

10.34.26.00

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 34 BOARD OF PHARMACY

Chapter 26 Patient Safety Improvement

Authority: Health Occupations Article, §12-205(a)(3), Annotated Code of Maryland

10.34.26.01

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "High-alert medication" means a medication with:

(a) A significant potential for involvement in a medication error due to the medication's name, packaging, appearance, dosing, or other characteristics of the agent; or

(b) A high potential for causing serious harm or injury if used incorrectly.

(2) Medication Error.

(a) "Medication error" means any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.

(b) "Medication error" includes events that may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

(3) Ongoing Quality Assurance Program.

(a) "Ongoing quality assurance program" means a program that systematically and routinely reviews the medication delivery system of a pharmacy for the purpose of minimizing the occurrence of medication errors.

(b) "Ongoing quality assurance program" includes:

(i) The systematic and routine collection of information regarding the performance of the medication delivery system as it becomes available;

(ii) The investigation of medication errors at the time the error is reported or discovered, or within a reasonable amount of time after the medication error is reported or discovered; or

(iii) A record, proceeding, file, or other document maintained to comply with Regulations .03 or .04 of this chapter, COMAR 10.34.21.03, COMAR 10.34.28.09, or COMAR 10.34.28.10.

10.34.26.02

.02 Patient Education.

A. The pharmacy permit holder shall establish methods to provide patients with information regarding the patient's role and responsibility in preventing medication errors in a manner that is reasonably likely to convey the information to the patient, and if applicable, the patient's health care agent or surrogate decision maker, under Health-General Article, Title 5, Subtitle 6, Annotated Code of Maryland, and that is in addition to any other patient counseling or information required to be given by other laws and regulations.

B. The information in §A of this regulation shall be provided to the patient before or at the time the drug or device is presented to the patient.

C. Exception. If the patient is an inpatient at a health care facility, the information in §A of this regulation shall be:

(1) Provided directly to a patient and, if applicable, a patient's health care agent or surrogate decision maker before discharge; or

(2) Available in a conspicuous location on the institution's premises where the patient and, if applicable, the patient's health care agent or surrogate decision maker, are reasonably likely to have an opportunity to review the information.

D. The information provided to patients shall include:

(1) A patient's rights when receiving a medication or a prescription;

(2) The patient's role and responsibility in preventing a medication error;

(3) The procedures to follow when reporting a suspected medication error to the pharmacy permit holder, pharmacist, health care facility, or other healthcare provider; and

(4) How to report a suspected medication error to the Board.

10.34.26.03

.03 Pharmacy Staff Education.

As part of a pharmacy permit holder's ongoing quality assurance program, the pharmacy permit holder shall:

A. Ensure that each member of the pharmacy staff involved in the medication delivery system receive at least once a year, education regarding the role and responsibility of pharmacy staff in preventing medication errors; and

B. Maintain records for a minimum of 2 years:

- (1) Verifying completion of education referred to in §A of this regulation; and
- (2) Demonstrating the content of the education.

10.34.26.04

.04 Ongoing Quality Assurance Program.

A. A pharmacy permit holder shall establish and maintain an ongoing quality assurance program to:

- (1) Identify, investigate, and promote the prevention of medication errors; and
- (2) Establish protocols and procedures to minimize the potential for medication errors.

B. The ongoing quality assurance program shall include the records, proceedings, files, and any other documents of the ongoing quality assurance program, including for each medication error:

- (1) The date of the error;
- (2) A brief description of the error;
- (3) The results of the evaluation by the ongoing quality assurance program's investigation; and
- (4) Remedial action taken or recommendations.

C. Periodic Review.

(1) A pharmacy permit holder shall analyze the records, proceedings, files, and any other documents of the ongoing quality assurance program required under §B of this regulation, including any medication errors relating to automated medication systems or unlicensed personnel, at least every 3 months as part of the periodic review that is required to maintain an ongoing quality assurance program.

(2) Each pharmacy permit holder shall conduct an analysis of its medication delivery system at least every 6 months to determine which medications in the prescription area of the pharmacy are high-alert medications, as part of the pharmacy's ongoing quality assurance program.

D. Documentation of Periodic Review. The records, proceedings, files, and any other documents of the ongoing quality assurance program shall include for each:

- (1) Periodic review required under §C(1) of this regulation:
 - (a) Documentation of the periodic review;
 - (b) A description of the system's weaknesses found during the periodic review; and
 - (c) A description of the actions taken to remedy any weaknesses identified in the medication system; and
- (2) Analysis of a pharmacy's medication delivery system to identify high-alert medications required under §C(2) of this regulation:

- (a) A list of high-alert medications present in the prescription area of the pharmacy;
- (b) The date that a high-alert medication was added to or removed from the list of high-alert medications;
- (c) Dates that the list was reviewed by the pharmacy permit holder; and
- (d) Remedial actions taken based on the review of the list of high-alert medications and any medication errors relating to the high-alert medications.

E. Unless otherwise specified in law, the permit holder shall maintain the ongoing quality assurance program records referred to in this regulation for 2 years.

F. The proceedings, records, and files of an ongoing quality assurance program that meets the requirements of Health Occupations Article, §1-401, Annotated Code of Maryland, and this chapter, are not discoverable and are not admissible in evidence in any civil action, as provided in Health Occupations Article, §1-401, Annotated Code of Maryland.