54 N.J.R. 1916(a)

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RULE ADOPTIONS

Reporter
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NJ - New Jersey Register > 2022 > OCTOBER > OCTOBER 3, 2022 > RULE ADOPTIONS > LAW AND PUBLIC SAFETY -- DIVISION OF CONSUMER AFFAIRS

Agency

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

Administrative Code Citation

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

Text

Continuous Quality Improvement Program

Proposed: September 20, 2021, at 53 N.J.R. 1562(a).

Adopted: April 27, 2022, by the State Board of Pharmacy, Linda Witzal, R.Ph., President.

Filed: August 26, 2022, as R.2022 d.122, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

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

Effective Date: October 3, 2022.

Expiration Date: November 3, 2024.

Summary of Public Comments and Agency Responses:

The official comment period ended on November 19, 2021. The State Board of Pharmacy (Board) received comments from:

1. Laura Mattaliano, Senior Project Manager, Regulatory Affairs, Memorial Sloan Kettering Cancer Center; and

2. Alicia Palombo, PharmD, RPh, Sr. Advisor, Pharmacy Regulatory Affairs, CVS Health.

1. COMMENT: As proposed, N.J.A.C. 13:39-1.9(b)5 requires the holder of a pharmacy permit and a registered pharmacist-in-charge to implement a continuous quality improvement (CQI) program which, among other things, includes a meeting of all pharmacy personnel at least once every three months. The commenters noted logistical challenges to holding meetings with all pharmacy personnel together, either in-person or through live, interactive webinars. One commenter recommended revising the meeting requirement to allow for information on quality reviews and findings to be communicated in other ways, such as through distribution of CQI findings or meeting minutes. One commenter requested that meetings be permitted to occur at different times and using different delivery modalities, as having complete attendance at one event is unlikely. This commenter suggested that N.J.A.C. 13:39-1.9(b)1iv be amended to delete the requirement that documentation of a CQI program include meeting minutes and attendance records and instead to allow this documentation to include a summary of CQI program meetings. The commenter also recommended that N.J.A.C. 13:39-1.9(b)5 be amended so that required meetings would not have to include all pharmacy personnel and to require that meetings either occur in-person through live, interactive webinars or through asynchronous electronic communication.

RESPONSE: The Board first notes that licensees that meet the requirements at N.J.A.C. 13:39-1.9(d) by working with a patient safety organization (PSO) are not required to meet the requirements at N.J.A.C. 13:39-1.9(b).

The Board declines to make the requested change at proposed N.J.A.C. 13:39-1.9(b)1iv because the Board believes that documenting meeting minutes and attendance records are important to the success of a CQI program and to the Board's ability to monitor compliance with the new rule.

The Board recognizes the logistical challenges to requiring all pharmacy personnel to be present at one meeting. However, the Board also recognizes the value of live, interactive communication to the CQI process. Upon adoption, the Board has revised N.J.A.C. 13:39-1.9(b)5 to require the presence of those personnel involved in an error under review and their supervisors, at minimum. While the rule requires the presence of only specific personnel, the Board emphasizes that CQI meetings need not be limited to those personnel, and that other personnel should be encouraged to participate in the CQI process. Additional public notice of this change is not required because it does not significantly enlarge or curtail who or what will be

affected by the proposed rule or the scope of the rule and the burden on those affected by it.

Since, pursuant to the revised new rule, all personnel are not required to be present at a CQI meeting, the Board is also changing N.J.A.C. 13:39-1.9(b)5 upon adoption to require the pharmacy permit holder to document that pharmacy personnel who did not attend the CQI meeting have [page=1917] received the CQI meeting minutes and that the pharmacy permit holder has communicated any changes to policies and procedures arising out of the CQI program to those personnel affected by such changes. Additional public notice of this change is not required because it does not significantly enlarge or curtail who or what will be affected by the proposed rule or the scope of the rule and the burden on those affected by it.

The Board declines to change N.J.A.C. 13:39-1.9(b)5 to require that meetings be conducted through live, interactive webinars because the regulation provides greater flexibility to pharmacies in how to conduct CQI meetings. The Board declines to change N.J.A.C. 13:39-1.9(b)5 to permit the entire CQI meeting to be conducted through asynchronous communication because the Board believes that an interactive process is important to a CQI program's effectiveness. However, the Board is revising N.J.A.C. 13:39-1.9(b)5 upon adoption so that all personnel are not required to attend every CQI meeting and may instead receive information asynchronously.

2. COMMENT: One commenter requested that the Board amend the proposal to allow individual permit holders that are part of a larger organization collectively to be part of a CQI program, similar to the allowance for pharmacies using a patient safety organization (PSO). The commenter stated that this would ensure that all its pharmacies, which utilize the same protocols and systems, participate in a singular CQI program to share experiences and lessons across locations.

RESPONSE: The Board believes that the new rule permits a pharmacy that is part of a larger organization, such as a hospital pharmacy, to meet the requirements of the rule by participating in the larger organization's PSO or CQI program. Accordingly, the Board declines to make any changes to the rule.

3. COMMENT: A commenter stated that the Federal Patient Safety and Quality Improvement Act of 2005 (PSQIA) recognized that providers fear that quality review activities may result in liability or professional sanctions, and the PSQIA allows information that could improve patient safety that is reported to a PSO to be labeled as privileged and confidential patient safety work product. The commenter asked that the New Jersey CQI rules be consistent with Federal PSQIA requirements and explicitly state that the Board will not require quality-related

events or the number of quality-related events reported to a PSO to be reported or made available for inspection by the Board. The commenter requested that N.J.A.C. 13:39-1.9(e) be amended upon adoption to recognize that the requirement that a licensee, registrant, or permit holder cooperate with Board inquiries, inspections, or investigations would have to be consistent with the Federal Patient Safety and Quality Improvement Act of 2005.

RESPONSE: The duty to cooperate with each Board inquiry, inspection, or investigation at N.J.A.C. 13:39-1.9(e) does not abrogate any applicable privileges or confidentiality protections afforded by Federal or State law. Accordingly, the Board declines to make this change.

Federal Standards Statement

A Federal standards analysis is not required because the adopted 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 new rule.

Full text of the adopted new rule follows (additions to the proposal indicated in boldface with asterisks ***thus***; deletions from the proposal indicated in brackets with asterisks *[thus]*):

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.