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Florida

Sec. 64B16-27.300. Standards of practice—Continuous quality improvement program.

(1) "Continuous Quality Improvement Program" means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

(2) "Quality-Related Event" means the inappropriate dispensing or administration of a prescribed medication including:

(a) A variation from the prescriber's prescription order, including, but not limited to:

1. Incorrect drug;
2. Incorrect drug strength;
3. Incorrect dosage form;
4. Incorrect patient; or
5. Inadequate or incorrect packaging, labeling, or directions.

(b) A failure to identify and manage:

1. Over-utilization or under-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.

(3)(a) Each pharmacy shall establish a Continuous Quality Improvement Program which program shall be described in the pharmacy's policy and procedure manual and, at a minimum shall contain:

1. Provisions for a Continuous Quality Improvement Committee that may be comprised of staff members of the pharmacy, including pharmacists, pharmacy interns, pharmacy technicians, clerical staff, and other personnel deemed necessary by the prescription department manager of the consultant of record;
2. Provisions for the prescription department manager or the consultant pharmacist of record to ensure that the committee conducts a review of Quality Related Events at least every three months.
3. A planned process to record, measure, assess, and improve the quality of patient care; and
4. The procedure for reviewing Quality Related Events.

(b) As a component of its Continuous Quality Improvement Program, each pharmacy shall assure that, following a Quality-Related Event, all reasonably necessary steps have been taken to remedy any problem for the patient.

(c) At a minimum, the review shall consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.

(4) Each Quality-Related Event that occurs, or is alleged to have occurred, as the result of activities in a pharmacy, shall be documented in a written record or computer database created solely for that purpose. The Quality-Related Event shall be initially documented by the pharmacist to whom it is described, and it shall be recorded on the same day of its having been described to the pharmacist. Documentation of a Quality-Related Event shall include a description of the event that is sufficient to permit categorization and analysis of the event. Pharmacists shall maintain such records at least until the event has been considered by the committee and incorporated in the summary required in subsection (5) below.

(5) Records maintained as a component of a pharmacy Continuous Quality Improvement Program are confidential under the provisions of Section 766.101, F.S. In order to determine compliance the Department may review the policy and procedures and a Summarization of Quality-Related Events. The summarization document shall analyze remedial measures undertaken following a Quality-Related Event. At a minimum, the review shall consider the effects on quality of pharmacy systems due to staffing levels, workflow, and technological support. No patient name or employee name shall be included in this summarization. The summarization shall be maintained for two years. Records are considered peer-review documents and are not subject to discovery in civil litigation or administrative actions.

Specific Authority 465.0155 FS. Law Implemented 465.0155  
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