# 247 CMR 15.00: CONTINUOUS QUALITY IMPROVEMENT PROGRAM

Section



## 15.01: Definitions

Continuous Quality Improvement Program or CQI Program means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

Quality Related Event or QRE means the incorrect dispensing of a prescribed medication that is received by a patient, including:

(a) a variation from the prescriber's prescription order, including, but not limited to:
1. dispensing an incorrect drug;
2. dispensing an incorrect drug strength;
3. dispensing an incorrect dosage form;
4. dispensing the drug to the wrong patient; or
5. providing inadequate or incorrect packaging, labeling, or directions; or

(b) a failure to identify and manage:
1. over-utilization;
2. therapeutic duplication;
3. drug-disease contraindications;
4. drug-drug interactions;
5. incorrect drug dosage or duration of drug treatment;
6. drug-allergy interactions; or
7. clinical abuse/misuse.

Pharmacy, as referenced in 247 CMR 15.00, means a pharmacy, or a group of pharmacies under common ownership and control of one entity, licensed by the Board pursuant to M.G.L. c. 112.

Pharmacy Personnel means pharmacist, pharmacy intern, pharmacy technician and pharmacy support personnel.

## 15.02: Continuous Quality Improvement Program

(1) Continuous Quality Improvement Program Requirements. Each pharmacy shall establish a Continuous Quality Improvement (CQI) Program for the purpose of detecting, documenting, assessing and preventing Quality Related Events (QREs). At a minimum, a CQI program shall include provisions to:

(a) designate an individual or individuals responsible for monitoring CQI Program compliance with the requirements of 247 CMR 15.00;
(b) identify and document QREs;
(c) minimize impact of QREs on patients;
(d) analyze data collected in response to QREs to assess causes and any contributing factors;
(e) use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs; and
(f) provide ongoing education at least annually in the area of CQI to pharmacy personnel.

(2) Implementation Date. The CQI Program requirements of 247 CMR 15.00 shall be implemented by each pharmacy by December 31, 2005.

## 15.03: Quality Related Event Discovery, Notification and Documentation

(1) QRE Discovery and Notification. All pharmacy personnel shall be trained to bring any QRE to the attention of the pharmacist on duty or the pharmacist Manager of Record immediately upon discovery. The pharmacist who has discovered or been informed of a QRE shall immediately provide:

15.03: continued

(a) notification to the patient or patient's representative, the prescriber (if indicated in the professional judgment of the pharmacist) and other members of the healthcare team;
(b) directions for correcting the error; and
(c) instructions for minimizing the negative impact on the patient.

(2) QRE Documentation.
(a) A QRE shall be initially documented by the pharmacist who has discovered or been informed of the QRE on the same day the QRE is discovered by or described to the pharmacist.
(b) QRE documentation shall include a description of the event that is sufficient to permit categorization and analysis of the event. QRE documentation shall include:
1. the date when the pharmacist discovered or received notification of the QRE and the name of the person who notified the pharmacy;
2. the names and titles of the persons recording the QRE information and performing the QRE analysis;
3. a description of the QRE reviewed; and
4. documentation of the contact with the patient, or patient's representative, and prescribing practitioner (if indicated in the professional judgment of the pharmacist), and other members of the healthcare team.

(3) QRE Analysis and Response.
(a) QRE Analysis. The investigative and other pertinent data collected in response to QREs shall be analyzed, individually and collectively, to assess the cause and any contributing factors such as system or process failures. The QRE analysis and assessment shall include:
1. a consideration of the effects on quality assurance related to workflow processes, technological support, personnel training and staffing levels;
2. any recommended remedial changes to pharmacy policies, procedures, systems, or processes; and
3. the development of indicators that identify means against which a pharmacy's program intends to measure its standards over a designated period of time.
(b) Response. Each pharmacy shall inform pharmacy personnel of changes to pharmacy policies, procedures, systems, or processes resulting from recommendations generated by the CQI Program.

15.04: Records

(1) Each pharmacy shall maintain a written copy of its CQI Program description on the pharmacy premises. The CQI Program description shall be readily available to all pharmacy personnel.

(2) Each pharmacy shall maintain a record of all QREs for a minimum period of two years from the date of the QRE report.

(3) QRE records shall be maintained in an orderly manner and filed by date.

(4) QRE records may be stored at a site other than the pharmacy where the QRE occurred.

15.05: Duty to Report Certain Improper Drug Dispensing to the Board

Effective January 1, 2010, a pharmacy licensed by the Board is required to report to the Board any improper dispensing of a prescription drug that results in serious injury or death, as defined in 247 CMR 6.14(1), within 15 business days of the pharmacy discovering or being informed of such improper dispensing, in accordance with the requirements of M.G.L. c. 112, § 39D and 247 CMR 6.00.

REGULATORY AUTHORITY

247 CMR 15.00: M.G.L. c. 112, §§ 37 through 39 and 42A.