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April 22nd, 2019

BOARD NOTICE

This Board notice is to provide all New Hampshire pharmacists with a copy of the new rules concerning ***Continuous Quality Improvement*** that were approved by statute effective September 8th, 2017 (RSA 318:45-a), and legislative rules April 19th, 2019 (Ph 1700). Board Compliance would like to highlight what Board Investigators and Inspectors will be looking for as part of normal Board inspections and/or audit requests:

1. Policy and Procedure Manual with all requirements noted in Ph 1703.01(d) (1-8).
2. Quarterly Meeting Minutes (Ph 1705(a) (b)).
3. Summarization Document (Ph 1706.01 (c) (1) (2)).

We would like to remind all Pharmacists that these are requirements by statute/rule and need to be readily retrievable upon Board request. Please discuss these new rules with your staff and make them aware of the processes involved with this new program.

In order to allow for time to develop the requirements of this legislation, Board staff will be looking for this information as part of the normal inspection process starting **September 1st, 2019**.

By Order of the Board,

Michael D. Bullek, BSP, R.Ph.
Administrator / Chief of Compliance

NH RSA 318:45-a Continuous Quality Improvement. –

I. Each licensed pharmacy shall establish a continuous quality improvement program (CQI). The purpose of the program shall be to assess errors that occur in the pharmacy during the review, preparation, and dispensing of prescription medications and to allow the pharmacy to take appropriate action to prevent or reduce the likelihood of a recurrence. The program is non-punitive and seeks to identify weaknesses in processes and systems, in order to make appropriate corrections to improve them.

II. A CQI program may be comprised of staff members of the pharmacy, including pharmacists, registered pharmacy interns, registered pharmacy technicians, clerical staff, and other personnel deemed necessary by the pharmacist in charge or the consultant pharmacist of record.

III. A CQI program shall require that the pharmacist in charge or the consultant pharmacist of record ensure that a review of quality-related events occurs at least every 3 months, contain a planned process to record and assess quality related events, include a process for documenting actions to improve the quality of patient care, and maintain a summary of the documented actions. The review should consider environment and systems-based contributing factors.

IV. (a) The pharmacy shall either:

(1) Report incidents and unsafe events as quality-related events through a contracted patient safety organization (PSO) recognized by the Agency for Healthcare Research and Quality (AHRQ) whose primary mission is pharmacy continuous quality improvement; or

(2) Document incidents and unsafe events as quality-related events in an internal program in the pharmacy in a written record or computer database created solely for that purpose.

(b) The quality-related event shall be documented by the individual who discovers the event or the individual to whom it is initially reported. Documentation of quality-related events shall include a description of the event that is sufficient to permit categorization and analysis of the event. Pharmacies shall maintain such records at least until the event has been considered and incorporated in a summary of documented actions.

V. As a component of its CQI program, each licensed pharmacy shall assure that, following a quality-related event, all reasonably necessary steps have been taken to prevent or minimize patient harm.

VI. CQI programs shall be confidential. The summarization document shall analyze process improvements undertaken following a quality-related event. No patient names or employee names shall be included in this summarization. The summarization shall be maintained for 4 years and be made available within 3 business days of a request by the board's inspectors. Continuous quality improvement records shall be considered peer-review documents and not subject to discovery in civil litigation or administrative actions.

VII. The board may establish by rules adopted under RSA 541-A program requirements and recordkeeping requirements of a pharmacy CQI program.

Source. *2017, 221:1, eff. Sept. 8, 2017.*

Adopt Ph 1700 to read as follows:

CHAPTER Ph 1700 CONTINUOUS QUALITY IMPROVEMENT

PART Ph 1701 PURPOSE AND SCOPE

Ph 1701.01 Purpose. The purpose of this chapter is to require that a pharmacy permit holder establish and manage a continuous quality improvement program in each pharmacy licensed by the permit holder. Said continuous quality improvement program is to assess errors that occur during the review, preparation, dispensing or administration of medications by pharmacy staff, and to ensure appropriate action is taken to prevent or reduce the likelihood of a recurrence of identified errors. Programs established pursuant to this section are for public safety, and shall be non-punitive and seek to identify improvements that can be made in processes, systems, technology, or training in order to make appropriate changes to improve them.

Ph 1701.02 Scope. This chapter shall apply to all pharmacies licensed by the board of pharmacy.

PART Ph 1702 DEFINITIONS

Ph 1702.01 Definitions. In this section the following definitions apply:

(a) "Continuous quality improvement (CQI)" means a system of standards and procedures to identify and evaluate quality-related events to improve patient care;

(b) "Continuous quality improvement (CQI) program" means a planned process to record and assess quality related events that includes a procedure for documenting actions to improve the quality of patient care, and maintenance of a summary of the documented actions;

(c) "Quality-related event" means an error, adverse incident, near miss, or unsafe condition that occurs in the review, preparation, dispensing or administration of medications by pharmacy staff; and

(d) "Patient Safety Organization" means an entity that has the same meaning as the term used in the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C section 299b-21(7), a private or public entity or component thereof that is listed by the Secretary of Health and Human Services pursuant to 42 U.S.C. section 299b-24(d).

PART Ph 1703 PROGRAM REQUIREMENTS

Ph 1703.01 General Requirements.

(a) A pharmacy shall either submit quality-related events to a patient safety organization (PSO) or shall create and maintain an internal program that captures and analyzes quality-related events that comply with this chapter.

(b) Licensed pharmacies shall ensure that all reasonably necessary steps have been taken to prevent or minimize patient harm following any quality-related event that reaches a patient.

(c) The permit holder of the pharmacy shall maintain within the pharmacy a current written policy and procedures manual that clearly states the organization philosophy and goals for a continuous quality improvement (CQI) program, delineate the parameters in which the organization interacts with its employees related to such a program, and provides a sound framework for operating and maintaining such a program.

(d) Said current policy and procedures manual shall include at least the following:

(1) Purpose of the program;

(2) Definitions used in the program;

(3) Policy on how to report a quality-related event;

(4) Policy for program meetings including frequency of meetings, staff to attend, and involvement of either the pharmacist-in-charge or consultant pharmacist;

(5) Policy for maintaining program integrity and confidentiality of information;

(6) Policy for staff education and ongoing training of employees related to CQI program;

(7) Policy for employee engagement and communication of changes made related to the program; and

(8) Policy for maintaining summarization documents for board inspection.

PART Ph 1704 CONFIDENTIALITY OF QUALITY-RELATED EVENT REPORTS

Ph 1704.01 Availability of Quality-Related Event Reports. All quality-related events and quality-related reports that are reported to a PSO shall be deemed by the board to be confidential and privileged patient safety work product under the Patient Safety and Quality Improvement Act of 2005 and shall not be required to be made available for inspection by or reported to the board. Quality-related events and quality-related event reports that are not reported to a PSO shall be considered confidential peer review documents not subject to discovery in civil litigation or administrative actions.

PART Ph 1705 CONTINUOUS QUALITY IMPROVEMENT MEETINGS

Ph 1705.01 Requirements for Continuous Quality Improvement Meetings.

(a) A pharmacy shall hold a continuous quality improvement (CQI) meeting at least once every 3 months.

(b) The pharmacist-in-charge or consultant pharmacist for the licensed pharmacy, or their designee, shall attend each meeting.

PART Ph 1706 SUMMARIZATION DOCUMENT

Ph 1706.01 Requirements for the Summarization Document.

(a) A summarization document shall be created after each CQI meeting and shall be retained onsite within the licensed pharmacy for a minimum of 4 years and made available within 3 business days upon request by the board.

(b) The summarization document shall not contain identifiable patient information, or information that would identify individuals involved in a quality-related event, or any information that can be used to identify the quality-related event.

(c) The summarization document shall include, at a minimum, the following information:

(1) A list of all individuals in attendance at the meeting; and

(2) A summary of steps or actions taken since the last meeting intended to improve processes, systems, technology or training related to the review, preparation, dispensing, or administration of medications.

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Appendix

Rule	Statute the Rule Implements
Ph 1701.01	RSA 541-A:7; RSA 318:45-a, VII
Ph 1701.02	RSA 541-A:7; RSA 318:45-a, VII; 42 U.S.C § 299b et seq.
Ph 1702.01	RSA 541-A:7; RSA 318:45-a, VII
Ph 1703.01	RSA 318:45-a, VII
Ph 1704	RSA 318:45-a, VII; 42 U.S.C § 299b et seq.
Ph 1705	RSA 318:45-a, VII
Ph 1706	RSA 318:45-a, VII