆ **N.J.A.C. 13:39-11.5** was recodified from the old N.J.A.C. 13:39-11.17 and was amended to substitute the term “cleanroom” for “controlled environment.”
- ◇ 13:39-11.5(b) adds a new provision describing the types of materials that can be used for cleanroom surfaces, all of which must be resistant to damage from cleaning agents, as well as sanitizing agents.
  - ◇ 13:39-11.5(c) was amended to clarify that junctures where ceilings meet walls must be covered, caulked, or sealed to avoid cracks and crevices where microorganisms and other contaminants can accumulate. The old N.J.A.C. 13:39-11.17(c) referred only to dirt accumulation.
  - ◇ 13:39-11.5(e) was amended to refer to “walls” instead of “solid walls” and to permit walls to be constructed of flexible materials such as heavy gauge polymer in addition to the other materials specified in the old N.J.A.C. 13:39-11.17(e) regulation.
  - ◇ 13:39-11.5(f) was amended to prohibit the use of floor drains.
  - ◇ 13:39-11.5(g) was amended to state that ledges (such as windowsills) should be avoided, but are not strictly prohibited as they were in the old N.J.A.C. 13:39-11.17(g).
  - ◇ 13:39-11.5(j) requires that refrigerators be within, or reasonably accessible to, cleanrooms in order to ensure the integrity of the compounded preparations.
  - ◇ The old N.J.A.C. 13:39-11.17(j), which required Board approval for cleanroom construction other than that specified in N.J.A.C. 13:39-11.17(a-i) prior to installation and use, was deleted.
- 13:39-11.5 Cleanroom Requirements**
- (a) The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the cleanroom shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby minimizing spaces in which microorganisms and other contaminants may accumulate.
  - (b) Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that the work surfaces may be readily cleaned and sanitized. All work surfaces shall be resistant to damage from cleaning and sanitizing agents.
  - (c) Junctures where ceilings meet walls shall be covered, caulked, or sealed to avoid cracks and crevices in which microorganisms and other contaminants can accumulate. All areas in ceilings and walls where the surface has been penetrated shall be sealed.
  - (d) Ceilings that consist of inlaid panels shall be impregnated with a polymer to render them impervious and hydrophobic and shall either be caulked or weighted and clipped.
  - (e) Walls shall be constructed of flexible material (for example, heavy gauge polymer), panels locked together and sealed, or of epoxy-coated gypsum board.
  - (f) Floors shall have a covering and shall be seamless or have heat-welded seams and coving to the sidewall. There shall be no floor drains.
  - (g) There shall be no dust-collection overhangs (such as ceiling utility pipes) and ledges (such as window sills) should be avoided. All sprinkler heads shall be flush with the ceiling.
  - (h) Ceiling lighting fixtures shall have exterior lens surfaces which are smooth, mounted flush, and air tight.

- (i) Carts shall be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility.
- (j) Refrigerators shall be within, or reasonably accessible to, the cleanroom in order to ensure the integrity of the compounded sterile preparations, consistent with the requirements of N.J.A.C. 13:39-11.12(b)3.
- ◆ **N.J.A.C. 13:39-11.6** was recodified from the old N.J.A.C. 13:39-11.20 and amended to refer to “ante areas” instead of “anterooms.”
  - ◇ 13:39-11.6(a) was amended to require that the ante area have appropriate environmental control devices capable of maintaining ISO Class 8 air quality conditions for non-hazardous drug compounding activities and ISO Class 7 air quality conditions for hazardous drug compounding activities. The old 13:39-11.20 required only that the anteroom have an air quality of ISO Class 7 or better, and did not differentiate between non-hazardous and hazardous drug compounding activities.
  - ◇ 13:39-11.6(b)(1) was amended to require that an ante area contain a sink with hot and cold running water with an integrated and closed plumbing system.
  - ◇ The old 13:39-11.20(c) (which required that a refrigerator be reasonably accessible to the anteroom) was deleted.

#### 13:39-11.6 Ante Area Requirements

- (a) The ante area shall have appropriate environmental control devices capable of maintaining ISO class 8 air quality conditions for non-hazardous drug compounding activities and ISO class 7 air quality conditions for hazardous drug compounding activities as provided in N.J.A.C. 13:39-11.4(d)2.
- (b) The ante area shall contain the following equipment:
  1. A sink with hot and cold running water with an integrated and closed plumbing system;
  2. Waste containers for all personal protective equipment;
  3. An eyewash station; and
  4. A hazardous waste spill kit.
- ◆ **N.J.A.C. 13:39-11.7** was recodified from the old N.J.A.C. 13:39-11.18 and amended to refer to “buffer areas” instead of “controlled environment for compounded sterile preparations.”
  - ◇ 13:39-11.7(a) requires that a buffer area have appropriate environmental control devices capable of maintaining ISO Class 7 air-quality conditions during normal activity.
  - ◇ 13:39-11.7(c) prohibits removal of any equipment or other items from the buffer area, with certain exceptions. The old N.J.A.C. 13:39-11.18(b) discouraged equipment removal but did not strictly prohibit it.

- ◇ 13:39-11.7(f) prohibits a buffer area from containing any sinks.
- ◇ 13:39-11.7(h) requires that buffer areas contain waste containers meeting the standards set forth by the Occupational Safety and Health Administration in 29 CFR 1910.1030, relating to the disposal of used needles and syringes, and in 29 CFR 1910.1200, relating to the disposal of chemotherapy waste.
- ◇ The old N.J.A.C. 13:39-11.18(e) (supplies required to be kept in the controlled environment area) has been deleted.

#### 13:39-11.7 Buffer Area Requirements

- (a) The buffer area shall have appropriate environmental control devices capable of maintaining ISO class 7 air quality conditions during normal activity consistent with the requirements of N.J.A.C. 13:39-11.4(d).
- (b) The buffer area shall contain only the following:
  1. Items such as furniture, equipment, supplies, and other materials that are required for the tasks to be performed there;
  2. Items that are nonpermeable, nonshedding, cleanable, and resistant to disinfectants; and
  3. Items that have been cleaned and disinfected immediately prior to their being placed in the buffer area.
- (c) Equipment and other items used in the buffer area shall not be taken from these areas except for calibration, servicing, or other activities associated with the proper maintenance of the item.
- (d) The buffer area shall be kept clean and arranged in an orderly fashion. All required equipment shall be maintained in good operating condition.
- (e) The buffer area shall not be used for bulk storage, warehousing, or clerical and secretarial functions.
- (f) The buffer area shall not contain any sinks.
- (g) The buffer area shall be a minimum of 100 square feet in size and shall be compatible with the volume of compounding being conducted.
- (h) The buffer area shall contain waste containers in compliance with Occupational Safety and Health Administration (OSHA) standards for disposal of used needles and syringes set forth in 29 CFR 1910.1030 and for disposal of chemotherapy waste set forth at 29 CFR 1910.1200, incorporated herein by reference, and available at [www.osha.gov](http://www.osha.gov).