OCTOBER 2022

NEW JERSEY STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Closed for Business

There are rules regarding temporarily closing and permanently closing a pharmacy. New Jersey Administrative Code (N.J.A.C.) 13:39-4.12 Business hours; unauthorized closing explains the regulations regarding an expected or unauthorized closing of a pharmacy:

> (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 and 4.11. (emphasis added)

Now that your pharmacy is discontinued, what should you do?

See 13:39-4.10 Discontinued pharmacies for details:

> (a) Whenever a pharmacy is to be discontinued and closed for any reason, including suspension or retirement of the permit holder, sale or insolvency, the permit holder shall immediately send written

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notification of the anticipated closing to the State Board of Pharmacy, the Office of Drug Control and the Drug Enforcement Administration **at least 15 days prior** to the anticipated closing date. Whenever a pharmacy is to be discontinued and closed as a result of an unanticipated occurrence, such as the death of the permit holder, the permit holder's representative shall send written notification to the Board, the Office of Drug Control and the Drug Enforcement Administration, as soon as possible prior to the actual closing date. All medications, including prescription legend and controlled drugs, should be transferred to the holder of a current pharmacy permit; a wholesaler; a reverse distributor; and/or a manufacturer. All medications not properly transferred shall remain on the pharmacy premises with all licenses and registrations in effect until such medications are disposed of in the manner prescribed by the Board, the Office of Drug Control and/or the Drug Enforcement Administration.

(b) Within 30 days of closing a pharmacy pursuant to (a) above, the permit holder or his or her representative shall remove all drug signs from both the inside and outside of the discontinued pharmacy and shall notify the Board in writing of the location of the **previous five years of prescription and patient profile records**. . . The permit holder or his or her representative shall return the permit to the Board for cancellation **within 30 days of the closing.** (emphasis added)

Please note, prescription records and other information may be requested by the New Jersey State Board of Pharmacy.

After a pharmacy is discontinued or closes, what should happen to the pharmacy records? See N.J.A.C. 13:39-4.11 Availability of records upon termination of business or change of ownership for complete details:

(a) When a pharmacy ceases operation as the result of a suspension, retirement, or death of the owner, sale, or other cause including insolvency, the permit holder, or the one responsible for supervising the disposition of the practice, shall make every effort to notify patrons that they have the right to obtain copies of currently valid prescriptions and/or copies of their patient profile and the location of the prescriptions and patient profile for a one-year period following notice, using all of the following methods:

1. Notification in writing to the Board;

2. Publication, once weekly for two successive weeks in a newspaper whose circulation encompasses the geographic area in which the pharmacy is located, of a notice advising patrons that they have the right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile for a one-year period following publication;

3. A sign placed in the pharmacy location informing the patrons that they have the right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile; and

4. For a permitted pharmacy that uses social media that is specific to individually identified locations, the pharmacy shall post notice on all social media platforms used by the pharmacy informing patrons of the pharmacy closure, that they have a right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile. The pharmacy shall also discontinue and remove all commercial advertising from social media sites.

(b) Upon a sale of assets or a change in ownership . . . both the new and former pharmacy permit holders shall ensure that there is access to patient prescription and profile records **within 24 hours** of the transfer of business assets, and that all telephone calls to the former pharmacy shall be forwarded to the new pharmacy. (emphasis added)

Don't Hesitate to Communicate!

A pharmacist shall make reasonable efforts to counsel the patient or the patient's caregiver. Best practice is that all patients should understand their medications and potential side effects of their prescribed therapy. Please read N.J.A.C. 13:39-7.21 Patient counseling for details. Some important rules are listed below.

Counseling may include the following:

1. The name and description of the medication prescribed;
2. The dosage form, dosage, route of administration, and duration of drug therapy;
3. Special directions and precautions for preparation, administration and use by the patient;
4. Common adverse or severe side effects or interactions and contraindications that may be encountered, including how to avoid such side effects, interactions and contraindications, and the action required if they occur;
5. Techniques for self-monitoring drug therapy;
6. Proper storage;
7. Prescription refill information; and
8. Action to be taken in the event of a missed dose.

The offer to counsel may be made by pharmacy personnel. However, counseling shall be performed only by a pharmacist, or by a pharmacy intern or pharmacy extern under the immediate personal supervision of a pharmacist. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such counseling. At the time of dispensing, the pharmacist shall document that counseling was provided or refused.

If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document accompanying the prescription. A written offer to counsel shall be in bold print, easily read, and shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population.

The aforementioned requirements shall not apply to a pharmacist who dispenses any drug to an inpatient at a hospital or a long-term care facility in which the resident is provided with 24-hour nursing care.

Always use reflective listening, ask the patient to repeat back your information and instructions, and use verbal **and** written communication to reinforce the drug information provided and to improve compliance. Make sure that your patient understands the importance of their prescribed therapy!

PIC Duties With CDS

The pharmacist-in-charge (PIC) has many duties, some of which involve the proper handling and documentation of controlled dangerous substances (CDS); see Subchapter 6, Pharmacist-in-charge; pharmacy personnel.

For this article, "pharmacy" means a retail pharmacy or a retail pharmacy department, an institutional pharmacy, or a nuclear pharmacy. Every pharmacy shall name a pharmacist whose license is in good standing in New Jersey as the PIC of the pharmacy. No pharmacy shall operate without a PIC for longer than 30 days. Whenever the PIC is absent from the pharmacy for more than 30 days, the PIC and the permit holder shall notify the Board of the name of the pharmacist who shall act as the interim PIC (see Figure 1, Figure 2, and Figure 3).

> (d) Whenever there is a change of a pharmacist-in-charge of a pharmacy, an inventory of all controlled dangerous substances as defined in N.J.A.C. 13:45H-10.1 shall be performed by **both the outgoing and incoming pharmacist-in-charge** consistent with the requirements of [N.J.A.C. 13:39-6.2(d),] N.J.A.C. 13:45H-5.4 and 5.5.
>
> 1. If the outgoing pharmacist-in-charge is unable to perform the inventory required in (d) above, the pharmacy permit holder shall designate an alternative pharmacist, other than the incoming pharmacist-in-charge, to perform the inventory and shall submit to the Board a documented explanation for choosing an alternate pharmacist.
>
> (e) Whenever a pharmacist assumes or terminates the duties as a pharmacist-in-charge of a pharmacy, **both the outgoing and incoming pharmacist-in-charge and the permit holder** shall so advise the Board in writing **within 30 days** by completing a form provided by the Board [on its website.] (emphasis added)

In addition to the initial CDS inventory performed, a biennial CDS inventory must be performed thereafter.

See N.J.A.C. 13:45H-5.4 Maintenance of records and inventories for complete information.

> (d) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:
>
> 1. Inventories and records of all controlled substances listed in schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and

(Article continues on page 7)

FIGURE 1, Instructions Page

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, P.O. Box 45013
Newark, New Jersey 07101

Instructions to submit a Notice of Change of Pharmacist-in-Charge

Whenever a registered pharmacist assumes or terminates the duties as a registered pharmacist-in-charge of a pharmacy, both the outgoing and incoming pharmacist-in-charge, and the permit holder shall so advise the Board in writing within 30 days by completing this form and **uploading it to the appropriate *MyLicense* account**. If there is a vacancy of the pharmacist-in-charge for longer than 30 days, the interim pharmacist-in-charge and the permit holder must notify the Board immediately of who shall act as the interim registered pharmacist-in-charge.

Pharmacies providing Board Notification -

- Once you have completed the Notice of Change of Pharmacist-in-Charge, please upload it to the pharmacy's New Jersey *MyLicense* account to be reviewed. (This is same account utilized to complete the pharmacy's annual renewals).
- To log in, please click the following link: *MyLicense*
- Once logged-in, you will be brought to your *MyLicense* homepage. To submit the Notice of Change of Pharmacist-in-Charge form to be reviewed, click "**Upload License Documents**" on the left-hand side menu, and follow the instructions to upload the form.

Outgoing pharmacist-in-charge providing Board Notification -

- Log in to your ***individual*** pharmacist *MyLicense* account, click "**Upload License Documents**" on the left-hand side menu, and follow the instructions to upload the form.

Incoming pharmacist-in-charge providing Board Notification -

- Log in to your ***individual*** pharmacist *MyLicense* account, click "**Upload License Documents**" on the left-hand side menu, and follow the instructions to upload the form.

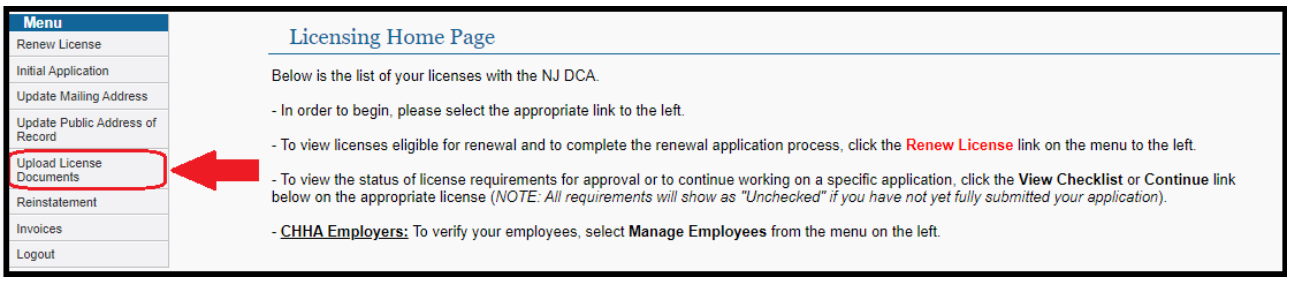
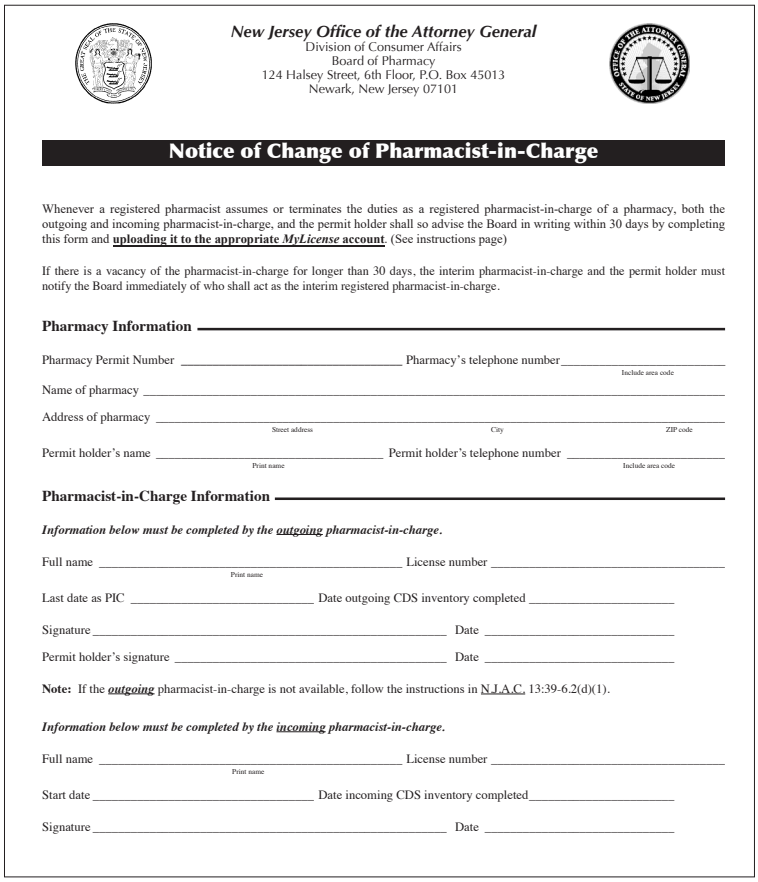


FIGURE 2, Notice of Change of PIC Form



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Whenever a registered pharmacist assumes or terminates the duties as a registered pharmacist-in-charge of a pharmacy, both the outgoing and incoming pharmacist-in-charge, and the permit holder shall so advise the Board in writing within 30 days by completing this form and **uploading it to the appropriate *MyLicense* account**. (See instructions page)

If there is a vacancy of the pharmacist-in-charge for longer than 30 days, the interim pharmacist-in-charge and the permit holder must notify the Board immediately of who shall act as the interim registered pharmacist-in-charge.

Pharmacy Information

Pharmacy Permit Number _____ Pharmacy's telephone number _____ (Include area code)

Name of pharmacy _____

Address of pharmacy _____ (Street address) _____ (City) _____ (ZIP code)

Permit holder's name _____ (Print name) Permit holder's telephone number _____ (Include area code)

Pharmacist-in-Charge Information

Information below must be completed by the outgoing pharmacist-in-charge.

Full name _____ (Print name) License number _____

Last date as PIC _____ Date outgoing CDS inventory completed _____

Signature _____ Date _____

Permit holder's signature _____ Date _____

Note: If the ***outgoing*** pharmacist-in-charge is not available, follow the instructions in N.J.A.C. 13:39-6.2(d)(1).

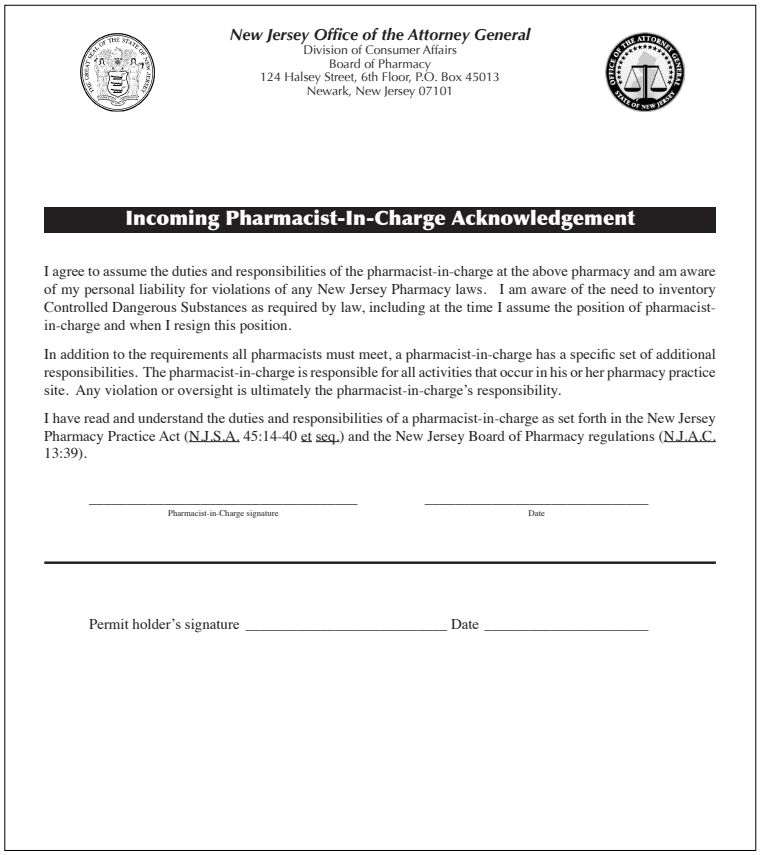
Information below must be completed by the incoming pharmacist-in-charge.

Full name _____ (Print name) License number _____

Start date _____ Date incoming CDS inventory completed _____

Signature _____ Date _____

FIGURE 3, PIC Acknowledgement Form



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Incoming Pharmacist-In-Charge Acknowledgement

I agree to assume the duties and responsibilities of the pharmacist-in-charge at the above pharmacy and am aware of my personal liability for violations of any New Jersey Pharmacy laws. I am aware of the need to inventory Controlled Dangerous Substances as required by law, including at the time I assume the position of pharmacist-in-charge and when I resign this position.

In addition to the requirements all pharmacists must meet, a pharmacist-in-charge has a specific set of additional responsibilities. The pharmacist-in-charge is responsible for all activities that occur in his or her pharmacy practice site. Any violation or oversight is ultimately the pharmacist-in-charge's responsibility.

I have read and understand the duties and responsibilities of a pharmacist-in-charge as set forth in the New Jersey Pharmacy Practice Act (N.J.S.A. 45:14-40 et seq.) and the New Jersey Board of Pharmacy regulations (N.J.A.C. 13:39).

_____ (Pharmacist-in-Charge signature) _____ (Date)

Permit holder's signature _____ Date _____

(Article continues from page 4)

> 2. Inventories and records of controlled substances listed in schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable.

See also 13:39-7.9 Filing and Storage of controlled substance prescriptions: the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one-inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances.

See also 13:45H-5.5 General requirements for inventories for more information regarding documentation requirements: "A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory was taken."

An inventory must be maintained in a written, typewritten, or printed form. An inventory taken by use of an oral recording device must be promptly transcribed to a written or printed form.

See N.J.A.C. 13:45H-10.1 Schedules of controlled dangerous substances for a complete explanation and detail of the CDS Schedules I-V.

Proper Storage of Medications, Don't Forget to Watch the Temperature!

Medications must be stored properly in the pharmacy. Following the rules of N.J.A.C. 13:39-5.7 Adequate storage, "(b) All prescription drugs and chemicals shall be maintained under adequate storage conditions, including proper lighting, ventilation, and temperature control, as recommended by the drug manufacturer."

If storage conditions are not specified by the drug manufacturer, the prescription drug or chemical shall be maintained according to the parameters set forth in the Drug Substance Monographs and Excipients of the United States Pharmacopeia – National Formulary (USP–NF), 2016 edition, as amended and supplemented, and which is available for purchase at the USP–NF website at *www.usp.org,* incorporated into the regulations by reference.

> 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 shall include storage at a temperature maintained thermostatically between 20 and 25 degrees Celsius (68 and 77 degrees Fahrenheit), protection from moisture, and, where necessary, protection from light.

Also, follow the proper humidity guidelines set by the manufacturer and Food and Drug Administration.

In addition, please follow N.J.A.C. 13:39-5.11 Control and monitoring of temperature of prescription drugs and chemicals:

(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. If the drug manufacturer has not specified the appropriate temperature, the prescription drug or chemical shall be maintained at a temperature maintained thermostatically between 20 and 25 degrees Celsius (68 and 77 degrees Fahrenheit).

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.

ii. A pharmacy shall maintain documentation of the recorded temperatures for two years.

(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, and the proper storage when prescription drugs or chemicals are delivered from the pharmacy to the patient, agent of the patient, or facility or healthcare provider providing care.

(e) In the event of a temperature excursion . . . 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.** (emphasis added)

(f) In the event of a temperature excursion . . . 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.

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