

Regulations of Connecticut State Agencies

TITLE 20. Professional & Occupational Licensing, Certification

Agency

Department of Consumer Protection

Subject

Quality Assurance Programs for Pharmacies

Inclusive Sections

§§ 20-635-1—20-635-6

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Quality Assurance Programs for Pharmacies

Sec. 20-635-1. Definitions

As used in section 20-635-1 to section 20-635-6, inclusive, of the Regulations of Connecticut State Agencies:

- (1) “Department” means the Department of Consumer Protection;
- (2) “Pharmacy personnel” means pharmacist, pharmacy intern, pharmacy technician, and pharmacy support personnel; and
- (3) “Prescription error” means “prescription error” as defined by section 20-635 of the Connecticut General Statutes.

(Adopted effective September 4, 2003)

Sec. 20-635-2. Quality assurance program

(a) Each pharmacy shall implement a quality assurance program to detect, identify and prevent prescription errors. The quality assurance program shall document and assess prescription errors to determine the cause and an appropriate response.

(b) The primary purpose of the quality assurance program 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.

(c) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent prescription errors.

(Adopted effective September 4, 2003)

Sec. 20-635-3. Notification to patient and prescribing practitioner

(a) Unless informed of a prescription error by the prescribing practitioner or the patient, a pharmacist who has discovered or been informed of a prescription error, shall immediately notify the patient and the prescribing practitioner that a prescription error has occurred. If the patient is deceased or unable to fully comprehend the notification of the error, the pharmacist shall notify the patient’s caregiver or appropriate family member.

(b) The pharmacist shall communicate to the patient and prescribing practitioner the methods for correcting the error and reducing the negative impact of the error on the patient.

(Adopted effective September 4, 2003)

Sec. 20-635-4. Review of prescription errors

(a) Each pharmacy shall perform a quality assurance review for each prescription error. This review shall commence as soon as is reasonably possible, but no later than two business days from the date the prescription error is discovered.

(b) Each pharmacy shall create a record of every quality assurance review. This record shall contain at least the following:

- (1) the date or dates of the quality assurance review and the names and titles of the

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persons performing the review;

- (2) the pertinent data and other information relating to the prescription error reviewed;
- (3) documentation of the patient and prescribing practitioner contact required by section 20-635-3 of the Regulations of Connecticut State Agencies;
- (4) the findings and determinations generated by the quality assurance review; and
- (5) recommended changes to pharmacy policy, procedure, systems, or processes, if any.

(Adopted effective September 4, 2003)

Sec. 20-635-5. Records

(a) Each pharmacy shall maintain a written copy of the quality assurance program on the pharmacy premises. This copy shall be readily available to all pharmacy personnel and the department.

(b) Each pharmacy shall maintain a record of the quality assurance review for all prescription errors for a minimum of three years. These records shall be maintained in an orderly manner and filed by date. These records, which may be stored outside of the pharmacy, shall be made available for inspection by the department within forty-eight (48) hours of request.

(Adopted effective September 4, 2003)

Sec. 20-635-6. Notice to pharmacy personnel

(a) A pharmacy shall make available a copy of its quality assurance program to each pharmacist employed at the pharmacy.

(b) Each pharmacy shall notify all pharmacy personnel that the discovery or reporting of a prescription error shall be relayed immediately to a pharmacist on duty.

(c) Each pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program.

(Adopted effective September 4, 2003)