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NEW JERSEY STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

To Copy or Not to Copy, That Is the Question

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New Jersey Administrative Code (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. 13:39-3.2 Replacement License

> A replacement initial license or renewal license shall be issued by the Board upon payment of a fee as prescribed in N.J.A.C. 13:39-1.3 and upon submission of proof of the applicant's identity and reasonable proof of the loss or destruction of the initial license or renewal license, or upon return of the damaged initial license or renewal license to the Board.

N.J.A.C. 13:39-6.12 Reproduction of Technician Registration Prohibited

> The initial registration, biennial registration, or wallet-sized registration issued by the Board to any pharmacy technician 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. 13:39-6.8.

National Pharmacy Compliance News

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Read National News

N.J.A.C. 13:39-6.8 Replacement of Technician Registration

A replacement initial registration or renewal registration shall be issued by the Board upon payment of a fee as prescribed in N.J.A.C. 13:39-1.3 and upon submission of proof of the applicant's identity and reasonable proof of the loss or destruction of the initial registration or renewal registration, or upon return of the damaged initial registration or renewal registration to the Board.

Pharmacist Present and On Duty – Know the Rules!

A pharmacist must always be present in the pharmacy when opened. Pharmacy technicians and other non-pharmacist personnel cannot be left in the pharmacy unsupervised by the pharmacist on duty. This includes opening the pharmacy when non-pharmacist personnel arrive before the pharmacist on duty arrives. A non-pharmacist permit holder is not allowed in the pharmacy unsupervised.

N.J.A.C. 13:39-4.15 Security of Pharmacies and Pharmacy Departments

a) The pharmacist(s) on duty in all pharmacies, including pharmacy departments, shall be responsible for: 1) 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 in the case of a pharmacy or, in the case of a pharmacy department.

Note, only the pharmacist-in-charge (PIC) shall be responsible for the security of the keys and the security system access code to the pharmacy or pharmacy department. A non-pharmacist permit holder may not have keys to the pharmacy or pharmacy department. If the sole pharmacist on duty goes on break for the restroom or a meal, then the pharmacist follows 13:39-6.4 Meal or Restroom Breaks.

N.J.A.C. 13:39-6.4 Meal or Restroom Breaks

a) A sole pharmacist on duty may take restroom breaks and 30-minute meal breaks while working in a pharmacy consistent with the following requirements:

1) The pharmacist shall remain in the pharmacy or, in the case of a pharmacy department, in the pharmacy department building, and shall be accessible for emergencies or for counseling, if requested;

2) The pharmacy shall remain open during the restroom or meal breaks, provided a pharmacy employee remains present in the pharmacy, for patient related services, which include, but are not limited to, the following:

i) The receipt of new written prescriptions; and

ii) The dispensing of prescription medications which have been checked by the pharmacist; and

3) A sign shall be posted in the prescription dispensing area stating, "Pharmacist on break, but available for emergencies and counseling."

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 their professional judgment, that the security of prescription legend drugs, devices, and controlled substances will be maintained in the pharmacist's absence.

The pharmacist on duty must also ensure 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.

Also, there are specific rules about unexpected closing of a pharmacy.

N.J.A.C. 13:39-4.12 Business Hours; Unauthorized Closing

a) All pharmacies shall be kept open for the transaction of business at least 40 hours per week and at least five days per week.

b) If any permanent changes are made in the opening or closing hours of a pharmacy, the Board office shall be notified in writing of these changes **within 30 days.**

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

d) Any temporary closing of a pharmacy for **more than 48 hours** shall be reported to and approved by the Board. Notification to the Board shall include contingency plans for accessing patient records. Any temporary closing of more than 48 hours without prior Board **approval** shall result in the pharmacy being deemed a discontinued pharmacy requiring compliance with the requirements of 13:39-4.10 [Discontinued Pharmacies] and 4.11 [Availability of Records Upon Termination of Business or Change of Ownership]. (emphasis added)

In summary, a pharmacist is always present in the pharmacy and pharmacy department during the course of business. When temporarily closing a pharmacy for more than 48 hours, make sure you **contact the Board for approval,** along with a plan for access to patient records!

Pilot Program to Distribute Opioid Antidotes Anonymously to Individual Patients

In recognition of the ongoing opioid crisis and statewide efforts to reduce overdose deaths, the Board, having worked with the New Jersey Department of Human Services (DHS), the Office of the New Jersey Coordinator for Addiction Responses and Enforcement Strategies, and the Division of Consumer Affairs, hereby approves a pilot program, pursuant to New Jersey Statutes Annotated (N.J.S.A.) 45:14-48(b)(10), to allow for the dispensing of opioid antidotes, at no cost, to anonymous recipients at pharmacies that have obtained standing orders from the commissioner of health or a New Jersey-licensed physician. In contrast to the previously approved pilot programs that authorized

dispensing of opioid antidotes for only a few days, this program will permit consumers to obtain free naloxone at any time.

After dispensing to an individual patient, pharmacies would be reimbursed through the New Jersey FamilyCare (NJFC)/Medicaid system, regardless of the Medicaid eligibility of the patient. This program is limited to individual patients; entities such as agencies and first responders have access to a different program*. Any pharmacy seeking to participate in this pilot program will be required to agree to comply with the terms and conditions set forth below. The agreement must be signed by an authorized representative of the permit holder and the registered PIC of the pharmacy, and then submitted to the Board as indicated below.

The pilot will operate as follows:

- Pharmacies will order naloxone from their regular wholesaler/distributors.
- Reimbursement rates will be set for all pharmacies based on acquisition costs, similar to the Medicaid reimbursement process.
- Billing is to be done through the NJFC/Medicaid system, as follows:
    - Pharmacies must bill naloxone claims for anyone seeking naloxone anonymously to BIN 610515. Other NJFC/Medicaid billing requirements shall not apply for naloxone provided anonymously.
    - When anonymously dispensed, pharmacies must report a first name of "Jane" in the NCPDP Patient First Name field (310-CA) and a last name of "Doe" in the NCPDP Patient Last Name field (311-CB).
    - When anonymously dispensed, pharmacies must report a date of birth of "010199" in the NCPDP Date of Birth field (304-C4).
    - Pharmacies must report the 12 byte recipient ID 580200000020 broken out across two fields, the 10 byte Cardholder ID field and the two byte Person Code field.
    - Pharmacies must also populate the NCPDP Prescriber ID field (411-DVB) with the National Provider Identifier (NPI) issued by the New Jersey Department of Health (DOH). Please refer to the DOH website for current standing order requirements.
- All available Food and Drug Administration-approved naloxone 4 mg nasal spray products are covered.
- Only one package containing two doses of naloxone product shall be covered per dispensing. Each package dispensed requires a new prescription number (ie, a prescription

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* NJ Human Services operates a separate naloxone distribution program, **Naloxone DIRECT,** by which eligible entities are able to receive naloxone directly through the department from an outside vendor. Eligible entities include harm reduction centers, community treatment, and prevention provider agencies, shelters, first responders, libraries, and more. More information about this program is available online at *https://dmhas.dhs.state.nj.us/NDP.* If you or organizations in your community have questions about New Jersey's naloxone distribution efforts and program eligibility, please reach out at Naloxone@dhs.nj.gov.

previously filled under this program cannot be "refilled" under the original prescription number).

- The number of naloxone products dispensed per week is not limited.
- Naloxone products should only be dispensed to those over the age of 14. An ID will not be required; oral confirmation of age is sufficient.
- At the time of dispensing, pharmacists shall:
    - Provide the recipient with the required opioid overdose response and prevention information, which may be found at: *https://www.njoag.gov/wp-content/uploads/2022/04/Opioid-Overdose-Response-Fact-Sheet.pdf.*
    - Make an inquiry as to whether the recipient is over the age of 14.
    - Advise that the opioid antidote should not be administered to persons with known allergies to any of the ingredients.
- Pharmacists should record all anonymously dispensed naloxone in the pharmacy's patient profile system required by N.J.S.A. 45:14-68, using the patient name "Jane Doe" with the date of birth as noted above. No drug utilization review is required for patients receiving naloxone anonymously.
- Records regarding naloxone purchased from manufacturers, wholesalers, or distributors, as well as dispensing information in the patient profile system, should be maintained consistent with the Board's record-keeping rule at N.J.A.C. 13:39-7.6. These records are subject to inspection by the Board and may be audited by DHS for compliance with this pilot program's requirements.
- If a patient presents with a prescription for naloxone, pharmacists may process and bill as with all other prescriptions. If the patient elects to obtain free naloxone under the pilot program (instead of having it billed to their insurance), the pharmacist should note in the patient's profile that naloxone was dispensed pursuant to the program and billed through the pilot program process set forth above.
- This pilot agreement shall be signed by the registered PIC of the pharmacy and an authorized representative of the permit holder, indicating their agreement to comply with all terms of this pilot program. The signed agreement shall be uploaded to **the pharmacy's** New Jersey ***MyLicense*** account (this is the same account utilized to complete the pharmacy's annual renewals).
    - Save this signed Naloxone Pilot Program Agreement as a pdf file named **"Naloxone Pilot Program Agreement."**
    - Click on this link, ***MyLicense,*** and log in to the pharmacy's account.
    - On the **Upload Documents** page, choose **"Naloxone Pilot Program"** as the **"Document Type"** from the drop-down list.
    - Follow the instructions to submit your signed agreement.

Naloxone Pilot Program Agreement

Pharmacy Name: _____

Pharmacy Permit Number: *28RS*_____

Permit Holder/Authorized Representative:

Name *(print)*: _____

Title: _____

License number *(if applicable)*: _____

Signature: _____ Date: _____

Pharmacist-in-Charge:

Name *(print)*: _____

License number: ***28RI***_____

Signature: _____ Date: _____

Additional Information:

- DHS contact information for pilot program inquiries (email): Naloxone@dhs.nj.gov
- Patient information to be distributed by pharmacists: *https://www.njoag.gov/wp-content/uploads/2022/04/Opioid-Overdose-Response-Fact-Sheet.pdf*
- DHS Newsletter addressing reimbursement can be found at: Welcome to New Jersey Medicaid: Document Download 3 *(njmmis.com)* (see Vol. 33, No. 01).
- Naloxone Standing Order From the New Jersey Department of Health: *https://nj.gov/governor/news/news/562021/docs/DOHSO202101.pdf*
- Naloxone promotional posters for pharmacy use:
  - English: *https://nj.gov/humanservices/assets/slices/Naloxone365_v1.pdf*
  - Spanish: *https://nj.gov/humanservices/assets/slices/Naloxone365_v1-SP.pdf*

Maintaining Adequate Storage of Medication Inventory

Maintaining a proper environment for medication storage is an essential professional practice standard for the safety and well-being of the patients we serve. The Board follows the United States Pharmacopeia (USP)/National Formulary for guidelines regarding room, refrigerator, and freezer temperature storage of medications and chemicals. The USP website is *www.usp.org.*

As per N.J.A.C. 13:39-5.7 Adequate Storage:

> Where no specific directions or limitations are provided in the packaging and storage section of individual monographs or in the manufacturer specifications, the conditions of storage [of medications and chemicals] shall include storage at [room] temperature maintained thermostatically between 20 and 25 degrees Celsius (68 and 77 degrees Fahrenheit), protection from moisture, and, where necessary, protection from light.

N.J.A.C. 13:39-5.11 Control and Monitoring of Temperature of Prescription Drugs and Chemicals states:

a) All prescription drugs and chemicals shall be stored, filled, dispensed, transported, and/or delivered to the patient, agent of the patient, or facility or healthcare provider providing care to the patient to assure and maintain the integrity and stability of the prescription drug or chemical at temperatures as specified by the drug manufacturer.

1) A pharmacy shall monitor and record the temperature of the pharmacy permitted area and refrigerator and, if applicable, freezer, no less than twice daily with an interval of at least eight hours.

i) Appropriate manual, electromechanical, or electronic temperature recording equipment and/or logs shall be utilized to document proper storage of prescription drugs and chemicals.

ii) A pharmacy shall maintain documentation of the recorded temperatures for 2 years. In the case of sterile compounding, those records will be kept for 5 years.

iii) A pharmacy shall calibrate thermometers or temperature monitoring devices at predetermined intervals according to the manufacturer specifications.

2) A pharmacy that delivers a filled prescription drug or chemical to the patient, agent of the patient, or facility or healthcare provider providing care to the patient by any method shall use adequate methods to ensure temperature controlled conditions are maintained during facility storage, transportation, and delivery.

i) To ensure that temperature control is maintained during delivery, the shipping processes may include the use of appropriate packaging material or devices according to information provided by the manufacturer, Chapter 1079 of USP, other learned treatises, or expert qualification analysis.

ii) When packaging material or devices are used to maintain temperature control during delivery, the contents of the package shall include instructions to the recipient how to easily detect improper storage or temperature variation, and instructions how to report the storage or temperature excursion to the pharmacy.

b) The temperature in a refrigerator and, if applicable, freezer that are used to store prescription drugs or chemicals must be maintained according to USP standards and guidelines.

c) The **pharmacist-in-charge** is responsible for ensuring proper temperature controls for all prescription drugs and chemicals in the pharmacy permitted area and all prescription drugs and chemicals that are shipped, mailed, distributed, or otherwise delivered from the pharmacy.

d) The **pharmacist-in-charge** shall develop and maintain written **policies and procedures** to ensure the proper storage in the pharmacy permitted area of all prescription drugs and chemicals:

1) Monitoring and **recording** the temperature of the pharmacy permitted area and refrigerator and, if applicable, freezer
2) Maintaining **documentation** of the recorded temperatures
3) Actions to be taken in the event of temperature excursions include, but are not limited to: notification of appropriate personnel, investigation of all temperature excursions, inspection and disposal, as applicable, of the stock in question, and corrective actions;
    i. A "temperature excursion" means any deviation from the manufacturer's specifications or, in the absence of manufacturer specifications, applicable USP standards.
4) Calibrating thermometers or temperature monitoring devices
5) **Actions** to be taken in the event that the prescription drugs and chemicals do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment or delivery; and
6) **Training** of all personnel who handle, or are responsible for overseeing the handling of, prescription drugs and chemicals to ensure the appropriate storage and delivery of all prescription drugs and chemicals, including refrigerated and frozen pharmaceuticals.

e) In the event of a temperature excursion, as defined in (d)3i above, at a permitted pharmacy practice site lasting **24 hours or more, the pharmacist-in-charge shall immediately notify the Board.** Notification shall be made in a manner such that notice is received by the Board within 48 hours of becoming aware of the temperature excursion.

f) In the event of a temperature excursion, as defined in (d)3i above, lasting **72 hours or more,** a **pharmacist shall not dispense any prescription drug or chemical** unless the pharmacist verifies with the manufacturer of the prescription drug or chemical that as a result of the temperature excursion, the drug or chemical has not been adulterated, is safe and efficacious, and its stability has not been adversely affected. (emphasis added)

As per N.J.A.C. 13:39-11.4 Cleanroom: Use, Access, Location; Temperature; Air Pressure, a pharmacy with a clean room for sterile compounding shall be "air conditioned to maintain a temperature of 59 to 77 degrees Fahrenheit with an ideal temperature of 66 degrees Fahrenheit."

In summary, temperatures (room, refrigerator, and freezer) of the pharmacy must be monitored at least twice daily and documented, and the documentation must be presented upon request to the Board inspector.

CQI for Patient Safety and Reducing Medication Errors

Continuous quality improvement (CQI) is an important process and tool for reducing potential patient harm and improving education of pharmacists and pharmacy technicians. CQI is a deliberate method to reduce medication errors, improve workflow processes, and increase education and awareness to avoid and reduce the risk for patient harm. The Board adopted new rule N.J.A.C. 13:39-1.9 Continuous Quality Improvement Program, effective October 3, 2022.

Subchapter 1. General Provisions
13:39-1.9 Continuous quality improvement program

(a) A pharmacy permit holder **and** registered pharmacist-in-charge shall implement a continuous quality improvement program (CQI) to detect, identify, and prevent prescription errors.

1. The primary purpose of the CQI shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a prescription error to assess the cause and any contributing factors, such as system or process failures.

(b) The continuous quality improvement program shall be set forth in the pharmacy's written policies and procedures manual and, at a minimum, include:

1. Required documentation including, but not limited to:
    i. Incident reports;
    ii. Resolutions;
    iii. Root cause analyses;
    iv. CQI program meeting minutes and attendance records; and
    v. Corrective action plans;
2. An internal incident reporting system;
3. Assessment of prescription errors to determine the cause of the error;
4. The appropriate response to the error; and

5. Meetings *[with all pharmacy personnel,]* conducted **at least once every three months,** to discuss the results of, and any issues identified from, the continuous quality improvement program, and any corrective action plans. Meetings shall be conducted in-person or through live, interactive webinars *and **must include, at a minimum, those personnel involved in an error under review and their supervisors.** The pharmacy permit holder must **document that pharmacy personnel who did not attend the CQI meeting have received the CQI meeting minutes and that the pharmacy permit holder has communicated any changes to policies and procedures** resulting from a CQI meeting with those personnel affected by such changes.*

(c) A pharmacy permit holder shall use the findings of its continuous quality improvement program to develop pharmacy systems and workflow processes designed to prevent prescription errors, as well as communicate those findings to all pharmacy personnel.

(d) For a pharmacy that submits quality-related events to a patient safety organization (PSO) for primary quality improvement, the Board shall deem the pharmacy as having a continuous quality improvement program if the PSO satisfies the minimum requirements of this section.

(e) Notwithstanding compliance with a continuous quality improvement program or participation in a patient safety organization, in accordance with N.J.A.C. 13:45C-1, each licensee, registrant, and permit holder retains a duty to cooperate with each Board inquiry, inspection, or investigation. (emphasis added)

To summarize, medication errors need to be reviewed, to be investigated, the root cause determined, corrective action taken, and all these actions need to be documented. In addition, the permit holder and PIC need to meet with the staff to discuss these actions. Staff who cannot attend the meeting must be provided with the documents and outcomes, and this communication must be documented. This documentation must be made available upon request by the Board.

The Board feels that CQI meets a national patient safety standard and best practices to reduce medication errors, improve patient safety, and enhance the education of pharmacists and pharmacy technicians. An effective CQI program protects public health and patient safety.

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