# New Jersey Regulations

Department of Law and Public Safety/Division of Consumer Affairs/Board of Pharmacy

**PROPOSED RULE**

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**DIVISION OF CONSUMER AFFAIRS**

**STATE BOARD OF PHARMACY**

**Continuous Quality Improvement Program**

**Proposed New Rule: N.J.A.C. 13:39-1.9**

Authorized By: Anthony Rubinaccio, Executive Director, State Board of Pharmacy.

Authority: N.J.S.A. 45:1-15.1, 45:14-47, and 48.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2021-091.

Submit written comments by November 19, 2021, to:

Anthony Rubinaccio, Executive Director

Board of Pharmacy

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or electronically at: http://www.njconsumeraffairs.gov/Propos als/Pages/default.aspx.

The agency proposal follows:

**Summary**


The State Board of Pharmacy (Board) is proposing new N.J.A.C. 13:39-1.9 to require each pharmacy permit holder and registered pharmacist-in-charge to implement a continuous quality improvement program (CQI) to detect, identify, and prevent prescription errors. Because a CQI fosters a culture of discussion and encourages using data to learn from mistakes and taking steps to prevent repeat errors, the Board believes that requiring pharmacies to have such a program will enhance patient safety.

The primary purpose of the CQI is 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. The Board's proposed new rule requires creation and implementation of a process for a pharmacy to investigate the reason for errors and to address them, so as to improve the process proactively. The Board does not intend for this requirement to be punitive, nor does it believe it is burdensome.

Proposed new N.J.A.C. 13:39-1.9(a) sets forth the Board's requirement for each pharmacy permit holder and registered pharmacist-in-charge to implement a continuous quality improvement program to detect, identify, and prevent prescription errors. Paragraph (a)1 describes the primary purpose of the CQI.

Subsection (b) requires the CQI to be set forth in the pharmacy's written policies and procedures manual. Paragraph (b)1 requires, at a minimum, that the policies and procedures include required documentation, including: incident reports, resolutions, root cause analyses, CQI meeting minutes and attendance records, and corrective action plans; an internal incident reporting system; assessment of prescription errors to determine the cause of the error; appropriate response to the error; and meetings with all pharmacy personnel. These meetings, which must be conducted at least once every three months, are to discuss the results of, and any issues identified from, the CQI, and any corrective action plans. In addition, the meetings must be conducted in-person or through live, interactive webinars.

Subsection (c) requires the pharmacy permit holder to use the findings of its CQI to develop pharmacy systems and workflow processes designed to prevent prescription errors and communicate those findings to all personnel.

The Board is aware that some pharmacies may currently utilize a patient safety organization (PSO), an independent, outside entity to assist with the analysis of data. Accordingly, subsection (d) provides that if a pharmacy submits quality-related events to a PSO for primary quality improvement, the Board will deem the pharmacy as having a CQI, as long as the PSO satisfies the minimum requirements of the proposed new rule, such as the frequency and format of meetings with pharmacy personnel.

Although the Board is requiring the CQI to encourage internal disclosure, discussion, and resolution of prescription errors, the Board retains its authority to inquire, inspect, or investigate complaints or incidents. Moreover, in accordance with N.J.A.C. 13:45C-1, each licensee, registrant, and permit holder has a duty to cooperate with Board inquiries, inspections, or investigations. Subsection (e) reiterates this duty to cooperate, notwithstanding compliance with the CQI or participation in a PSO.

As the Board has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

**Social Impact**

The Board believes that the proposed new rule will have a positive social impact by improving patient safety. The Board believes that the proposed new rule will help foster a just culture that encourages pharmacy personnel to reveal and discuss prescription errors, and that by having a CQI, a pharmacy will ensure there will be processes in place to safeguard against, and to educate pharmacy personnel to prevent, the recurrence of errors.

**Economic Impact**

The Board believes that the proposed new rule will have an economic impact to the extent that there are costs associated with developing a continuous quality improvement program. The costs will vary depending upon the method(s) the pharmacy chooses to use. The Board believes that any increased costs are outweighed by the interest in protecting public health and safety.

**Federal Standards Statement**

A Federal standards analysis is not required because the proposed new rule is governed by N.J.S.A. 45:14-40 et seq., and there are no Federal laws or standards applicable to the proposed new rule.

**Jobs Impact**

The Board does not anticipate that the proposed new rule will increase or decrease jobs in the State.

**Agriculture Industry Impact**

The Board does not believe that the proposed new rule will have any impact on the agriculture industry of this State.

**Regulatory Flexibility Analysis**

Currently, the Board regulates approximately 2,230 in-State pharmacies and registered pharmacists-in-charge. If these pharmacies are considered "small businesses," within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., then the following analysis applies.

The proposed new rule imposes new compliance and recordkeeping requirements upon pharmacy permit holders and pharmacists-in-charge, which are discussed in the Summary above. The proposed new rule does not impose any reporting requirements. Pharmacy permit holders may choose to engage professional services to establish a CQI. The costs associated with engaging professional services are difficult to estimate, as they will vary depending upon the amount of work that each pharmacy permit holder will require and the rate that the professional will collect for his or her services. The costs of compliance with the proposed new rule are discussed in the Economic Impact above. The Board believes that the proposed new rule should be uniformly applied to all pharmacy permit holders and registered pharmacists-in-charge and, therefore, no differing compliance requirements for any businesses are provided based upon size.

**Housing Affordability Impact Analysis**

The proposed new rule will have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that the proposed new rule would evoke a change in the average costs associated with housing because the proposed new rule concerns continuous quality improvement programs for pharmacies.

**Smart Growth Development Impact Analysis**

The proposed new rule will have an insignificant impact on smart growth and there is an extreme unlikelihood that the proposed new rule would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan because the proposed new rule concerns continuous quality improvement programs for pharmacies.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Board has evaluated this rulemaking and determined that it will not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

Full text of the proposed new rule follows:

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.

(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.