

# **Rules of Various States Pertaining to Pharmacy Business Practices**

The following document is a compilation of rules and regulations concerning various aspects of pharmacy business practices in a variety of states. The document is a sampling of rules that other state Boards of Pharmacy have implemented relating to staffing, workload, performance metrics and quotas, meals and breaks, quality control, space for clinical services, transfer incentives, and accountability. This is by no means a complete survey of all the pertinent rules in all the states--the information is time consuming and difficult to search and just reaching this point was an arduous task. Much of the information I have gleaned from state regulations as I have been studying for the various MPJE's. A more thorough search would probably require reading each state's regulations in their entirety.

I am not promoting adoption of any of these rules. I just think it would be helpful to the Pharmacy Business Practices Committee, the public, the stakeholders, and the other Commission members to see what other states have done. I have attempted to place the rules into the appropriate subject categories by state of origin; however, some rules may have crossover value in other categories. Some topics such as quality assurance are ubiquitous, so I tried to put in examples of regulations that address specifics rather than vague requirements. I have also included a rules petition from the state of Virginia that is relative to the Committee's work. It is currently pending review by the Virginia Secretary of Health and Human Services.

**THESE RULES MAY OR MAY NOT APPLY TO THE WASHINGTON RULES THE COMMITTEE IS OPENING. THEY ARE FOR REFERENCE PURPOSES ONLY AND MAY BE USED FOR OTHER RULEMAKING PURPOSES IN THE FUTURE.**

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## WORKLOAD

### **ALABAMA:**

**AL BReg 680-X-2-.22.**

#### **Code of Professional Conduct.**

(f) A pharmacist and a pharmacy should not agree to practice under terms or conditions that interfere with or impair the proper exercise of professional judgment and skill, that cause a deterioration of the quality of professional services, or that require consent to unethical conduct.

### **NEBRASKA:**

**NE BReg Chapter 8 Section 006.**

#### **Standards for the Operation of a Pharmacy.**

8-006.01 Staffing Requirements: Each pharmacy must maintain a sufficient number of staff with the qualifications, training, and skills necessary to meet patient needs. The pharmacy must ensure that the staff hired meets the following requirements:

### **OKLAHOMA:**

**OK BReg 535:15-3-2.**

#### **Pharmacy responsibilities.**

(a) Pharmacy staffing responsibility. Each pharmacy shall employ an adequate number of pharmacists to perform the practice of pharmacy as defined by the Oklahoma Pharmacy Act with reasonable safety.

**OK BReg 535:15-5-10.**

#### **Director of Pharmacy responsibilities.**

(j) Pharmacist staffing. The Director of Pharmacy shall maintain adequate staffing levels of pharmacist to insure pharmaceutical patient-focused care support. This staffing shall be a sufficient number of additional registered pharmacists as may be required to operate such a pharmacy competently, safely and adequately to meet the needs of the patients of the hospital facility as to meet requirements described in 535:15-5-4.

## **OKLAHOMA (cont):**

### **OK BReg 535:15-3-16.**

#### **Adequate staffing rules for pharmacists and pharmacies.**

(a) Adequate staffing to safely fill prescriptions is the responsibility of the pharmacy, the pharmacy manager, and the pharmacist. If conditions exist that could cause prescriptions to be filled in an unsafe manner they shall take action to correct the problem.

(b) In order to ensure adequate staffing levels there shall be a staffing report form available in each pharmacy. A copy of this form, when executed, will be given to the immediate supervisor and a copy must remain in the pharmacy for Board inspection.

(1) Such form shall include, but not be limited to the following:

(A) Date and time the inadequate staffing occurred;

(B) Number of prescriptions filled during this time frame;

(C) Summary of events; and

(D) Any comments or suggestions.

(2) Such forms are not to be sent to the Board.

(c) A pharmacist shall complete the staffing report form when:

(1) A pharmacist is concerned regarding staffing:

(A) inadequate number of support persons (cashiers, technicians, auxiliary supportive personnel, etc.); or,

(B) excessive workload;

(2) Filling out the form may enable management to make a better decision concerning staffing.

(d) If the pharmacy manager feels the situation warrants earlier Board review the pharmacy manager should inform the Board.

(e) Each pharmacy shall review completed adequate staffing forms and address any issues described as well as documenting any corrective action taken or justification for inaction to assure continual self-improvement. If issue is not staffing related, describe what measures are being taken to address the issue.

## **OKLAHOMA (cont):**

(f) Each pharmacy shall retain completed adequate staffing forms until reviewed and released by the Board. Such forms requiring further review may be held by the Board and may become part of an investigation file.

(g) A registrant including pharmacy, a pharmacy manager, or a pharmacist shall not be subject to discipline by the employing pharmacy for completing a staffing report form in good faith.

## **OREGON:**

### **OR BReg 855-041-1170**

#### **Grounds for Discipline**

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

(3) Failure to provide a working environment that protects the health, safety and welfare of a patient which includes but is not limited to:

(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety.

(c) Adequate time for a pharmacist to complete professional duties and responsibilities including, but not limited to:

(A) Drug Utilization Review;

(B) Immunization;

(C) Counseling;

(D) Verification of the accuracy of a prescription; and

(E) All other duties and responsibilities of a pharmacist as specified in Division 19 of this chapter of rules.

## **TENNESSEE:**

### **TN BReg 1140-02-.01.**

#### **Pharmacists and pharmacy interns.**

(7) A pharmacist shall not agree to practice under terms or conditions which tend to interfere with or impair the proper exercise of professional judgment and skill, which tend to cause a deterioration of the quality of professional service and patient care, or which require the pharmacist to consent to unethical conduct.

### **TN BReg 1140-03-.03.**

#### **Medical and prescription orders.**

(6) No pharmacist, or pharmacy intern or pharmacy technician under the supervision of a pharmacist, shall compound or dispense any medical or prescription order except upon the following conditions:

(e) At a rate, based on the actual number of medical and prescription orders compounded and dispensed per hour or per day, that does not pose a danger to the public health, safety or welfare.

### **TN BReg 1140-04-.02.**

#### **Personnel.**

(2) Pharmacists. The pharmacist in charge shall be supported by a sufficient number of pharmacists to provide appropriate practice of pharmacy for the patients served by the institutional facility. Employment of pharmacists by the institutional facility shall be determined by the pharmacist in charge.

(4) Supportive personnel. The pharmacist in charge shall be assisted by a sufficient number of pharmacy technicians, as defined in 1140-2-.02 pharmacy interns, and other supportive personnel as may be required to operate the pharmacy competently, safely, and adequately to meet the needs of the patients served by the institution.

(5) Supervision. All of the activities associated with the practice of pharmacy and the operations of the pharmacy at a specific institutional pharmacy practice site shall be supervised by a sufficient number of pharmacists to ensure that all functions and activities are performed competently, safely and without risk of harm to patients.

## **TEXAS:**

### **TX BReg291.32.**

#### **Personnel**

(c) Pharmacists.

(1) General.

(A) The pharmacist-in-charge shall be assisted by sufficient number of additional licensed pharmacists as may be required to operate the Class A pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.

## **VIRGINIA:**

### **Pharmacy Workload Regulations**

Regulations are currently pending review by Virginia Secretary of Health and Human Resources.

See separate article.

## **WEST VIRGINIA:**

### **WV BReg 15-1-14.**

#### **Regulations Governing Pharmacy Permits.**

14.8. Professional Work Environment.

14.8.a. No pharmacist may work more than twelve (12) hours within a twenty-four (24) hour period without at least eight (8) hours off duty in that 24 hours, except in a case of emergency when a pharmacist calls off work, the pharmacist on duty may work more than twelve (12) hours in order to keep the pharmacy open. The pharmacists would have to document and date and amount of time worked beyond the twelve (12) hour limit along with the reason for the extended hours of work and make it available to the Board.

14.8.b. Any pharmacy dispensing more than fifteen (15) prescriptions per hour on average during a day shall have a registered pharmacy technician or a pharmacy technician trainee assisting the pharmacist. The pharmacist-in-charge shall determine the work schedule for pharmacy technicians and pharmacy technician trainees based upon prior dispensing records.

14.8.c. The pharmacist on duty or the pharmacy permit holder shall notify the pharmacist-in-charge whenever a prescription error, loss of drugs, or a violation of any statute or rule occurs and the pharmacist-in-charge is not present.

## **WEST VIRGINIA (cont.):**

### **WV BReg 15-1-19.**

#### **Rules of Professional Conduct.**

19.2.a. No pharmacist shall engage in conduct, in the practice of pharmacy or the operation of a pharmacy, which tends to reduce the public confidence in the ability and integrity of the profession of pharmacy, or endangers the public health, safety and welfare; nor shall he or she interfere in the provision of pharmaceutical care or offer pharmaceutical services under any terms or conditions which tend to impair the free and complete exercise of the professional skill and judgment of another pharmacist. A pharmacist shall at all times practice his or her profession in conformity with federal and state laws and regulations and the rules of this Board.

## PERFORMANCE METRICS AND QUOTAS

### MISSISSIPPI:

**MS BReg 30-20-3001:VII.**

**Responsibility of Pharmacist-In-Charge (PIC).**

(6) That if quotas or formulas such as prescription volume are used to set staffing, conditions such as peak workload periods, workplace design and the training of staff must be taken into consideration.

### OREGON:

**OR BReg 855-041-1170**

**Grounds for Discipline**

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

(4) Introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public.

## MEAL BREAKS AND REST BREAKS

### ALABAMA:

#### AL BReg 680-X-2-.28.

#### Temporary Absences of Pharmacists During Break and Meal Period

- (1) This rule is to allow pharmacists to have breaks and meal periods without unreasonably impairing the ability of a pharmacy to remain open.
- (2) In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy area or department, temporarily, for breaks and meal periods without closing the pharmacy and removing interns/externs and technicians from the pharmacy, if the pharmacist reasonably believes that the security of the controlled substances will be maintained in his or her absence.
  - (a) If, in the professional judgment of the pharmacist, the pharmacist determines that the pharmacy should be closed during his or her absence, then the pharmacist shall close the pharmacy area or department and remove all interns/externs and technicians from the pharmacy during his or her absence.
- (3) During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a new or refill medication that the pharmacist has checked, released for furnishing to the patient and was determined not to require the consultation of a pharmacist.
- (4) During such times that the pharmacist is temporarily absent from the pharmacy area or department, the interns/externs and technicians may continue to perform the non-discretionary duties authorized to them by any applicable law or rule. However, any duty performed by an intern/extern or technician shall be reviewed by a pharmacist upon his or her return to the pharmacy.
- (5) The temporary absence authorized by this rule shall be limited to thirty (30) minutes. The pharmacist shall remain within the facility during the break period and be available to handle all emergency situations.
- (6) The pharmacy shall have written policies and procedures regarding the operations of the pharmacy area or department during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of interns/externs and technicians, the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the Board or its designee at all times during business hours.

## **CALIFORNIA:**

### **BReg 1714.1.**

#### **Pharmacy Operations During the Temporary Absence of a Pharmacist.**

This section is to ensure that pharmacists are able to have duty free breaks and meal periods to which they are entitled under Section 512 of the Labor Code and the orders of the Industrial Welfare Commission, without unreasonably impairing the ability of a pharmacy to remain open.

(a) In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy temporarily for breaks and meal periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy and removing ancillary staff from the pharmacy if the pharmacist reasonably believes that the security of the dangerous drugs and devices will be maintained in his or her absence.

If in the professional judgment of the pharmacist, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy and remove all ancillary staff from the pharmacy during his or her absence.

(b) During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a refill medication that the pharmacist has checked, released for furnishing to the patient and was determined not to require the consultation of a pharmacist.

(c) During such times that the pharmacist is temporarily absent from the pharmacy, the ancillary staff may continue to perform the non-discretionary duties authorized to them by pharmacy law. However, any duty performed by any member of the ancillary staff shall be reviewed by a pharmacist upon his or her return to the pharmacy.

(d) During the temporary absence of a pharmacist as authorized by this section, an intern pharmacist may not perform any discretionary duties nor otherwise act as a pharmacist.

(e) The temporary absence authorized by this section shall be limited to the minimum period authorized for pharmacists by section 512 of Labor Code or orders of the Industrial Welfare Commission and any meal shall be limited to 30 minutes. The pharmacist who is on break shall not be required to remain in the pharmacy area during the break period.

(f) The pharmacy shall have written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of ancillary staff, the pharmacist's responsibilities for checking all work performed by ancillary staff and the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the board or its designee at all times during business hours.

(g) For the purposes of this section, ancillary staff includes: an intern pharmacist, a pharmacy technician, non-licensed personnel as defined in Section 1793.3 of Title 16 of the California

## **CALIFORNIA (cont.):**

Code of Regulations and a pharmacy technician trainee as defined in Section 4115.5(a) of the Business and Professions Code.

## **FLORIDA:**

### **FL BReg 64B16-27.1001.**

#### **Practice of Pharmacy.**

(6) The pharmacist may take a meal break, not to exceed 30 minutes in length, during which the pharmacy department of a permittee shall not be considered closed, under the following conditions

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(a) The pharmacist shall be considered present and on duty during any such meal break if a sign has been prominently posted in the pharmacy indicating the specific hours of the day during which meal breaks may be taken by the pharmacist and assuring patients that a pharmacist is available on the premises for consultation upon request during a meal break.

(b) The pharmacist shall be considered directly and immediately available to patients during such meal breaks if patients to whom medications are delivered during meal breaks are verbally informed that they may request that a pharmacist contact them at the pharmacist's earliest convenience after the meal break, and if a pharmacist is available on the premises during the meal break for consultation regarding emergency matters. Only prescriptions with the final certification by the pharmacist may be delivered.

(c) The activities of registered pharmacy technicians during such a meal break shall be considered to be under the direct and immediate personal supervision of a pharmacist if the pharmacist is available on the premises during the meal break to respond to questions by the technicians, and if at the end of the meal break the pharmacist certifies all prescriptions prepared by the registered pharmacy technicians during the meal break.

## **MASSACHUSETTS:**

### **Policy 2000-03**

#### **Policy on Pharmacy Operations during the Temporary Absence of a Pharmacist**

Board Regulations at 247 CMR § 6.02(9)(a) state:

" A registered pharmacist shall be on duty and shall be present at all times when non-pharmacist personnel have unrestricted access to the pharmacy department"

This requirement shall not apply during the temporary absence of a pharmacist as set forth below

## **MASSACHUSETTS (cont.):**

provided that the following requirement is strictly adhered to at all times during the temporary absence of the pharmacist.

This policy is adopted to ensure that pharmacists are able to have necessary and appropriate duty free breaks and meal periods without unreasonably impairing the ability of a pharmacy to remain open.

- a. In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy temporarily for necessary and appropriate breaks and meal periods without closing the pharmacy and removing ancillary staff from the pharmacy if the pharmacist reasonably believes that the security of the dangerous drugs and devices will be maintained in his or her absence.  
If in the professional judgment of the pharmacist, for reasons of security or otherwise, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy and remove all ancillary staff from the pharmacy during his or her absence.
- b. During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a refill medication that the pharmacist has checked; and determined not to require the consultation of a pharmacist; prior to being released for furnishing to the patient.  
A new prescription which has been previously prepared, visibly checked by a pharmacist and had a drug utilization performed by a pharmacist, may be picked up by a patient provided that a log, including the patients phone number, of all such transactions is kept. The pharmacist, upon return from break, and within a reasonable time, shall call the patient to review any pertinent counseling deemed appropriate.
- c. During such times that the pharmacist is temporarily absent from the pharmacy, the pharmacy technical support staff may continue to perform the non-discretionary duties authorized to them by pharmacy law. However, any duty performed by any member of the ancillary staff shall be reviewed by a pharmacist upon his or her return to the pharmacy.
- d. Pharmacist managers, at their discretion, may develop a written policy for allowing Pharmacy Technician Certification Board ("PTCB") and/or Board approved certified technicians and pharmacy interns to receive telephone prescription orders from practitioners, unless otherwise prohibited by law.
- e. In pharmacies where there are two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the pharmacy is not left without a pharmacist for a temporary period.
- f. The temporary absence authorized by this section shall not exceed 30 minutes. The pharmacist who is on break shall not be required to remain in the pharmacy area during the break period, however the pharmacist shall be required to remain on the premises, licensed by the Board. The total temporary absence shall not exceed more than 30 minutes absence during any work period of at least six consecutive hours.

## **MASSACHUSETTS (cont.):**

- g. The pharmacy shall have written policies and procedures regarding the operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of ancillary staff, the pharmacist's responsibilities for checking all work performed by ancillary staff and the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the Board or its designee at all times during business hours.

*A pharmacist who temporarily leaves the pharmacy for a break or meal period in compliance with this section shall not be subject to Massachusetts Board of Registration in Pharmacy disciplinary action or for acts that he or she did not authorize and that he or she, by the exercise of reasonable care, could not have prevented during his or her absence.*

## **MISSISSIPPI:**

**MS BReg 30-20-3001:VII.**

**Responsibility of Pharmacist-In-Charge (PIC).**

(4) That all staff should have the opportunity to take periodic breaks and/or meal periods to relieve fatigue and mental and physical stress. Nothing in this paragraph suggests closing the pharmacy; and

## **MONTANA:**

**MT BReg 24.174.411.**

**Pharmacist meal/rest breaks**

(1) In any pharmacy staffed by a single pharmacist, the pharmacist shall take a meal/rest break for a period of up to 30 minutes per shift without closing the pharmacy and removing support personnel, provided the pharmacist reasonably believes that the security of prescription drugs will be maintained in the pharmacist's absence.

(2) The time of the meal/rest break will be conspicuously posted in clear view of patients approaching the prescription area.

(3) In the pharmacist's absence a sign indicating that no pharmacist is on duty will be conspicuously displayed in clear view of patients approaching the prescription area.

## **MONTANA (cont.)**

(4) The pharmacist will remain on the premises if the prescription area is to remain open, and be available for emergencies.

(5) When authorized by the pharmacist, only registered technicians directly involved in the process of filling prescriptions may remain in the prescription department to perform nondiscretionary duties as delineated by the pharmacist.

(6) Upon returning, the pharmacist shall review any work performed in the pharmacist's absence.

(7) In the pharmacist's absence there may be no dispensing of new prescriptions that the pharmacist has checked and that are waiting to be picked up, nor may counseling be provided.

(8) At the discretion of the pharmacist, previously checked medication refills may be handed to patients or their agents by registered technicians in the pharmacist's absence, and the technicians must offer the patient counseling by the pharmacist. If the patient desires counseling, the patient may wait for the pharmacist to return or may leave a telephone number for the pharmacist to call upon return.

(9) Telephoned new prescriptions must not be accepted by support personnel in the pharmacist's absence.

(10) New hardcopy prescriptions may be accepted and processed by registered technicians in the pharmacist's absence. These prescriptions may not be dispensed until the pharmacist has performed prospective drug review and completed the final check.

(11) If two or more pharmacists are on duty, the pharmacists shall stagger their breaks so that the prescription department is not left without a pharmacist on duty.

(12) The pharmacist-in-charge shall develop written policies and procedures for operation of the prescription department in the temporary absence of the pharmacist.

## **NORTH CAROLINA:**

### **NC BReg 2512.**

#### **Pharmacist work conditions.**

A permit holder shall not require a pharmacist to work longer than 12 continuous hours per work day. A pharmacist working longer than six continuous hours per work day shall be allowed during that time period to take a 30 minute meal break and one additional 15 minute break.

## **NEW JERSEY:**

### **NJ BReg 13:39-6.4.**

#### **Meal or restroom breaks.**

(a) A sole pharmacist on duty may take restroom breaks and 30-minute meal breaks while working in a pharmacy consistent with the following requirements:

1. The pharmacist shall remain in the pharmacy or, in the case of a pharmacy department, in the pharmacy department building, and shall be accessible for emergencies or for counseling, if requested;
2. The pharmacy shall remain open during the restroom or meal breaks, provided a pharmacy employee remains present in the pharmacy, for patient related services, which include, but are not limited to, the following:
  - i. The receipt of new written prescriptions; and
  - ii. The dispensing of prescription medications which have been checked by the pharmacist; and
3. A sign shall be posted in the prescription dispensing area stating “Pharmacist on break, but available for emergencies and counseling.”

## **OREGON:**

### **OR BReg 855-041-1170**

#### **Grounds for Discipline**

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

- (3) Failure to provide a working environment that protects the health, safety and welfare of a patient which includes but is not limited to:
  - (b) Appropriate opportunities for uninterrupted rest periods and meal breaks.

## **TENNESSEE:**

### **TN BReg 1140-03-.07.**

#### **Temporary absence of pharmacist.**

A pharmacist is permitted one (1) temporary absence for a period not exceeding one (1) hour per day. During the absence of a pharmacist from the pharmacy practice site, a sign containing the words “pharmacist not on duty” must be conspicuously displayed in the pharmacy practice site. It shall be unlawful to fail or refuse to display the required sign in a conspicuous place when a pharmacist is absent. No medical or prescription order may be compounded or dispensed during the absence of a pharmacist. Additionally, during the absence of the pharmacist the prescription department shall be closed off by physical barrier from floor to ceiling.

## **VERMONT:**

### **VT BReg 20-4-1400:9.21.**

#### **Pharmacist Meal/Rest Breaks**

- (a) Whenever the prescription department is staffed by a single pharmacist, the pharmacist may take a meal/rest break for a period of up to 30 minutes without closing the pharmacy and removing support personnel from the pharmacy, provided that the pharmacist reasonably believes that the security of the prescription drugs will be maintained in the pharmacist's absence.
- (b) No pharmacist shall work more than 8 hours without a meal/rest break. Breaks should be scheduled as close as possible to the same time each day, so that patients may become familiar with the approximate time of the breaks
- (c) The pharmacist shall remain on the premises of the drug outlet during the meal/rest break and shall be available for emergencies.
- (d) If two or more pharmacists are on duty in the prescription department, the pharmacists shall stagger their meal/test breaks so that the prescription department is not left without a pharmacist on duty.
- (e) Whenever the pharmacist temporarily leaves the prescription department for a meal/rest break, a sign indicating that there is no pharmacist on duty shall be conspicuously displayed. The sign shall also indicate the time when the pharmacist will return.

## **VERMONT (cont.):**

- (f) Only support personnel directly involved in the prescription dispensing process and authorized by the pharmacist on duty may remain in the prescription department while the pharmacist is on a meal/rest break.
- (g) When the pharmacist is temporarily absent from the prescription department, support personnel authorized by the pharmacist on duty may continue to perform non-discretionary duties as delineated by the pharmacist. All such duties performed by support personnel shall be reviewed by the pharmacist upon return from the meal/rest break.
- (h) When a pharmacist is not in the prescription department, there shall be no dispensing of new prescriptions that the pharmacist has checked and that are waiting to be picked up, nor shall counseling be provided by support personnel.
- (i) New, written prescriptions presented by the patient or the patient's agent may be accepted by support personnel. The processing of such prescriptions, up to the final check, may occur in the absence of the pharmacist. However, no prescription may be dispensed until the final check is completed by the pharmacist after return to the prescription department.
- (j) New prescriptions conveyed by telephone shall not be accepted by support personnel. The caller should be instructed to call back, or a telephone number should be obtained for the pharmacist to call upon return to the prescription department.
- (k) During the pharmacist's absence, prescription refills which have been previously prepared and checked by a pharmacist may be picked up by the patient or the patient's agent. Support personnel must offer the patient counseling by the pharmacist. If the patient has no questions, dispensing may proceed as usual, with the patient signing for the counseling refusal. If the patient desires counseling, the patient should be asked to wait for the pharmacist to return from the meal/rest break. Alternatively, the patient may be asked to leave a telephone number for the pharmacist to call later the same day.
- (l) Telephone refill orders and refill requests presented in person by the patient or the patient's agent may be accepted by support personnel. Such refill orders may be processed by support personnel up to the final check. However, no such refill orders shall be dispensed until the final check is completed by the pharmacist after return from the meal/rest break.
- (m) Under this rule, the pharmacist-manager remains responsible for the direct management, supervision, and control of the prescription department.
- (n) If, for security reasons or otherwise, the pharmacist determines that the prescription department should close during the pharmacist's absence, the pharmacist shall close the prescription department and remove all support personnel from the prescription department

during the pharmacist's absence. A sign informing the public of the pharmacist's temporary absence and time of return shall be conspicuously posted.

## **VERMONT (cont.):**

(o) Using this rule as a guide, the pharmacist-manager, in conjunction with the pharmacy license holder, should develop written policies and procedures regarding operation of the prescription department while the pharmacist is temporarily absent on a meal/rest break.

(1) The policies and procedures should include authorized duties of support personnel and should define the pharmacist's responsibilities for checking all work performed by support personnel and for maintaining security of the prescription department. The pharmacist-manager should review the policies and procedures with support personnel.

(2) After review, each support person should be requested to initial the policies and procedures to indicate that the policies and procedures are understood.

## **WASHINGTON D.C.:**

### **BReg 1901.**

#### **General operating standards.**

1901.2 A licensed pharmacist shall be on duty at all times that a pharmacy is open for business. Where only one pharmacist is on duty, the pharmacy shall be closed for business during the pharmacist's meal period and breaks.

## **TRANSFER INCENTIVES**

### **ALABAMA:**

#### **AL BReg 680-X-2-.22.**

#### **Code of Professional Conduct.**

(h) A pharmacist and a pharmacy should never offer or participate in the offering a financial award or benefit, not related to competitive retail pricing of any drug, to induce or encourage any individual to transfer a prescription from one pharmacy to another.

### **MISSISSIPPI:**

#### **Prohibition of Transfer Incentives:**

Mississippi Board of Pharmacy Newsletter, July 2011:

#### **INCENTIVES FOR TRANSFER OF PRESCRIPTIONS**

During the May 12, 2011, meeting of the Board, the Board discussed the issue of pharmacies offering incentives for transfer of prescriptions. After discussion, it is the Board's opinion that repeated transfers of prescriptions between pharmacies compromises patient care and is not in the patient's best interest. The Board voted, effective July 1, 2011, that pharmacies be prohibited from offering incentives of any kind for the transfer of prescriptions from another pharmacy. Pharmacist/Pharmacies have no obligation under the current Pharmacy Practice Regulations to transfer prescriptions and transfers of controlled substance prescriptions between pharmacies located within the state or to pharmacies located in another state is not acceptable.

### **OREGON:**

#### **OR BReg 855-041-1170**

#### **Grounds for Discipline**

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

(5) Incenting or inducing the transfer of a prescription absent professional rationale.

## **VIRGINIA:**

### **Prohibition of Transfer Incentives**

Regulations are currently pending review by Virginia Secretary of Health and Human Resources.

See separate article.

## **SPACE FOR CONSULTATION/CLINICAL SERVICES**

### **ALABAMA:**

#### **AL BReg 680-X-2-.27.**

##### **Private Consultation Areas for Pharmacies.**

(1) Since the implementation of patient consultation requirements as a result of OBRA '90 guidelines, it has become evident that the current setup in pharmacies is not conducive to proper communication with patients by pharmacists. Research shows that private consultation areas will facilitate proper consultation with patients by pharmacists and the resultant patient outcomes will be enhanced. Therefore, in order to protect the health of the public and enhance their medication outcomes, private consultation areas must be furnished by pharmacy owners.

(2) The size of the consultation areas must be large enough to accommodate the participants and must be entirely devoted to enhancing patient outcomes and not a storage room for merchandise or other non-related items. The area must be accessible by the patient from outside of the pharmacy area without having to traverse a stock room or pharmacy area and must have the capability of being private to both sounds and viewing by unauthorized parties. The area must be away from checkout areas and flows of traffic that would present a barrier to patient communication.

### **MAINE:**

#### **ME BReg 3.**

##### **Operation of Drug Administration Clinics.**

###### **1. Site Suitability**

A drug administration clinic must be located in a sanitary, well-maintained, adequately-equipped space that is appropriately sized for the expected patient volume and facilitates interaction among clinic staff and patients.

### **WYOMING:**

#### **WY BReg Section 2.**

##### **Definitions.**

(e) "Private Space" means a physical area separated from the pharmacy that is no less than 48 square feet and has at least an 6 feet tall partition to ensure patient safety and confidentiality. The partition cannot be a curtain. The requirement for private space will be in effect on July 20, 2014.

## ACCOUNTABILITY

### ALABAMA:

#### AL BReg 680-X-2-.12.

#### Supervising Pharmacist.

(6) If the actions of the permit holder have deemed to contribute to or cause a violation of any provision of this section, the Board may hold the permit holder responsible and/or absolve the supervising pharmacist from the responsibility of that action.

### NEBRASKA:

#### NE BReg Chapter 8 Section 008.

#### Denial, Refusal to Renew, or Disciplinary Action.

8-008.01B The Department may take disciplinary action against a provisional pharmacy license or a pharmacy license for any of the following grounds:

6. Discrimination or retaliation against a pharmacy patient or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;

### TEXAS:

#### TX BReg291.32.

#### Personnel

(b) Owner. The owner of a Class A pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(4) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice;

## **VIRGINIA:**

### **VA BReg 18 VAC 110-20-110.**

#### **Pharmacy Permits Generally.**

B. The pharmacist-in-charge (PIC) or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

## **WEST VIRGINIA:**

### **WV BReg 15-1-2.1.nn.2.**

#### **Definitions.**

The "Pharmacist-in-charge" has the responsibility for the practice of pharmacy, as defined in this rule, at the pharmacy for which he or she is pharmacist-in-charge. The pharmacy permit holder has responsibility for all other functions, administrative and operational, of the pharmacy. The pharmacist-in-charge may advise the pharmacy permit holder in writing of administrative and operational matters. The pharmacist-in-charge is not legally responsible if the permit holder does not follow the written advice;

### **WV BReg 15-1-20.**

#### **Duties and Responsibilities of the Pharmacist-in-Charge**

20.2. The pharmacist-in-charge has the following responsibilities:

20.2.a. The pharmacist-in-charge shall be responsible for the practice of pharmacy, as defined in this rule, at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacy permit holder shall be responsible for all other functions, administrative and operational, of the pharmacy. The pharmacist-in-charge may advise the pharmacy permit holder in writing of administrative and operational matters. The pharmacist-in-charge is not legally responsible if the permit holder does not follow the written advice;

20.2.b. The pharmacist-in-charge shall notify the pharmacy permit holder of potential violations of any statute, rule or court order existing within the pharmacy. If appropriate action has not been taken within a reasonable amount of time the pharmacist-in-charge shall reduce to writing the above and submit to the pharmacy permit holder with a copy to the Board. No pharmacist-in-charge shall be sanctioned by the Board for any violation of any statute, rule or court order if they have previously given this written notice to the pharmacy permit holder. The pharmacy permit holder shall be responsible for such violations;

## QUALITY CONTROL

### ARIZONA:

#### **AZ BReg R4-23-620. Continuous Quality Assurance Program**

**A.** Each pharmacy permittee shall implement or participate in a continuous quality assurance (CQA) program. A pharmacy permittee meets the requirements of this Section if it holds a current general, special or rural general hospital license from the Arizona Department of Health Services and is any of the following:

1. Certified by the Centers for Medicare and Medicaid Services to participate in the Medicare or Medicaid programs;
2. Accredited by the Joint Commission on the Accreditation of Healthcare Organizations; or
3. Accredited by the American Osteopathic Association.

**B.** A pharmacy permittee or the pharmacist-in-charge shall ensure that:

1. The pharmacy develops, implements, and utilizes a CQ program consistent with the requirements of this Section and A.R.S. § 32-1973;
2. The medication error data generated by the CQA program is utilized and reviewed on a regular basis, as required by subsection (D); and
3. Training records, policies and procedures, and other program records or documents, other than medication error data, are maintained for a minimum of two years in the pharmacy or in a readily retrievable manner.

**C.** A pharmacy permittee or pharmacist-in-charge shall:

1. Ensure that policies and procedures for the operation and management of the pharmacy's CQA program are prepared, implemented, and complied with;
2. Review biennially and, if necessary, revise the policies and procedures required under subsection (C)(1);
3. Document the review required under subsection (C)(2);
4. Assemble the policies and procedures as a written or electronic manual; and

## **ARIZONA (cont.):**

5. Make the policies and procedures available within the pharmacy for employee reference and inspection by the Board or its staff.

**D.** The policies and procedures shall address a planned process to:

1. Train all pharmacy personnel in relevant phases of the CQA program;

2. Identify and document medication errors;

3. Record, measure, and analyze data collected to:

a. Assess the causes and any contributing factors relating to medication errors, and

b. Improve the quality of patient care;

4. Utilize the findings from subsections (D)(2) and (3) to develop pharmacy systems and workflow processes designed to prevent or reduce medication errors; and

5. Communicate periodically, and at least annually, with pharmacy personnel to review CQA program findings and inform pharmacy personnel of any changes made to pharmacy policies, procedures, systems, or processes as a result of CQA program findings.

**E.** The Board's regulatory oversight activities regarding a pharmacy's CQA program are limited to inspection of the pharmacy's CQA policies and procedures and enforcing the pharmacy's compliance with those policies and procedures.

**F.** A pharmacy's compliance with this Section shall be considered by the Board as a mitigating factor in the investigation and evaluation of a medication error.

## **CALIFORNIA:**

### **CA BReg 1711.**

#### **Quality Assurance Programs.**

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as

## **CALIFORNIA (cont.):**

defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;
2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
3. the findings and determinations generated by the quality assurance review; and,
4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

## **CALIFORNIA (cont.):**

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

- (f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.
- (g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.
- (h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

## **CONNECTICUT:**

### **CT BReg 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 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.

## **FLORIDA:**

### **FL BReg 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, registered pharmacy interns, registered pharmacy technicians, clerical staff, and other personnel deemed necessary by the prescription department manager or the consultant pharmacist 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.

## **FLORIDA (cont.):**

(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. 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.

## **IOWA:**

### **IA BReg 657-8.26 (155A).**

#### **Continuous quality improvement program.**

Each pharmacy licensed to provide pharmaceutical services to patients in Iowa shall implement or participate in a continuous quality improvement program or CQI program. The CQI program is intended to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate, and prevent medication errors, thereby improving medication therapy and the quality of patient care. A pharmacy that participates as an active member of a hospital or corporate CQI program that meets the objectives of this rule shall not be required to implement a new program pursuant to this rule.

8.26(1) Reportable program events. For purposes of this rule, a reportable program event or program event means a preventable medication error resulting in the incorrect dispensing of a

## **IOWA (cont.):**

prescribed drug received by or administered to the patient and includes but is not necessarily limited to:

- a. An incorrect drug;
- b. An incorrect drug strength;
- c. An incorrect dosage form;
- d. A drug received by the wrong patient;
- e. Inadequate or incorrect packaging, labeling, or directions; or
- f. Any incident related to a prescription dispensed to a patient that results in or has the potential to result in serious harm to the patient.

8.26(2) Responsibility. The pharmacist in charge is responsible for ensuring that the pharmacy utilizes a CQI program consistent with the requirements of this rule. The pharmacist in charge may delegate program administration and monitoring, but the pharmacist in charge maintains ultimate responsibility for the validity and consistency of program activities.

8.26(3) Policies and procedures. Each pharmacy shall develop, implement, and adhere to written policies and procedures for the operation and management of the pharmacy's CQI program. A copy of the pharmacy's CQI program description and policies and procedures shall be maintained and readily available to all pharmacy personnel. The policies and procedures shall address, at a minimum, a planned process to:

- a. Train all pharmacy personnel in relevant phases of the CQI program;
- b. Identify and document reportable program events;
- c. Minimize the impact of reportable program events on patients;
- d. Analyze data collected to assess the causes and any contributing factors relating to reportable program events;
- e. Use the findings to formulate an appropriate response and to develop pharmacy systems and workflow processes designed to prevent and reduce reportable program events; and
- f. Periodically, but at least annually, meet with appropriate pharmacy personnel to review findings and inform personnel of changes that have been made to pharmacy policies, procedures, systems, or processes as a result of CQI program findings.

## **IOWA (cont.):**

8.26(4) Event discovery and notification. As provided by the procedures of the CQI program, the pharmacist in charge or appropriate designee shall be informed of and review all reported and documented program events. All pharmacy personnel shall be trained to immediately inform the pharmacist on duty of any discovered or suspected program event. When the pharmacist on duty determines that a reportable program event has occurred, the pharmacist shall ensure that all reasonably necessary steps are taken to remedy any problems or potential problems for the patient and that those steps are documented. Necessary steps include, but are not limited to, the following:

- a. Notifying the patient or the patient's caregiver and the prescriber or other members of the patient's health care team as warranted;
- b. Identifying and communicating directions or processes for correcting the error; and
- c. Communicating instructions for minimizing any negative impact on the patient.

8.26(5) CQI program records. All CQI program records shall be maintained on site at the pharmacy or shall be accessible at the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the record. When a reportable program event occurs or is suspected to have occurred, the program event shall be documented in a written or electronic storage record created solely for that purpose. Records of program events shall be maintained in an orderly manner and shall be filed chronologically by date of discovery.

- a. The program event shall initially be documented as soon as practicable by the staff member who discovers the event or is informed of the event.
- b. Program event documentation shall include a description of the event that provides sufficient information to permit categorization and analysis of the event and shall include:
  - (1) The date and time the program event was discovered and the name of the staff person who discovered the event; and
  - (2) The names of the individuals recording and reviewing or analyzing the program event information.

8.26(6) Program event analysis and response. The pharmacist in charge or designee shall review each reportable program event and determine if follow-up is necessary. When appropriate, information and data collected and documented shall be analyzed, individually and collectively, to assess the cause and any factors contributing to the program event. The analysis may include, but is not limited to, the following:

## **IOWA (cont.):**

- a. A consideration of the effects on the quality of the pharmacy system related to workflow processes, technology utilization and support, personnel training, and both professional and technical staffing levels;
- b. Any recommendations for remedial changes to pharmacy policies, procedures, systems, or processes; and
- c. The development of a set of indicators that a pharmacy will utilize to measure its program standards over a designated period of time.

## **INDIANA:**

### **IN BReg 856 IAC Rule 1-28.1-11.**

#### **Performance improvement events, sentinel events, corrective and avoidance measures, review, records, and documentation.**

(a) The pharmacist in charge shall, as a part of the pharmacy's performance improvement program, assure or be responsible for assuring that data are collected to:

- (1) monitor the stability of existing medication use processes;
- (2) identify opportunities for improvement; and
- (3) identify changes that will lead to and sustain improvement.

(b) Identification of quality related or sentinel event as defined in section 1 of this rule (856 IAC 1-28.1-1) shall be cause for:

- (1) an intensive analysis of causal factors involved in the event; and
- (2) plans for corrective actions.

(c) Records of all processes, analysis, and corrective measures instituted involving such pharmacy quality related or sentinel event shall be maintained for a period of not less than two (2) years.

(d) The committee created under section 5(c)(1) of this rule (856 IAC 1-28.1-5) shall, at a minimum, consider the effects on quality of the pharmacy system due to the following:

- (1) Staffing levels of both professional and technical personnel.

## **INDIANA (cont.):**

(2) Workflow.

(3) Use of technology.

(e) Requirements for documentation of performance improvement monitoring of medication use processes, confidentiality of records, summarization, and examination by the board shall be as follows:

(1) Each quality related or sentinel event that occurs, or is alleged to have occurred, as the result of activities involving pharmacy operations, shall be documented in a written or electronic storage record created solely for that purpose.

(2) The quality related or sentinel event shall be:

(A) initially documented by the pharmacist to whom it is first described; and

(B) recorded on the same day of its having been so described to the pharmacist.

(3) Documentation shall include a description of the event that is of sufficient detail to permit analysis of the event.

(4) The pharmacist in charge shall summarize, or cause to be summarized, efforts to improve the medication use process on a semiannual basis.

(5) No patient names or employee names shall be included in this summary report.

(6) This report shall be maintained for a period of not less than two (2) years.

(7) The records created and maintained as a component of a pharmacy performance improvement program are confidential to the extent law permits. However, to assure compliance, the board or its representative may review the policies and procedures manual and a summarization of events described in subsection (b).

## **MARYLAND:**

### **MD BReg Chapter 26 Section .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

## **MARYLAND (cont.):**

(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.