

## 55 N.J.R. 954(b)

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### RULE ADOPTIONS

#### Reporter

55 N.J.R. 954(b)

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#### Agency

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LAW AND PUBLIC SAFETY > DIVISION OF CONSUMER AFFAIRS > STATE BOARD OF PHARMACY

#### Administrative Code Citation

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**Adopted New Rules: N.J.A.C. 13:39-4A**

#### Text

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##### **Remote Processing of Prescriptions**

Proposed: May 2, 2022, at 54 N.J.R. 771(a).

Adopted: September 28, 2022, by State Board of Pharmacy, Mitch G. Sobel, R.Ph., President.

Filed: April 5, 2023, as R.2023 d.055, **without change**.

Authority: N.J.S.A. 45:14-47 and 48.

Effective Date: May 1, 2023.

Expiration Date: November 3, 2024.

[page=955] **Summary** of Public Comment and Agency Response:

The official comment period ended on July 1, 2022. The State Board of Pharmacy (Board) received one comment from Laura Mattaliano, Senior Project Manager, Regulatory Affairs, Memorial Sloan Kettering Cancer Center.

COMMENT: N.J.A.C. 13:39A-4A.2(o) states that the remote location is considered part of the pharmacy and allows the Board

to inspect the remote location and any equipment and/or devices used in connection with the remote processing of prescriptions. The commenter recommends revising N.J.A.C. 13:39-4A.2(o) to remove the provision that makes the remote location part of the pharmacy. The commenter also recommends that the rule be amended so that the Board may inspect only the equipment and/or devices used in connection with remote processing. The commenter believes that this change would focus the Board's review on the items used within the remote location to perform pharmacy-related services.

RESPONSE: New N.J.A.C. 13:39-4A.1(a) provides that a "remote location" is a location where the pharmaceutical functions specified in the subchapter are performed, other than on the premises of a pharmacy. The Board believes that the remote processing location, in addition to the equipment used in remote processing, must be considered part of the pharmacy because the new rules regulate the remote processing location as a whole and the Board would not have the power to enforce the rules in their entirety if the remote processing location were not considered part of the pharmacy.

For example, the proposed new rule provides that remote processing does not include the storing and dispensing of medication. N.J.A.C. 13:39-4A.1(a) and (p). The proposed new rule prohibits utilizing, maintaining, or storing prescriptions and other health information in hard copy format at the remote location. N.J.A.C. 13:39(g)li. These provisions apply to the remote processing location as a whole, rather than only to the equipment and devices used in remote processing. Therefore, the remote location must be part of the pharmacy.

Moreover, to enforce compliance with the proposed new rule, the Board must be able to inspect the remote processing location, in addition to the equipment used at the remote location. For example, new N.J.A.C. 13:39-4A.2(l) provides that remote processing shall be conducted in a work environment that is conducive to providing quality patient treatment decisions, private counseling, or other permissible pharmaceutical functions. This subsection requires that process-related documentation or materials and work equipment be properly secured when not in use. To ensure compliance with this subsection and with others that may require Board access to the remote processing location, the Board must be able to inspect the entire remote processing location, in addition to the equipment and devices used at that location. The Board does not interpret "remote location" to be the entire building, unless remote processing occurs in the entire building. New N.J.A.C. 13:39-4A.2(l) specifies that individuals engaging in remote processing out of a home environment perform the work in a designated space and that access to the space be limited and not

actively used as their primary living, household, or family space while performing remote processing. The Board must have the ability to inspect that designated space, but it does not intend to inspect the entire building of which that space is a part, unless the entire building is used for remote processing.

Therefore, the Board declines to make the requested change. The Board also notes that engaging in remote processing is voluntary.

### **Federal Standards Statement**

Requirements at N.J.A.C. 13:39-4A.2(1) require compliance with all Federal laws, rules, and regulations, including the Federal Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, concerning confidentiality of patient information. There are no other Federal laws or standards applicable to the adopted new rules, which are governed by N.J.S.A. 45:14.

**Full text** of the adopted new rules follows:

#### SUBCHAPTER 4A. REMOTE PROCESSING OF PRESCRIPTIONS

##### 13:39-4A.1 Definitions

(a) For purposes of this subchapter, the following words shall have the following meanings, unless the context clearly indicates otherwise:

"Remote location" means a location where the pharmaceutical functions specified in this subchapter are performed, other than on the premises of a pharmacy. The remote location must be located in New Jersey or in another state, territory, or possession of the United States whose regulatory body overseeing the practice of pharmacy is a member of the National Association of Boards of Pharmacy (NABP).

"Remote processing of prescriptions" means the performance of pharmaceutical functions specified in this subchapter at a remote location as defined in this section. "Remote processing of prescriptions" does not:

1. Include the storing or dispensing of any medication; or
2. Involve more than one licensed pharmacy.

##### 13:39-4A.2 Remote processing of prescriptions by a New Jersey pharmacy

(a) A pharmacy may engage in the remote processing of prescriptions, provided that the pharmacy complies with the requirements of this subchapter.

(b) A pharmacy that engages in the remote processing of prescriptions shall notify the Board that it is engaging in the remote processing of prescriptions and shall provide the name of the pharmacist-in-charge who shall be responsible for ensuring and attesting to compliance with the requirements of this subchapter. Such notification shall be made on a form supplied by the Board.

(c) As part of the permit renewal process pursuant to N.J.A.C. 13:39-4.2, a pharmacy engaging in the remote processing of prescriptions, on an annual basis, shall have the permit holder and pharmacist-in-charge attest to compliance with the provisions of this subchapter.

(d) A pharmacy using remote processing of prescriptions shall ensure that:

1. A pharmacist performing pharmaceutical functions at the remote location holds an active New Jersey pharmacist license in good standing;

2. A pharmacy technician performing pharmaceutical functions at the remote location holds an active New Jersey pharmacy technician registration in good standing; and

3. All pharmaceutical functions performed by a pharmacy technician at a remote location are reviewed and approved by a licensed pharmacist.

(e) A pharmacist or pharmacy technician performing pharmaceutical functions for a pharmacy at a remote location shall be an employee of the pharmacy.

(f) A pharmacy engaging in remote processing of prescriptions shall have the following:

1. A written policy and procedures manual maintained pursuant to this section;

2. A certification by the pharmacist-in-charge that all pharmacy technicians performing pharmaceutical functions at a remote location are registered with the Board pursuant to N.J.A.C. 13:39-6.6;

3. The address of the remote location(s) and a description of the work environment consistent with the requirements at (1) below;

4. The security controls to ensure the confidentiality of all patient information consistent with the requirements at (m) below;

5. The names and license or registration numbers of all personnel performing pharmaceutical functions at the remote location(s); and

6. A certification from each person performing pharmaceutical functions at the remote location(s) that the training described at (i)2 and 3 below has been completed.

(g) A pharmacy may allow a pharmacist at a remote location to perform only the following pharmaceutical functions using technology consistent with (k) below:

1. Receipt, interpretation, and clarification of prescription orders received from a prescriber.

i. Prescriptions shall only be in electronic format subject to the security requirements set forth at (k) below. Prescriptions or other health care information shall not be utilized, maintained, or stored in hard copy format at the remote location;

2. Data entry of prescription medication information;

3. Prospective drug utilization review;

[page=956] 4. Refill authorizations;

5. Product verification provided that there is compliance with the restrictions set forth at (p) below;

6. Interventions;

7. Patient counseling;

8. Claims submission; and

9. Claims resolution and adjudication.

(h) A pharmacy may allow a registered pharmacy technician to perform only the following pharmaceutical functions at a remote location using technology consistent with (k) below:

1. Data entry of prescription medication information;

2. Refill authorizations consistent with the requirements at N.J.A.C. 13:39-6.15(a)7;

3. Claims submission; and

4. Claims resolution and adjudication.

(i) The pharmacist-in-charge shall be responsible for all pharmaceutical functions performed in connection with the remote processing of prescriptions. The pharmacist-in-charge shall be responsible, at a minimum, for ensuring that:

1. No medications are stored at, or dispensed from, a remote location;

2. Prior to performing any services in connection with remote processing, all pharmacists and pharmacy technicians engaged in the remote processing of prescriptions have received adequate training relevant to performing pharmaceutical functions at a remote location;

3. Prior to performing any services in connection with remote processing, all pharmacists and pharmacy technicians are trained in the pharmacy's policy and procedures manual with regard to remote processing of prescriptions;

4. All pharmaceutical functions performed by a pharmacy technician at a remote location are reviewed and approved by a New Jersey licensed pharmacist;

5. The pharmacist or pharmacy technician performing pharmaceutical functions at a remote location has access to the pharmacy's electronic prescription files and that adequate security controls as described at (k) below are in place to ensure the confidentiality of all patient information; and

6. There is a policy and procedures manual with regard to the remote processing of prescriptions that meets the requirements at (j) below.

(j) A pharmacy engaging in the remote processing of prescriptions shall operate according to the pharmacy's written policy and procedures manual.

1. The policy and procedures manual shall include, at a minimum, policies and procedures governing the following:

i. Security controls, including measures to ensure that patient information cannot be captured, copied, downloaded, printed, reproduced, retained, or stored at a remote location;

ii. Work environment for the remote location;

iii. Responsibilities of the pharmacist-in-charge;

iv. Reporting to the Board within seven days of the violations of (m) below and any incidents of other compliance issues with this subchapter that negatively impact patient safety;

v. Methods to ensure that a New Jersey licensed pharmacist reviews and approves all pharmaceutical functions performed by a pharmacy technician at a remote location;

vi. Methods to ensure that access to the records of medications and other medical information of the patients maintained by the pharmacy is limited to New Jersey licensed pharmacists or

registered pharmacy technicians approved to have access to the records, for the purpose of complying with N.J.A.C. 13:39-7.19;

vii. Criteria for selecting employees to engage in the remote processing of prescriptions; and

viii. Training of all pharmacists and pharmacy technicians engaging in the remote processing of prescriptions.

2. The policy and procedures manual shall set forth methods that shall ensure retention of each amendment, addition, deletion, or other change to the policies and procedures of operation for at least two years after the change is made. Each change shall be signed or initialed by the pharmacist-in-charge and shall include the date on which the pharmacist-in-charge approved the change.

3. The policy and procedures manual shall be reviewed, at least annually, and updated, if necessary.

4. A copy of the written policy and procedures manual adopted pursuant to this section shall be available and immediately accessible at the pharmacy and each remote location. Upon request, the pharmacy shall provide to the Board a copy of the written policy and procedures manual for inspection and review.

(k) Security controls to ensure the confidentiality of all patient information shall include at least a two-factor positive authentication of the authorized user, encryption of all data exchanged between the equipment located at the remote location and the pharmacy, and measures designed to prevent unauthorized storage or transfer of patient information. The security controls must include measures designed to ensure that patient information cannot be captured, copied, downloaded, printed, reproduced, retained, or stored at a remote location.

(l) Remote processing of prescriptions shall be conducted in a work environment that is conducive to providing quality patient treatment decisions, private counseling, or other pharmaceutical functions permissible pursuant to this section. Individuals who engage in the remote processing of prescriptions out of a home environment shall perform the work in a designated space and, when performing this work, access to the space shall be limited and not actively used as their primary living, household, or family space. This space shall be open and accessible for Board inspection. When not in use, process-related documentation or materials and work equipment shall be properly secured.

(m) All pharmacists and pharmacy technicians participating in the remote processing of prescriptions shall ensure the confidentiality of patient information in compliance with all Federal and State laws, rules, and regulations, including the

Federal Health Insurance Portability and Accountability Act of 1996, P.L. 104-191.

(n) A pharmacy engaging in the remote processing of prescriptions shall maintain an audit trail that records and documents all pharmaceutical functions performed by a pharmacist or pharmacy technician at a remote location, consistent with the requirements at N.J.A.C. 13:39-7.6.

(o) The remote location shall be considered part of the pharmacy. The remote location and any equipment and/or devices used in connection with the remote processing of prescriptions shall be subject to Board inspection.

(p) No medications shall be stored at, or dispensed from, a remote location.

#### 13:39-4A.3 Remote processing of prescriptions by out-of-State pharmacy

An out-of-State pharmacy registered with the Board pursuant to N.J.A.C. 13:39-4.20 may engage in the remote processing of prescriptions that are to be shipped, mailed, distributed, or delivered to New Jersey, provided that the remote processing of prescriptions is authorized under the pharmacy laws and regulations in the jurisdiction where the out-of-State pharmacy is located, and provided that such functions are performed by a pharmacist or pharmacy technician who is licensed or registered and has been adequately trained, as required by the applicable law of the out-of-State jurisdiction(s).

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